OVERVIEW

Who We Are

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.

The chart below illustrates our innovative therapeutics pipeline 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				(1)		IND approved in January 2025	Global
		Advanced solid tumors (in combination with anti-PD-1/L1 monoclonal antibodies)	NMPA			(2)			To enter Phase II in Q4 2028	Global
SK10 ☆	LBP	Chemotherapy-induced diarrhea	FDA						To enter Phase II in Q1 2028	Global
			NMPA				(3)		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:

(1) 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.;

(2) 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

(3) 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.

OUR COMPETITIVE STRENGTHS

A Pioneer in Second-generation LBP in China

SK08 and SK10 Mark Multiple Industry Milestones for LBP

We are a pioneer and leading enterprise in the field of second-generation LBP in China. By virtue of our core technological breakthroughs and rapid clinical advancement, we have positioned ourselves among the first tier of global LBP R&D. Our Core Product SK08 and key product SK10 have achieved multiple industry-defining milestones, establishing our first-mover and leadership advantages.

As a benchmark in China's second-generation LBP field, SK08 has delivered multiple important milestones and achievements. According to Frost & Sullivan, SK08 is the first LBP to obtain registrational clinical trial approvals from both the NMPA and the U.S. FDA. SK08 is currently in the Phase III clinical trial for IBS-D, making it the only late-stage clinical biological drug candidate in the global IBS-D field, as of the Latest Practicable Date.

SK08 has also received NMPA approval for the clinical trial targeting pediatric rotavirus diarrhea, representing a major breakthrough for LBP in pediatric medicine in China and further expanding the clinical application scope of LBP. As of the Latest Practicable Date, SK08 is the only clinical-stage LBP candidate targeting pediatric rotavirus diarrhea globally. Concurrently, SK08 was the first LBP in China approved to conduct registrational clinical trial in oncology patients. The strain safety evaluation study of SK08 was recognized as a classic research work in NGP on *Frontiers*, and SK08 was highlighted as a representative LBP candidate on *Nature Microbiology*, thereby providing evidence of our recognized R&D capabilities and Core Product competitiveness.

In addition, we were also the first company in China to advance an inactivated second-generation LBP into clinical development, and our key product SK10 has achieved multiple breakthroughs. It was the first LBP using *Bacteroides fragilis* to receive FDA clearance for clinical trials in the U.S., and also the world's first FDA clearance for an LBP targeting CID. SK10 has successfully completed its Phase I clinical trial in the U.S., demonstrating our ability to conduct global R&D and navigate complex regulatory pathways.

Industry Recognition for Our Technical Excellence and Market Leadership

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) (the "**Center**"), accredited by the Guangdong Provincial Department of Science and Technology, is the first engineering research center in China dedicated to LBP, with our Company serving as the lead supporting entity. The Center focuses on the R&D and translation of key generic technologies for LBP, aiming to enhance the development and industrialization capabilities as well as international competitiveness of China's LBP sector. The China LBP Summit Forum hosted by the Center brings together leading experts to exchange findings and plays an role in guiding the industry's development. Furthermore, as a pioneer in China's LBP and NGP industry, we are currently participating in the 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).

Our core R&D team has led and participated in six national and/or provincial major research projects, receiving broad recognition from the industry and authoritative institutions for our technological capabilities. Specifically, the SK08 project has been supported by key national, provincial and/or municipal research programs, including the National High-tech R&D Program of China (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). In addition, we have been honored with several prestigious awards, including the 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), fully demonstrating our outstanding technological innovation capabilities and industry influence.

R&D Platform with IP Protection Framework as Core Competitive Barriers

Systematic R&D Platform Supporting LBP Development

The development of LBP encompasses multiple complex steps, including strain screening, functional validation, and quality control, which presents significant technical barriers. The industry at large continues to face challenges such as inefficient strain screening, inadequate safety evaluation frameworks, difficulties in studying *in vivo* colonization of live bacterial drugs, and protracted CMC development cycles. To address these challenges, we have established ZYMIRS which comprises four core R&D platforms that collectively form a comprehensive technology support system covering the entire LBP development value chain. The details of these four core R&D platforms are set forth below:

Clinical Disease-bacteria Interaction Research Platform

To address the early-stage challenges in LBP development, including the lack of foundational data and the unclear mechanistic understanding of the relationship between gut microbiota and diseases, we have employed metagenomics and microbial culturomics approaches to construct compositional profiles of commensal and pathogenic bacteria associated with major intestinal diseases such as IBS, UC, and CID. Combined with bioinformatics analysis to decipher the interactions between gut microbiota and the host, we have established a comprehensive research methodology system for intestinal microecology, providing foundational data to support our drug development.

Strain Safety Evaluation Platform

We have established a specialized platform in China to systematically evaluate the safety of new bacterial strains at the whole-genome level. It has addressed the industry-wide technical challenge of lacking standardized safety evaluation systems and incomplete evaluation dimensions, while also carrying out multiple pioneering research studies. Taking the safety evaluation of the SK08 strain as an example, it represents one of the earliest systematic safety evaluation of an intestinal beneficial bacterium ever conducted in China. Using whole-genome sequencing and other methodologies, we evaluated the strain's physiological and biochemical characteristics, genetic stability, metabolites, adhesion and colonization properties. The findings have been recognized as a classic NGP research study on *Frontiers* and have been widely cited and referenced within the industry.

Screening and Developability Evaluation Platform

To address the industry challenges of low strain screening efficiency, limited availability of bacterial strains with drug development potential, and an underdeveloped drug developability evaluation system, we have established high-quality proprietary strain libraries including a colorectal cancer mucosal bacterial library, a neonatal feces and colostrum bacterial library, among others. We have adopted improved strain-directed isolation and screening techniques that expand the range of culturable bacterial species while simplifying operational procedures. Compared to previously reported methods, these improvements have reduced workload by nearly 40%, increased culture yield by approximately 30%, successfully isolated novel bacterial genera. The optimized process also maintained a strain loss rate below 10%, compared with an estimated average strain loss rate of approximately 20% generally observed in the industry. The technical advancements of our research have been cited in multiple core journals.

To resolve the specific detection bottleneck for intestinal autochthonous bacteria, we have developed a proprietary fluorescent labeling method that enables real-time observation of the *in vivo* dynamic distribution of target bacteria through live imaging, resolving the difficulties in studying the colonization and distribution of LBP. This innovative research has been cited by *Nature Reviews Chemistry*. Additionally, we have constructed more than 20 animal models suitable for evaluating the efficacy of live bacterial drugs, including stable models of antibiotic-associated diarrhea, *clostridium difficile*-associated diarrhea, and necrotizing enterocolitis caused by *Cronobacter sakazakii*, further refining our developability evaluation system.

CMC Platform

To address the industry challenges of lengthy CMC development cycles for LBP at the IND stage and the difficulty of industrialization, our CMC platform has established a technology system covering the entire R&D process, with the capability to develop multiple product types, including both aerobic and anaerobic formulations as well as powder and capsule dosage forms. We have also established CMC research strategies and technical standards for each stage of development from PCC to IND to NDA, resolving key technical challenges in the transition of LBP from laboratory to industrialization.

Our CMC development capabilities have enabled us to complete the relevant CMC work for certain projects within eight months, demonstrating the efficiency of our CMC platform. We have independently developed dozens of technologies for large-scale fermentation, lyophilization, and formulation of probiotics, with a particular focus on overcoming the technical and quality control challenges associated with anaerobic microorganisms. SK08 features substantially improved processes compared to existing LBP, including the reduced use of animal-derived components, enhanced process controls, tighter impurity controls, improved stability during storage and transportation, and higher viable bacterial count standards. Moreover, our platform also possesses core advantages in the inactivated LBP field, with SK10 becoming China's first inactivated LBP to receive FDA clearance to proceed with clinical trials.

Our R&D platforms operate in synergy, covering the entire R&D process, and demonstrate significant technical advancement and originality in strain screening, safety and druggability evaluation, as well as CMC research, collectively forming core technical barriers that are difficult for peers to replicate. In the study of *Bacteroides fragilis*, we have successfully screened the strain ZY-312 and conducted systematic, in-depth research, making us the first company globally to advance a *Bacteroides fragilis*-based LBP into clinical development, thus solving its long-standing industrialization challenges of strain screening and high technological barriers for drug conversion. We have also independently developed the PROFORCARE® precision inactivation technology for our inactivated LBP candidates and NGP raw materials, which enables complete bacterial inactivation with no viable bacterial residues while preserving key cell-wall components relevant to product quality. With respect to *Akkermansia muciniphila* ("**AKK**"), we are one of the earliest institutions in China to conduct AKK research and has successfully isolated and commercialized the breast milk-derived AKK strain-based product, with our processes having reached an industrial-scale production level. According to Frost & Sullivan, our self-developed 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.

Intellectual Property Protection Safeguarding Our Commercial Interests

The intellectual property protection of LBP differs significantly from that of traditional small-molecule drugs. The core technological assets of LBP typically consist of specific bacterial strains, bioactive materials, and their methods of preparation and application. As a result, it is difficult to build a complete protective barrier relying solely on a single compound patent. Instead, a more effective approach requires a layered, portfolio-based that integrates strain composition, disease indications, culture and scale-up processes, formulation stabilization technologies, and quality control methods.

Based on this industry characteristic, we have developed a protection model that combines "core patents, peripheral patents, and trade secrets." Our patent strategy is anchored around core patents covering key strains, therapeutic indications, and critical formulation approaches, which are complemented by peripheral patents covering culture media, fermentation methods, inactivation processes, formulation optimization, and analytical testing methods. At the same time, we maintain ongoing protection of proprietary process details through trade secrets. This model is precisely tailored to the specific needs of the LBP industry and effectively strengthens the long-term competitiveness of our products following commercialization.

For our Core Product SK08, our key product SK10 and our AKK, we have established a global patent portfolio with China as the central hub and strategic overseas markets as complementary extensions. We hold over 50 patents in total, with potential coverage extending to key overseas markets including Europe, the U.S., and Australia, providing a solid intellectual property foundation to support our global business expansion.

Our Core and Key Products Targeting Diseases with Traditional Therapy Limitations and Market Potential

Leveraging our R&D platform and strain library, both of which are protected by fully proprietary intellectual property rights, we have developed a portfolio of LBP products with SK08 and SK10 as our Core Product and key product, targeting major disease areas including gastrointestinal diseases, oncology, cancer therapy-related complications, metabolic disorders, and autoimmune diseases.

Core Product SK08 — The World's First Clinical-stage LBP Derived from Bacteroides fragilis

SK08 Demonstrates Multi-mechanism Synergy and Diverse Therapeutic Potential with Multiple Indications Approved for Clinical Trials

Studies have shown that SK08 contains a unique capsular polysaccharide component that regulates intestinal immunity and suppresses intestinal inflammation. In addition, SK08 repairs intestinal mucosal damage, maintains intestinal barrier integrity, sustains intestinal immune homeostasis by modulating the Th1/Th2 and Th17/Treg cell balances, and improves the gut microbiota by increasing microbial diversity, resisting pathogenic bacterial colonization, and enhancing the abundance of beneficial bacteria. SK08 also alleviates visceral hypersensitivity by upregulating intestinal epithelial serotonin transporter ("**SERT**") expression and promoting 5-HT reuptake. Through these mechanisms, SK08 has demonstrated potential therapeutic value across multiple diseases, including irritable bowel syndrome ("**IBS**"), pediatric rotavirus diarrhea, and oncology. We have conducted preclinical *in vivo* animal studies across these indications, all of which have shown favorable efficacy. For further details, see "— Our Product Pipelines (Pharmaceutical Pipelines)" in this section.

Based on our preclinical findings, we have advanced multi-indication clinical development of SK08. A Phase III clinical trial for the treatment of IBS-D is currently ongoing. SK08 has also received NMPA approval to conduct clinical studies for pediatric rotavirus diarrhea, which represents one of our next key development priorities. For combination therapy with anti-PD-1/L1 monoclonal antibodies in advanced solid tumors, SK08 received NMPA approval for a Phase Ib/II clinical trial in 2022. Considering our overall pipeline prioritization and development sequencing, as well as significant changes in the competitive landscape of marketed PD-1/L1 inhibitors in recent years, we plan to resubmit the IND application for this program and then commence the relevant clinical trial in the fourth quarter of 2028. Moreover, a Phase II clinical trial for UC is expected to commence in China in the fourth quarter of 2027.

Overcoming Current Clinical Limitations in Pursuit of Significant Market Potential

Patients with IBS-D often experience recurrent episodes, with approximately 40%-50% of patients relapsing after stopping treatment, that severely impact their quality of life and no targeted therapeutic drug is available for IBS-D as of now. Most patients require repeated use of antispasmodics, loperamide, rifaximin, and other medications to alleviate symptoms, and the long-term usage of these drugs may be associated with certain side effects. Overall patient satisfaction with existing treatments remains low. The absence of a safe and effective precision therapy has left millions of patients suffering from chronic pain and unpredictable bowel dysfunction, leading to reduced work productivity, increased psychological distress, and a substantially diminished quality of life. Quality-of-life studies cited in the American College of Gastroenterology (ACG) guidelines indicate that IBS patients are willing to pay a high price, accept significant side-effect risks and even give up to 10-15 years of life expectancy for instant cure, to achieve effective symptom control. According to Frost & Sullivan, IBS also imposes an economic burden on patients and the healthcare system in China, with total costs of managing IBS estimated at RMB123.8 billion, accounting for approximately 3.3% of total healthcare spending, and productivity losses representing over 25% of total costs. Furthermore, the lack of disease-modifying treatments not only perpetuates patient suffering but also constrains the overall market growth, thus a truly effective drug could expand the treatment-seeking population and unlock substantial commercial opportunities.

According to Frost & Sullivan, in 2025, the prevalence of IBS-D patients were 116.1 million in China, and the China IBS-D drug market was RMB4.0 billion. With such a large patient population, the market is expected to grow considerably upon the introduction of a novel precision therapy, and the scarcity of advanced-stage pipeline candidates addressing IBS-D underscores the need for and commercial potential of novel treatments.

Pediatric rotavirus diarrhea is a common form of pediatric infectious diarrhea that imposes a considerable physical burden on infants and young children. According to Frost & Sullivan, in 2025, the incidence of pediatric rotavirus diarrhea in China was 19.0 million, and the corresponding market size was RMB2.0 billion. In the diagnosis and treatment of pediatric rotavirus diarrhea, aside from rehydration and symptomatic supportive care, no specific therapeutic drugs are currently available. The primary treatment goals remain symptom relief, the prevention of dehydration, and the management of complications. Compared to adult medications, pediatric drugs are subject to more stringent requirements in terms of formulation suitability, safety evaluation, and age-appropriate dosing regimen design, resulting in a more limited range of treatment options. The severity of pediatric rotavirus diarrhea is often compounded by rapid dehydration, electrolyte imbalance, and prolonged hospitalization, which can lead to severe developmental setbacks and even life-threatening complications in vulnerable infants and children. The limited availability of pediatric-specific therapies may not only place psychological and financial burdens on families but also create a barrier to market expansion, thus the introduction of an effective, pediatric-specific therapy would catalyze rapid market adoption. Furthermore, parents are considered to demonstrate a strong willingness to seek medical care and pay for pediatric treatments, which provides support for the rapid market uptake of products with clear clinical advantages.

The Only LBP Backed by High-quality Clinical Evidence for IBS-D with Proven Efficacy and Safety and the Potential to Redefine Future Clinical Guidelines

In current clinical practice, traditional microecological drugs have been widely used in the gastroenterology field largely because of their relatively mild side effect profiles. Clinicians often prescribe marketed microecological products to patients with IBS-D to alleviate diarrhea and other related symptoms, under existing clinical guidelines. However, most of the traditional microecological drug products approved and marketed in China were approved years ago and lack registrational clinical trials for IBS-D. The industry has yet to reach a consensus on their mechanisms of action or clinical efficacy. Against this backdrop, SK08 emerges as the only LBP in China that is being evaluated in a rigorous, well-controlled registrational clinical trial specifically for the IBS-D indication, as of the Latest Practicable Date.

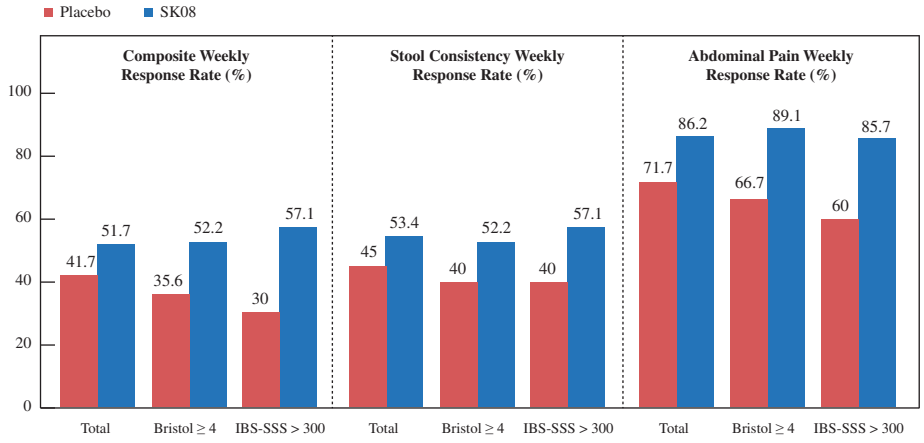
According to the 2020 China Expert Consensus on Irritable Bowel Syndrome (《2020年中國腸易激綜合徵專家共識意見》), "visceral hypersensitivity" is considered the core pathogenic mechanism of IBS and an important contributor to abdominal pain. Based on our preclinical mechanism findings and clinical observations, SK08 is supposed to take therapeutic effect in IBS by reducing visceral hypersensitivity. For further details, see "— SK08, Our Core Product — Drug Design and Mechanism of Action" in this section. Beyond addressing the core pathogenic mechanism, SK08 improves intestinal conditions and alleviates IBS-related symptoms through multiple pathways. SK08 enhances the defense function of the intestinal mucus layer, reinforces the tight junction protein between intestinal epithelial cells, reduces intestinal permeability, and maintains intestinal mucosal barrier integrity. Its capsular polysaccharide also effectively promotes intestinal immune tolerance, and further improves IBS-related symptoms. Accordingly, we believe SK08 has the potential to address the underlying pathophysiological mechanisms of IBS, including visceral hypersensitivity, impaired intestinal barrier function and dysregulated local immune responses.

The Phase II clinical results supported further clinical development of SK08, with the high-dose group demonstrating numerical improvement in the primary efficacy endpoint recognized for IBS-D, and showing continued improvement with long-term treatment. During the treatment period, the high-dose SK08 group achieved an eight-week composite weekly response rate of 51.7%, compared to 41.7% in the placebo group, representing a treatment difference of 10.0%. In patients with more severe disease (Bristol ≥4[1]), the high-dose group and placebo group achieved eight-week composite weekly response rates of 52.2% and 35.6%, respectively, with a difference of 16.6%. Although no head-to-head trial has been conducted, the data from this subgroup are comparable to the Phase III clinical data of eluxadoline, an FDA-approved drug for IBS-D. The baseline characteristics of the SK08 Bristol ≥4 subgroup were broadly comparable to those of the overall eluxadoline study population, and both trials used placebo as a control. Against this backdrop, the difference in composite weekly response rate between the high-dose SK08 group and placebo was higher than that of eluxadoline, suggesting superior clinical efficacy.

In IBS-D patients with more severe symptoms (Bristol ≥4 or IBS-SSS score >300), compared with the overall population, the placebo group showed a declining trend in composite response rate, weekly stool consistency response rate and weekly abdominal pain response rate. In contrast, the response rates in the SK08 high-dose group remained stable or further improved in these subgroups compared with the

1. refers to the patients with ≥4 days per week of diarrhea

overall population, suggesting that SK08 continued to demonstrate clear therapeutic benefit potential in patients with severe IBS-D. The diagram below illustrates the efficacy data of high-dose SK08 group and placebo group in both the overall patient population and patients with severe symptoms:



At the individual efficacy endpoint level, the high-dose SK08 group demonstrated particularly notable improvements in abdominal pain, which is the core symptom of IBS-D. The difference in the eight-week abdominal pain weekly response rate between the high-dose SK08 group and the placebo group reached 14.5%. Among patients with Bristol ≥4, the difference widened to 22.4%, which was statistically significant (p=0.010). Moreover, when compared to eluxadoline and rifaximin, commonly used IBS-D therapies, the treatment difference relative to placebo was higher for SK08, further reinforcing its significant clinical benefit in alleviating core IBS-D symptoms and benefiting patients with more severe disease.

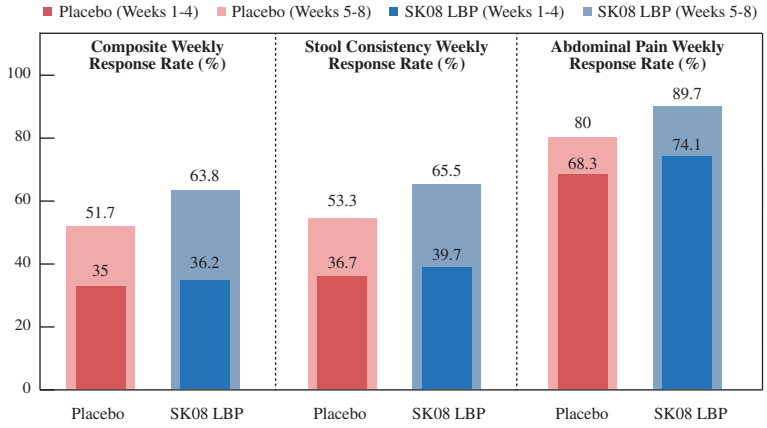
The efficacy data of SK08, rifaximin, and eluxadoline in improving abdominal pain symptoms in IBS-D patients are presented in the table below:

SK08, Rifaximin and Eluxadoline Efficacy Comparison in IBS-D Abdominal Pain Improvement

	SK08		Rifaximin		Eluxadoline	
Clinical Trial Phase	Phase II	Phase II (weekly diarrhea days ≥4)	Phase III Trial-1	Phase III Trial-2	Phase III IBS-3001	Phase III IBS-3002
Sample Size	118	91	623	635	853	764
Treatment Duration	8 weeks	8 weeks	2 weeks	2 weeks	12 weeks	12 weeks
Difference in Abdominal Pain Weekly Response Rate vs. Placebo	14.5%	22.4%	9%	9%	4%	6%

In addition, SK08 demonstrated strong long-term efficacy. Building on the onset-of-action data observed during the first four weeks of treatment, the high-dose SK08 group showed more pronounced symptom improvement compared to the placebo group starting from the fifth week onward, highlighting

the stability and durability of its therapeutic effect. The table below illustrates the improvement profile of high-dose SK08 with long-term administration:



SK08 also demonstrated a substantially more favorable safety profile than eluxadoline and rifaximin. The prescribing information for eluxadoline identifies specific safety risks, including pancreatitis, sphincter of Oddi spasm and severe constipation, while the prescribing information for rifaximin warns of the risk of *Clostridioides difficile*-associated diarrhea and the need to monitor the development of drug-resistant bacteria. In the Phase II clinical trial of SK08 in subjects with IBS-D, no such related serious events were observed. The common adverse reactions listed in the prescribing information for eluxadoline, with an incidence of 5% or greater, include constipation, nausea, abdominal pain and upper respiratory tract infection. In the Phase II clinical trial of SK08, among drug-related adverse events, only one case of constipation was observed, representing 1.7%, and no adverse events related to nausea, abdominal pain or upper respiratory tract infection were observed.

Key Product SK10 — Innovative Inactivated LBP with Both Therapeutic and Preventive Potential, Poised to Transform the CID Treatment Landscape

CID Represents a Significant Unmet Clinical Need with Substantial Market Opportunity

Chemotherapy is one of the core treatment modalities for cancer and plays an irreplaceable role in oncology. However, CID, as a common and challenging adverse reaction, can directly lead to dose reduction, treatment delay, treatment discontinuation, or even regimen modification, and in severe cases, may become life-threatening. Moreover, given that cancer patients are already physically weakened, severe diarrhea further exacerbates their physical burden and diminishes their quality of life.

More critically, as of the Latest Practicable Date, there are no approved drugs specifically for the treatment or prevention of CID globally, and existing therapies are often supportive or symptom-based with safety concerns. For example, loperamide, a commonly used clinical drug, carries a risk of serious cardiotoxicity, and its maximum duration of use is strictly limited to 48 hours, making it inadequate for patients requiring long-term management or those with severe CID. In addition, the lack of approved preventive therapies means that patients generally cannot receive effective prophylactic intervention before the onset of CID, leaving clinicians to manage diarrhea only after symptoms occur, which may limit their ability to reduce the incidence, severity or recurrence of CID during cancer treatment. The availability of an effective preventive therapy could potentially shift the current treatment paradigm from post-symptom management to proactive prevention, thereby expanding the addressable patient population and creating a new growth driver in the CID market. These factors have collectively resulted in a persistent clinical need in the CID field, leaving a substantial clinical gap to be filled. According to Frost & Sullivan, the global incidence of CID was 20.3 million cases in 2025 and is expected to increase to 22.4 million cases in 2030, representing a CAGR of 2.0% from 2025 to 2030.

SK10 Demonstrates Favorable Safety in Clinical Trials

SK10 has completed a randomized, double-blind, placebo-controlled Phase I clinical trial in the U.S., in which 50.0% of the enrolled subjects were of Chinese descent. All treatment-emergent adverse events ("**TEAEs**") were mild in severity, with no moderate or severe TEAEs reported, no serious adverse events ("**SAEs**") occurred, and there was no significant difference in the incidence of TEAEs between the SK10 dose groups and the placebo group. All laboratory tests, vital signs, electrocardiograms, and physical examinations revealed no clinically significant abnormalities. Hence, SK10 demonstrated a favorable safety and tolerability profile, with dose escalation not leading to increased incidence or severity of adverse events.

SK10 Offers Multiple Advantages Targeting the Treatment Challenges for CID Patients

SK10 is an inactivated LBP designed to precisely address the key clinical pain points in current CID treatment. It offers three core advantages: firstly, it has a superior safety profile with a lower incidence of adverse reactions compared to live bacterial formulations, making it suitable for immunocompromised cancer patients. Secondly, it possesses excellent commercial potential as it can be stored and transported at room temperature without special conditions, resulting in lower commercialization and distribution costs. Thirdly, it has the potential to be used prophylactically before or during chemotherapy, which may shift CID management from post-symptom treatment to proactive prevention, expand the addressable treatment setting and create incremental market opportunities. Fourthly, it has a well-defined mechanism of action supported by preclinical efficacy data. SK10 exerts its therapeutic effects through repairing the intestinal mechanical barrier and regulating the intestinal immune barrier.

Preclinical studies have demonstrated that in a mouse model of CID induced by irinotecan, a commonly used chemotherapeutic agent, SK10 reduced the incidence of Grade 3 diarrhea by 20.0%, and the area under the curve (AUC) of diarrhea scores decreased by 39.0% compared to the model group. Mechanistically, SK10 exerts its therapeutic effects through two primary pathways: repairing the intestinal mechanical barrier and regulating the intestinal immune barrier. Through mechanical barrier repair, SK10 inhibits chemotherapy-induced intestinal epithelial cell damage and apoptosis, modulates the expression of proteins related to apoptosis and anti-apoptosis, and repairs the damaged intestinal barrier. Through immune regulation, SK10 suppresses chemotherapy-induced intestinal inflammatory responses, reduces the production of inflammatory cytokines, and decreases intestinal inflammatory injury, thereby effectively treating CID.

Establishment of an End-to-End R&D-Clinical-Manufacturing Platform Solving LBP Commercial-scale Production Hurdles

We have established an end-to-end, full-lifecycle industrial value chain spanning laboratory research, clinical translation, and commercial manufacturing. We have built an industry-leading, GMP-compliant integrated platform for both anaerobic and aerobic fermentation and formulation at a 5,000-liter scale. By overcoming key technical challenges including high-density microbial fermentation, room-temperature stable formulation, and plant-derived culture media fermentation, we have achieved a complete transition from laboratory research and clinical validation to early-stage commercial manufacturing for LBP. With large-scale production and delivery capabilities, we have laid a solid industrial foundation to support the future commercial launch of our products and drive our growth trajectory.

Manufacturing Scale Ready for Early-stage Drug Commercialization

Our manufacturing platform can meet commercial supply needs at the early stage following product launch. We have built a GMP-compliant, large-scale fermentation production line at a 5,000-liter scale, with an annual production capacity of approximately 15 million packets of powder and 100 million capsules which can support hundreds of millions of RMB in annual output value.

In addition, we possess established process scale-up and technology transfer capabilities. We have mastered the key control parameters for core LBP manufacturing processes, effectively breaking through the technical barriers that often hinder the transition from laboratory-scale processes to industrial-scale production. This enables efficient replication and smooth technology transfer of R&D-stage processes to GMP-compliant large-scale production lines. We also have the capability for continuous process optimization, allowing us to steadily reduce costs and improve efficiency while ensuring product quality consistency, thereby enhancing the economic viability of our industrial-scale operations.

Addressing Core Technical Challenges in the Industrial-scale LBP Production

High-density Fermentation Technology: Leveraging our 5,000-liter fermentation platform, we have broken through key technical barriers in high-density fermentation for both anaerobic and aerobic bacteria, achieving fermentation densities of up to 10^{10} CFU/mL. This ensures stable quality and reliable supply of core active pharmaceutical ingredients from the source, solidifying the foundation for our industrial-scale production capacity.

Customized Culture Media Development Strategy: We have adopted a plant-derived component and chemically defined culture media system. By tailoring media formulations and conducting customized design based on the biological characteristics of each strain, we mitigate the risk of exogenous factor contamination at the source and have established a comprehensive biosafety control system. This quality control strategy aligns with internationally recognized standards, significantly enhancing product safety and quality controllability while paving the way for future international registration and global market expansion.

Room-temperature Stable Formulation Technology: Leveraging our proprietary core lyophilization and formulation technologies, we have overcome the industry challenge of room-temperature storage for live bacterial drugs. Our products exhibit excellent stability and reduce heavy reliance on cold-chain transportation. This effectively expands the geographic reach of our products while significantly lowers our commercial logistics and channel operating costs.

High-standard Quality Control Strategy: Guided by the "Quality by Design" (QbD) philosophy, we proactively align with regulatory requirements and have established stringent internal control standards for critical parameters such as cell bank purity and potency. We were among the first in the industry to implement higher internal standards for viable bacterial count and have developed specialized analytical testing methods to exercise meticulous control over key risk points, including culture media residuals and exogenous factors. This ensures precise and consistent dosing and stable, uniform clinical efficacy. Through systematic research on key quality attributes of second-generation LBP and the establishment of industry-leading quality control standards, we have set a quality benchmark in the LBP field.

Inactivation Technology Expansion Supporting Next-generation Drug Discovery

Based on a deep understanding of the biological characteristics of different bacterial strains, we have broken through the core technical barriers of precise thermal inactivation. Our inactivation process achieves 100% absence of viable bacterial residues while completely preserving the cell wall structure, thereby maximizing the retention of active functional components, including functional proteins and short-chain fatty acids. Concurrently, we have established scientific and precise analytical methods for quantifying inactivated bacterial components. Leveraging these breakthroughs, we have built a comprehensive next-generation drug development platform. Our key product, SK10, being the first inactivated LBP candidate developed by a China-based company to receive FDA IND approval, has completed Phase I clinical trials in the U.S. In parallel, we have successfully developed AKK AM06™, a NGP raw material. This dual-track approach enables synergistic development across therapeutic and health ingredient pipelines, continuously expanding the scope of our business.

Next-generation Probiotic Business Targeting the Broad Consumer Market

The traditional probiotic raw material market has reached a relatively mature stage, characterized by widespread product homogeneity and insufficient functional differentiation. Benefiting from breakthroughs in microbiome and bioinformatics research, NGP, which undergo scientific screening and functional validation, offer more pronounced functional specificity and greater potential for health benefits. As a result, this market is entering a period of rapid growth.

Supported by our long-established R&D system, strain development capabilities, and industrialization experience in the LBP field, we are able to accurately assess the functionality, safety, and commercial potential of bacterial strains, enabling us to proactively identify high-quality NGP candidates. Furthermore, we have extended our pharmaceutical-grade R&D logic and quality control systems into the NGP sector. Drawing on our strong CMC development capabilities, we have successfully transitioned our technologies to probiotic raw material development, establishing high-quality technical barriers that are difficult to replicate and creating differentiated competitive advantages.

According to publicly available information, our proprietary AKK AM06™, derived from healthy human breast milk, is the first and one of only two breast milk-derived AKK strains on the market to have obtained recognition from the FDA. Based on our research data, it offers excellent characteristics including high genetic stability, and robust tolerance to pH and bile salt variations, making it suitable for the development of next-generation consumer health products. In addition, we have independently developed the PROFORCARE® precision inactivation technology tailored to the characteristics of the AKK strain. This technology achieves 100% bacterial inactivation with no viable bacterial residues while fully preserving the nutritional and structural integrity of the AKK, representing industry-leading inactivation capabilities.

AKK is a representative strain in the NGP field. Its abundance abnormality is closely associated with the onset and progression of various metabolic diseases. AKK has already received approval as a novel probiotic raw material in Europe, North America, and other regions, with increasing market acceptance and rapidly growing market size. According to Frost & Sullivan, the global probiotic raw materials for human health market size is expected to reach USD3.0 billion by 2030, while the China market size is expected to reach USD0.5 billion.

Experienced R&D and Management Team with Deep Expertise and Industry Insight Supported by Reputable Biotech Investors

The LBP industry has high technical barriers and demands strong professional backgrounds and extensive hands-on experience from R&D personnel. We place great emphasis on talent development, and our core R&D team is stable and experienced, with strong R&D execution capabilities that effectively drive our sustained growth. Under the strategic guidance of Dr. Zhi, we have built an R&D and management team with global vision and incisive industry insight. As of the Latest Practicable Date, our R&D team comprised 58 members, 20 of whom hold master's degrees or above. Our core R&D team consists of eight members with expertise spanning the fields of novel drug R&D, clinical trials, and pharmaceutical microbiology technologies, and they have an average of over 14 years of experience working 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).

Our Chairman, Dr. Zhi, with over 40 years of professional experience, is responsible for our overall strategic business planning. Dr. Zhi is an expert entitled to the Special Government Allowance granted by the State Council of the PRC, a nationally recognized young and middle-aged expert with outstanding contributions by the National Health and Family Planning Commission (中華人民共和國國家衛生和計劃生育委員會), and the project lead of a major National 863 Program. Moreover, he has received numerous honors, including the inaugural "National Outstanding Physician — Exemplary Role Model (國之名醫•優秀風範)" award. He possesses deep expertise in the prevention and treatment of small intestinal inflammatory diseases, endoscopic diagnosis and treatment of pancreatic and biliary diseases, and translational research on intestinal microecology, and is recognized as an influential expert in gastroenterology and digestive endoscopy in China.

Our general manager, Dr. Wang Ye, is responsible for the implementation of our development strategy, management of financing and investment matters, and the coordination of various subordinate business divisions. Dr. Wang has over 20 years of experience in the pharmaceutical industry and has previously served at Bio-Thera Solutions (Guangzhou) Co., Ltd. (百奧泰生物科技(廣州)有限公司) (currently known as Bio-Thera Solutions, Ltd. (百奧泰生物製藥股份有限公司)) (688177: SH) and the Guangdong South China New Drug Creation Center (廣東華南新藥創制中心). His deep industry expertise and management acumen in the pharmaceutical sector have been instrumental in helping us achieve our strategic objectives, thereby maintaining stable and sustained business performance.

Our deputy general manager, Dr. Liu Yangyang, is responsible for the R&D and business collaboration matters. With over 15 years of academic research and industry experience in the field of LBP, Dr. Liu possesses in-depth knowledge of product development and translational processes for LBP and NGP. During his tenure at our Company, he successfully advanced multiple projects and provided critical support to our business expansion.

Since our inception, we have received strong support from a number of renowned investment institutions in the biotechnology sectors, such as Shenzhen Capital Group and other leading state-owned venture capital firms, top-tier industry strategic investors and prominent international venture capital funds. Such robust backing from both industry players and institutional investors underscores the market's recognition of our technological capabilities and confidence in our long-term growth trajectory. These strategic partnerships not only provide us with financial resources but also bring valuable industry expertise, network access and operational guidance, further strengthening our competitive position in the rapidly evolving biotechnology landscape.

OUR STRATEGIES

Advancing Core and Key Products from R&D to Commercialization

We are dedicated to developing LBP that address significant unmet clinical needs and overcome the limitations of traditional drug therapies. Currently, multiple clinical trials are being conducted simultaneously across various indications for SK08 and SK10 and we will prioritize the clinical development and global commercialization of our Core and key products.

SK08 Clinical Development Plan

IBS-D: The Phase III clinical trial commenced in March 2024, with a planned enrollment of 1,298 patients. As of the Latest Practicable Date, 690 patients have been enrolled. We plan to complete Phase III enrollment and primary efficacy endpoint assessment in 2027 and submit an NDA application to the NMPA in 2028. Subject to the regulatory approval, we will actively advance the large-scale manufacturing and commercialization of SK08.

Pediatric Rotavirus Diarrhea: We have received NMPA approval for a Phase II clinical trial and this is the first second-generation LBP approved in China for the clinical development of a pediatric disease. We plan to initiate the Phase II clinical trial in 2027 and expect to complete such trial by 2028.

Combination Therapy with Anti-PD-1/L1 Monoclonal Antibodies for Advanced Solid Tumors: In 2022, we received NMPA approval to conduct an Ib/II Phase clinical trial evaluating the safety and tolerability of this combination therapy in patients with advanced solid tumors. We plan to resubmit an IND application for a Phase II clinical trial, with the expected initiation in 2028 and the expected completion in 2029.

UC: Both the NMPA and the FDA have granted approval for us to conduct a Phase II clinical trial of SK08 for the treatment of mild active UC. We plan to initiate this Phase II trial in China in 2027 and expect to complete such trial by 2029.

SK10 Clinical Development Plan

SK10 has completed a Phase I clinical trial in the U.S. and demonstrated a favorable safety profile. Further, we received the Acceptance Notice from the CDE regarding a Phase II clinical trial of SK10 in the prevention and treatment of CID on June 10, 2026, and we plan to commence this trial in the fourth quarter of 2026. In addition, we plan to conduct a Phase II clinical trial in the U.S., which is expected to commence in 2028 and to be completed by 2029.

Strengthening Early-stage and Collaborative R&D to Enrich Our Product Pipeline

We have established an internationally competitive research platform for studying the relationship between human pathogenic/commensal microbial spectra and diseases, a platform for screening novel functional strains and identifying targets, and a live bacterial drug development platform. Hence, this platform provides us with the capability to continuously generate new product pipelines. We currently have multiple preclinical-stage candidates in our pipeline, including ZY19 (a natural bacterial drug) and TP2 (a bacterial component-based drug). These products have demonstrated promising efficacy data in preclinical studies, reflecting the development potential of our early-stage product pipeline. We will continue to strengthen our technology platform capabilities and enhance our investment in early-stage R&D, continuously expanding the therapeutic applications of LBP and further solidifying our industry leadership.

In parallel, in light of the rapid growth of the LBP and NGP markets, coupled with high R&D and industrialization barriers and the lack of full-chain development capabilities among most market participants, we are actively advancing our collaborative R&D strategy. We provide business partners with one-stop solutions ranging from strain screening to industrialization, thereby bridging their capability gaps. By doing so, we aim to fully unlock the synergistic value and production potential of our mature R&D platform, enrich our pipeline through sharing in commercial returns, and further consolidate our industry leadership position.

Enhancing End-to-End Operational Capabilities from Manufacturing to Commercial Launch

With respect to manufacturing capacity, we have built pilot-scale plants capable of fully supporting clinical-stage supply for SK08 and R&D needs for other product candidates. To support the early commercial production needs of SK08 following its anticipated market launch, we plan to upgrade and renovate our existing pilot plants. At the same time, given the significant market potential of SK08 for the treatment of IBS-D, the capacity of the renovated plants is expected to be insufficient to meet long-term commercial demand. Accordingly, we plan to further develop a larger-scale production line to provide sufficient and stable production capacity to support the market expansion of SK08. Upon completion, the existing plant used for early-stage commercial production will be repurposed for the clinical-stage production of multiple subsequent pipeline products, or the commercial-scale production of NGP AKK AM06™, thereby enabling efficient utilization of our production capacity.

With respect to sales and commercialization, following the anticipated regulatory approval of SK08, we plan to establish collaborations with distributors and CSO to leverage their sales and marketing capabilities and established distribution networks, thereby rapidly expanding the reach of SK08 into target medical institutions and pharmacies and benefiting a broader patient population. Concurrently, we will actively pursue the inclusion of SK08 in the National Reimbursement Drug List ("**NRDL**") for Basic Medical Insurance, Maternity Insurance and Work-related Injury Insurance, with the aim of reducing patients' out-of-pocket expenses and accelerating product uptake. Based on the foregoing, and given the favorable safety profile of SK08, we intend to apply for the reclassification of SK08 as an over-the-counter product, which would lower the access threshold for patients and further broaden the product's market reach.

R&D-powered Next-generation Probiotics Driving Competitiveness and Value

Building on our proven R&D leadership in the LBP field and capitalizing on industry growth opportunities, we are committed to advancing the approval and commercialization of our Core Product while simultaneously pursuing our NGP business. This dual-pronged approach is designed to fully unlock the value of our R&D platform and achieve sustainable long-term growth.

In the NGP business segment, we will capitalize on the unique advantage of AKK AM06™ as the first and one of only two breast milk-derived AKK strains on the market to have obtained recognition from the FDA. Through participation in industry exhibitions and academic promotional activities, we will actively expand our customer channels both domestically and internationally, promoting the core strengths of our products to downstream manufacturers and brands in the broader health and wellness sector. These efforts are designed to increase our market share and unlock the significant potential of the consumer market. Concurrently, we will continue to leverage our technological platform advantages to advance the screening and development of second-generation probiotic strains with differentiated competitiveness, continuously identifying new revenue growth drivers within the expansive consumer market.

Strengthening R&D and Management Talent to Sustain Industry Competitiveness

We believe that talent is the cornerstone of innovation and that our achievements to date are attributable to the contributions of our R&D and management teams. We will continue to attract outstanding industry talent to build a competitive, industry-leading R&D and management team, while continuously improving our internal trainings and incentive systems. By maintaining the stability of our core team and consistently identifying and developing exceptional talent, we expect to further enhance our R&D efficiency and execution capabilities. This will enable us to capitalize on opportunities in the rapidly evolving industry environment and to further consolidate our leading position in the market.

Pursuing Strategic Partnerships to Expedite Global Business Expansion

Against the backdrop of rapid global development in the LBP industry and the sustained release of demand for high-quality products in overseas markets, we have established a R&D and industrialization platform for LBP, laying a solid foundation for our global business expansion. Going forward, we will pursue a multi-tiered global market strategy while focusing on two core initiatives: out-licensing of our Core Product and key product, and in-licensing of high-quality pipeline assets. Our Core Product and key product, SK08 and SK10, are among the global leaders in the clinical development for their respective indications, demonstrating significant out-licensing value and commercial potential. We will actively seek strategic partners worldwide to accelerate the clinical development, regulatory filing, and commercial rollout of both the Core and key products in overseas markets, thereby maximizing their asset value. In addition, we will continuously monitor promising early-stage projects in the global LBP field. Through inbound licensing, strategic collaborations, and other diversified approaches, we will introduce high-quality innovative pipelines and cutting-edge technologies from abroad, further enriching our product portfolio, enhancing our global product matrix, and continuously strengthening our core competitive advantages in the global market.

OUR PRODUCT PIPELINES (PHARMACEUTICAL PIPELINES)

As of the Latest Practicable Date, we have developed six drug candidates, including one Core Product, one key product and four other products, across gastrointestinal diseases, oncology, cancer therapy-related complications, metabolic disorders, and autoimmune diseases. These candidates target indications including irritable bowel syndrome ("**IBS**"), pediatric rotavirus diarrhea, ulcerative colitis ("**UC**"), advanced solid tumors, chemotherapy-induced diarrhea ("**CID**"), oral mucositis ("**OM**"), metabolic diseases, atopic dermatitis ("**AD**"), psoriasis, and other autoimmune diseases.

All of our pipeline candidates are biological products, as categorized by the Competent Authority, including (i) two clinical-stage products, including (a) SK08, our Core Product, a live biotherapeutic product ("**LBP**") containing the novel *Bacteroides fragilis* strain ZY-312, for the treatment of IBS, 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, including (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 chart below summarizes our drug candidates and their development status as of the Latest Practicable Date:

New Drug Pipeline

Notes:

(1) 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.;

(2) 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

(3) 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.

SK08, Our Core Product

Overview

SK08, our Core Product, is an in-house-developed, orally administered LBP based on a novel strain of *Bacteroides fragilis* (ZY-312), for the treatment of IBS, pediatric rotavirus diarrhea, UC, and advanced solid tumors in combination with anti-PD-1/L1 monoclonal antibodies. As of the Latest Practicable Date, our patent portfolio relating to this product candidate comprised 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, covering, among others, its bacterial strain, method of use and manufacturing process. According to Frost & Sullivan, SK08 is the first LBP to obtain registrational clinical trial approvals from both the NMPA and the U.S. FDA. It is also the world's first LBP entered into clinical development using *Bacteroides fragilis*. Furthermore, SK08 is currently in the Phase III clinical trial for IBS-D, making it the only late-stage clinical biological drug candidate in the global IBS-D field, as of the Latest Practicable Date.

As of the Latest Practicable Date, we have completed a Phase I clinical trial in healthy subjects in China, and after completing this trial, (i) for IBS indication, we have completed a Phase II clinical trial and are conducting a Phase III clinical trial in China, with the expectation to complete enrollment by the third quarter of 2027 and submit the NDA in the second half of 2028; (ii) for pediatric rotavirus diarrhea indication, we have obtained approval for a Phase II clinical trial in China and expect to commence the trial in the third quarter of 2027; (iii) for UC indication, we have obtained regulatory approvals to initiate Phase II clinical trials in both China and the U.S. and expect to commence the trial in China in the fourth quarter of 2027; (iv) for advanced solid tumor in combination with anti-PD-1/L1 monoclonal antibodies, we plan to resubmit the IND application for this program and then commence the relevant clinical trial in the fourth quarter of 2028, as the validity period of the previous IND approval had expired.

Drug Design and Mechanism of Action

As an LBP candidate based on a novel strain of *Bacteroides fragilis*, SK08 primarily exerts its effects by protecting the intestinal barrier, modulating local immune responses and enhancing the body's ability to respond to viruses or tumors, with potential applications in IBS, pediatric rotavirus diarrhea, UC and advanced solid tumors in combination with anti-PD-1/L1 monoclonal antibodies. In IBS, SK08 alleviates visceral hypersensitivity by upregulating SERT expression in the intestinal epithelium and promoting 5-HT reuptake.

Mechanism of Action of SK08 in IBS and UC

IBS and UC are distinct intestinal diseases with partially overlapping pathophysiological features. IBS is mainly characterized by visceral hypersensitivity, while UC is an inflammatory disease characterized by intestinal mucosal inflammation and injury. Common features of these two diseases include impaired intestinal barrier function, dysregulated local immune responses. Based on our preclinical data and published literature, SK08 may act through overlapping mechanisms in IBS and UC, with different disease-specific emphasis.

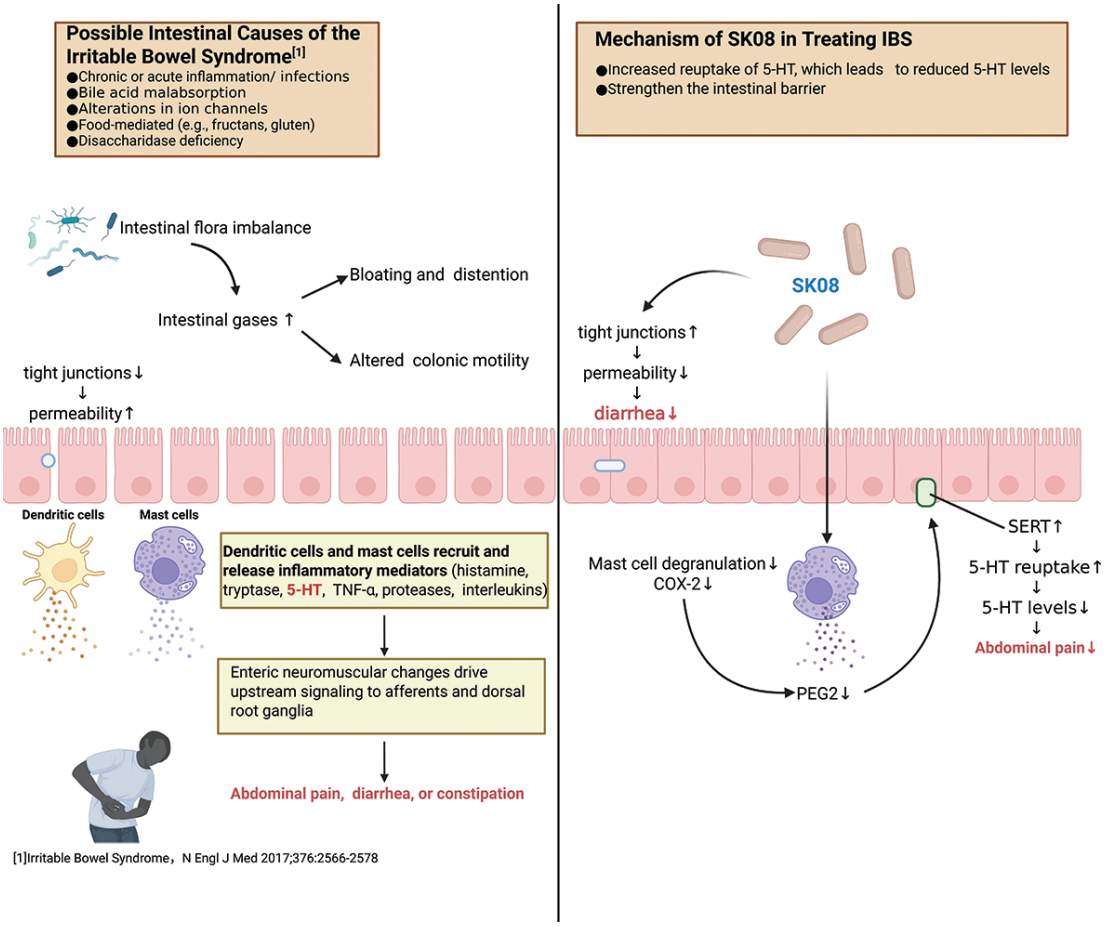
Mechanism of Action of SK08 in IBS:

- **Reducing Visceral Hypersensitivity:** In preclinical *in vivo* animal studies, SK08 reduced the abdominal withdrawal reflex score by 49% relative to the model group in an acetic acid plus restraint stress-induced model, thus demonstrating a significant improvement in pain sensitivity. Further research revealed that the analgesic effect of SK08 is closely associated with its unique mechanism of action. Our preclinical data suggest that SK08 does not directly reduce the release of certain pain-related substances (particularly 5-HT) in the intestine, but instead promotes more efficient reabsorption of 5-HT by intestinal cells through SERT, thereby reducing persistent stimulation of intestinal nerves by 5-HT and alleviating abdominal pain and other discomfort. In other words, by enhancing 5-HT reuptake to reduce free 5-HT in the intestinal mucosa, SK08 reduces pain without directly blocking receptor activity. This mechanism is particularly relevant to IBS, where visceral hypersensitivity is a hallmark feature.

- **Repairing Intestinal Barrier Protection:** Our preclinical data suggest that SK08 may enhance the protective mucus layer on the intestinal surface by upregulating mucin2 ("**MUC2**"), and strengthen the connections between intestinal cells by increasing zonula occludens-1 ("**ZO-1**") expression, thereby reducing intestinal permeability and limiting the entry of external irritants and harmful substances into deeper intestinal tissues. This effect is particularly important in IBS, as symptoms are often more likely to recur or worsen once the intestinal barrier is impaired.

- **Promoting Intestinal Immune Tolerance:** Our preclinical data and related literature (e.g., Mazmanian S. K. et al. *Nature*, 2008) suggest that SK08 and its related components, such as polysaccharide A ("**PSA**"), may help restore balance in intestinal immune responses and reduce unnecessary immune overactivation, potentially by (i) modulating signaling involving immune cells, such as regulatory T cells ("**Treg cells**"), that help coordinate immune responses; and (ii) promoting a more tolerant local immune environment, which may reduce mast cell degranulation or activation (i.e., the release of inflammatory substances or the triggering of inflammatory responses) and thereby alleviate inflammation and irritation.

The following figure illustrates the mechanism of action of SK08 in IBS:



Source: the Company

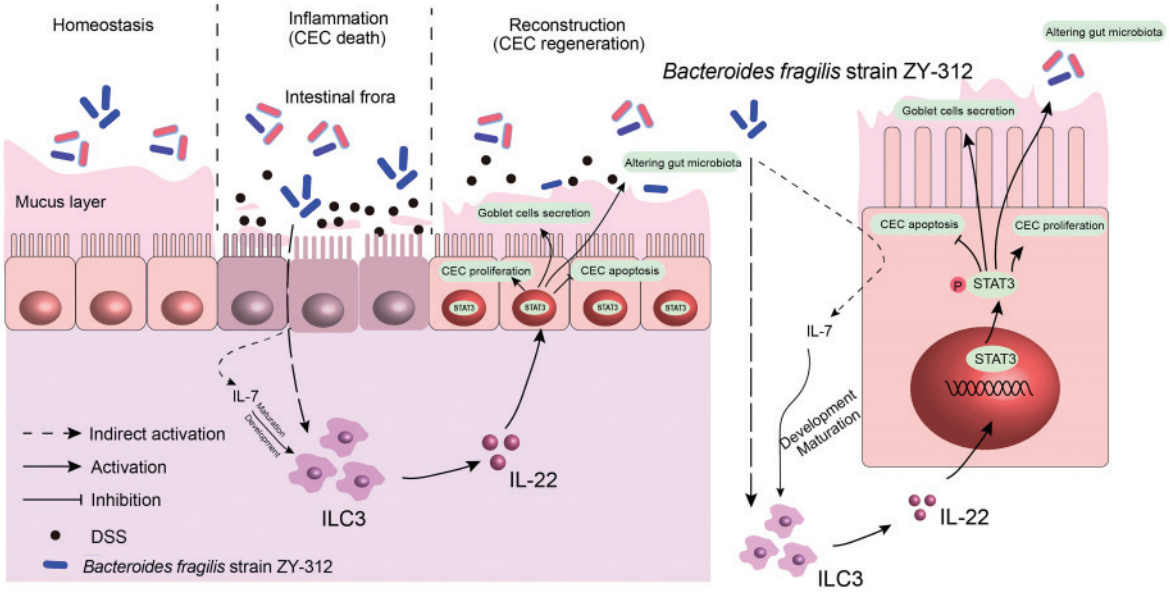
Mechanism of Action of SK08 in UC:

- **Repairing Intestinal Barrier Protection and Promoting Mucosal Healing:** Similar to its proposed effect in IBS, SK08 may enhance the protective mucus layer by upregulating MUC2 and strengthen intestinal epithelial connections by increasing ZO-1 expression, thereby reducing intestinal permeability. In UC, SK08 may promote group 3 innate lymphoid cells ("**ILC3**") to secrete interleukin-22 ("**IL-22**") through interleukin-7 ("**IL-7**") signaling. Specifically, SK08 stimulates intestinal epithelial cells to secrete IL-7, which promotes the differentiation and maturation of ILC3. In addition, by activating ILC3, SK08 increases the secretion of IL-22, which in turn activates the signal transducer and activator of transcription 3 (STAT3) pathway to promote intestinal mucosal regeneration and healing.

- **Promoting Intestinal Immune Tolerance and Suppressing Inflammation:** Similar to its proposed immunomodulatory effect in IBS, SK08-related components, such as PSA, may help restore balance in intestinal immune responses and reduce unnecessary immune overactivation, potentially through modulation of Treg cells. In UC, SK08 may also inhibit inflammatory pathways in intestinal tissue, including toll-like receptor 2 (TLR2), toll-like receptor 4 (TLR4), myeloid differentiation primary response 88 (MyD88) and nuclear factor kappa B p65 (NF-κB p65), thereby suppressing excessive intestinal inflammation.

- **Modulating Gut Microbiota:** Based on our preclinical data, SK08 may modulate gut dysbiosis in animals of intestinal inflammation, with a reduced relative abundance of the genus *Allobaculum* and increased relative abundances of the genera *Ruminococcus* and *Lactobacillus*. This mechanism is relevant to UC because gut microbiota dysbiosis is associated with intestinal inflammation and disruption of intestinal homeostasis.

The following figure illustrates the mechanism of action of SK08 in UC:

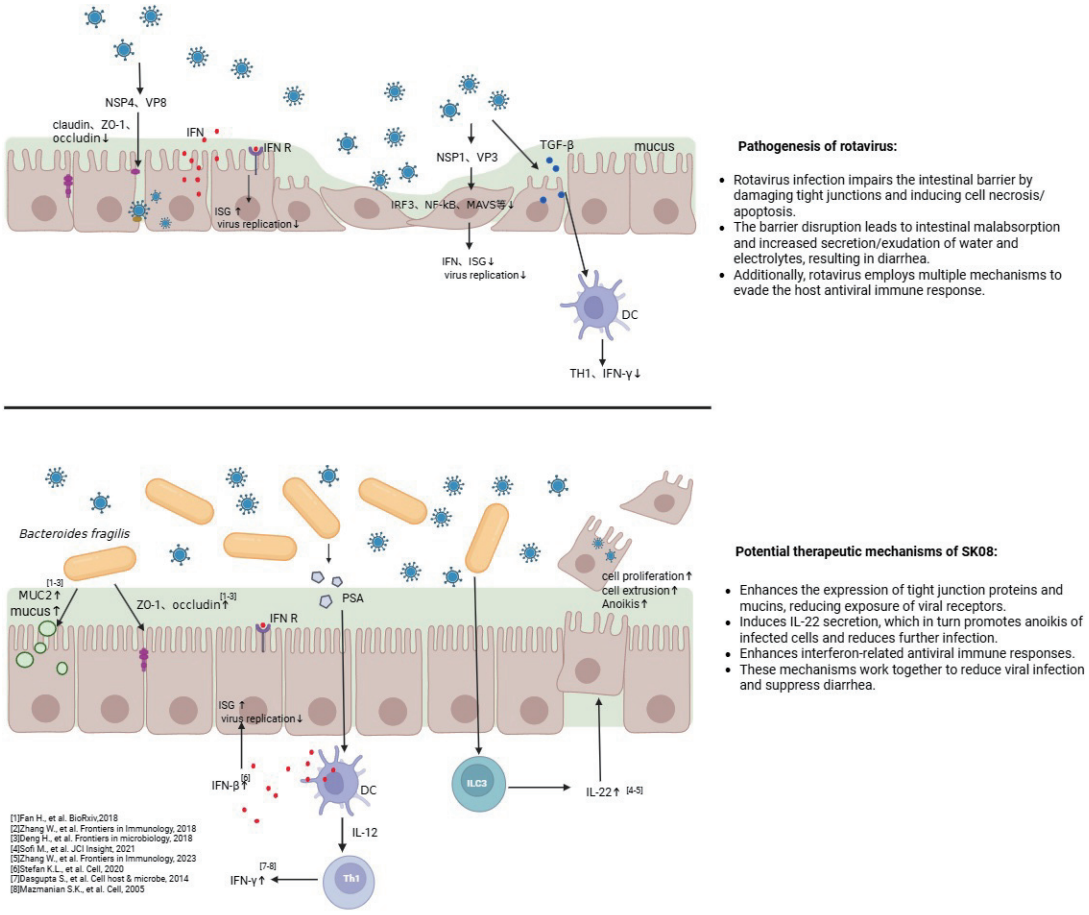


Source: Zhang W. et al., Front. Immunol., 2017

Mechanism of Action of SK08 in Pediatric Rotavirus Diarrhea

Pediatric rotavirus diarrhea is primarily associated with rotavirus-induced damage to the intestinal barrier, including injury to intestinal surface cells and disruption of their connections. Similar to the mechanism observed in IBS and UC indications, once the intestinal barrier is impaired, its protective function is weakened and the intestine becomes more susceptible to viral attack and other external stimuli, which may in turn lead to reduced absorption and increased secretion or exudation, ultimately resulting in diarrhea.

Based on published literature (e.g., Stefan K. L., et al. *Cell*, 2020; Mazmanian S. K., et al. *Cell*, 2005) and our preclinical data, SK08 is supposed to act in this indication mainly by (i) strengthening the intestinal barrier, on the one hand by increasing the expression of intestinal mucins and tight junction proteins (such as ZO-1 and occludin), may reduce the exposure of viral receptors and decrease infection, and on the other hand, SK08 stimulates the secretion of IL-22, which promotes intestinal repair and facilitates the extrusion of infected cells into the intestinal lumen, thereby reducing subsequent infection of other intestinal cells; as well as (ii) enhancing the body's antiviral response by promoting the production of immune molecules (e.g., IFN-β and IFN-γ) that help defend against viral infection and suppress viral replication. Such a mechanism is illustrated by the diagram below:

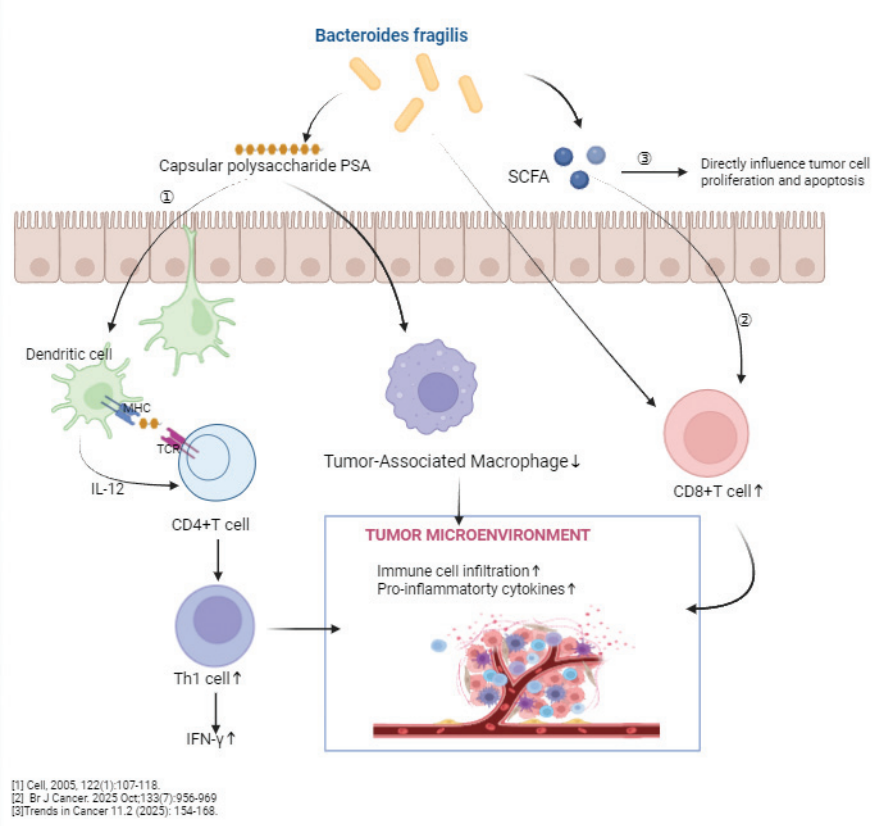


Source: the Company

Mechanism of Action of SK08 in Advanced Solid Tumor (with anti-PD-1/L1 Monoclonal Antibodies)

In tumor treatment, a key role of immune checkpoint inhibitors (e.g., anti-PD-1/L1 monoclonal antibodies) is to restore the immune system's ability to recognize and attack tumor cells. However, not all patients achieve satisfactory efficacy, and one important reason is that the anti-tumor immune response may be insufficiently active. According to published literature (Vétizou M., et al. *Science*, 2015; Matson V., et al. *Curr Opin Pharmacol*, 2020; An D., et al. *Chem Sci*, 2023), *Bacteroides fragilis*-related components and metabolites, such as PSA and short-chain fatty acids ("**SCFAs**"), may help activate immune cells involved in anti-tumor responses and enhance the immune system's recognition and attack of tumor cells, for example by (i) promoting dendritic cell maturation and IL-12 secretion triggers Th1 responses and facilitates anti-tumor immune activation; and (ii) enhancing the infiltration of CD8+ T cells into the tumor microenvironment, which facilitates the direct killing of tumor cells. Certain related metabolites, such as SCFAs, may also directly affect tumor cell growth, including by inducing

programmed tumor cell death or inhibiting cell proliferation. Overall, in this setting, *Bacteroides fragilis*, including SK08, is not intended to directly replace anti-tumor therapies, but rather to enhance the efficacy of immune checkpoint inhibitors by improving the body's immune environment. Such a mechanism is illustrated by the diagram below:



Source: the Company

Market Opportunity and Competition

SK08 is a product candidate developed based on the concept of LBPs, and is intended for IBS, UC, pediatric rotavirus diarrhea and oncology-related indications. According to Frost & Sullivan, the patient populations for the above indications are substantial, and significant unmet medical needs generally remain in disease management. Meanwhile, as an emerging therapeutic category, LBPs are still at a stage of rapid development, with a limited number of approved products overall and a growing number of pipeline candidates under development, which may provide SK08 with broad market opportunities and differentiated competitive positioning.

Overview of the LBP Market

Pursuant to the draft guidance of Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information, the FDA defines LBPs as a class of biological products containing live organisms, such as bacteria, that are intended for the prevention, treatment, or cure of human diseases or conditions, and that are not classified as vaccines. In China, although the term "LBPs" is not expressly used as a standalone statutory category, products of this nature are generally regulated under the framework for biological products, as biological products are defined to include products made from microorganisms and other biological materials under the Requirements for Registration Classification and Application Dossiers of Biological Products issued by the NMPA in 2020.

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 development indications, clinical evidence requirements and CMC controls, according to Frost & Sullivan. Nowadays, LBPs represent an emerging, high-potential segment of the global biopharmaceutical industry, and also an expansion beyond drugs based on defined active entities, such as antibodies and proteins, towards systematic treatments based on microecological modulation.

According to Frost & Sullivan, the global LBPs market was valued at USD4.7 billion in 2025 and is expected to reach USD7.5 billion by 2030, representing a CAGR of 9.8% from 2025 to 2030, while the China LBP market was valued at USD1.1 billion in 2025 and is expected to reach USD1.9 billion by 2030, representing a CAGR of 11.6% from 2025 to 2030. 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. For further details, see "Industry Overview — Overview of the LBP Market."

SK08 in the LBP Market

SK08 has several distinguishing features in China's LBP market, including its pioneering clinical milestones, novel strain R&D basis and orally administered product form. Firstly, according to Frost & Sullivan, SK08 is the first LBP to obtain registrational clinical trial approvals from both the NMPA and the U.S. FDA, and it is the only late-stage clinical biological drug candidate in the global IBS-D field, as of the Latest Practicable Date. Secondly, the scientific potential of *Bacteroides fragilis* across multiple diseases has long been recognized by the industry, while its pharmaceutical translation involves high technical barriers, according to Frost & Sullivan. In this context, according to Frost & Sullivan, as of the Latest Practicable Date, SK08 is the first and only clinical-stage LBP candidate globally developed based on *Bacteroides fragilis*, which provides a differentiated biological basis for the product. Thirdly, as an orally administered LBP, SK08 offers a convenient route of administration, which may improve patient compliance and facilitate outpatient or home-based use.

SK08 for IBS: Market, Treatment and Competitive Landscape

IBS is a common chronic functional gastrointestinal disorder characterized by recurrent abdominal pain, bloating and altered bowel habits, which may materially impair patients' quality of life and create a substantial long-term healthcare burden. IBS with diarrhea ("**IBS-D**") is a major subtype of IBS characterized predominantly by diarrhea, often accompanied by recurrent abdominal pain, urgency, and other bowel-related symptoms. According to Frost & Sullivan, among patients with IBS, IBS-D accounts for approximately 70.0% of the patient population. In 2025, the number of IBS patients, prevalence rate and diagnosis rate were 165.8 million, 11.8%, and 25.0%, respectively, in China. 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, representing a CAGR of 4.8% from 2025 to 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, representing a CAGR of 5.0% from 2025 to 2030. These growing patient populations and market sizes highlight the market opportunity in IBS and IBS-D treatment.

Current therapeutic options for IBS remain limited and mainly aim to relieve individual symptoms rather than provide comprehensive disease control, and most of them have limitations regarding long-term use. For example, antispasmodics act on specific ion channels in intestinal smooth muscle to alleviate spasms. However, as such drugs primarily provide symptomatic relief by reducing smooth muscle contraction, they do not directly address the broader pathophysiological mechanisms of IBS-D, such as visceral hypersensitivity and intestinal barrier impairment. Furthermore, certain agents, such as eluxadoline and rifaximin, are recommended for IBS-D in some guidelines, but their use may be limited

by safety concerns or restricted indications. Antidepressants, including TCAs and SSRIs, may be used in selected patients, but are not IBS-specific therapies and their tolerability may affect treatment adherence. Probiotics are also used in clinical practice, however, their clinical efficacy is highly dependent on specific strains, and evidence supporting overall symptom improvement remains limited. As a result, existing treatments often fail to achieve satisfactory overall symptom control and are not suitable for long-term use, resulting in low patient satisfaction.

As of the Latest Practicable Date, 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. For further details, see "Industry Overview — Irritable Bowel Syndrome Drug Market."

SK08 for Pediatric Rotavirus Diarrhea: Market, Treatment and Competitive Landscape

Pediatric rotavirus diarrhea is one of the most common infectious diarrheal diseases in infants and young children and may lead to dehydration, hospitalization and, in severe cases, death. As the disease primarily affects pediatric patients and presents clear clinical needs in symptom management and disease course control, patients' families may demonstrate a relatively strong willingness to pay for safe, effective and convenient treatment options, supporting a meaningful potential market opportunity. According to Frost & Sullivan, in China, the incidence of pediatric rotavirus diarrhea patients was 19.0 million in 2025 and is expected to reach 19.4 million by 2030, representing a CAGR of 0.4% from 2025 to 2030. Frost & Sullivan estimates that the China pediatric rotavirus diarrhea treatment market was RMB2.0 billion in 2025 and is expected to reach RMB2.4 billion by 2030.

According to Frost & Sullivan, current treatment paradigms remain mainly supportive and do not directly address underlying microbiome dysfunction. Furthermore, while probiotics are commonly used in clinical practice, there remains limited robust clinical evidence supporting their efficacy in the treatment of pediatric rotavirus diarrhea. This creates market opportunities for innovative therapies with differentiated mechanisms of action, including LBPs that aim to restore microbial homeostasis, enhance barrier integrity, and modulate immune responses. 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. For further details, see "Industry Overview — Pediatric Rotavirus Diarrhea Drug Market."

SK08 for UC: Market, Treatment and Competitive Landscape

UC is a chronic inflammatory bowel disease affecting the colonic and rectal mucosa and is commonly associated with diarrhea, rectal bleeding and abdominal pain, with severe cases potentially resulting in hospitalization, surgery and long-term complications. In addition, according to the guideline published by the European Crohn's and Colitis Organization, patients with UC also have an increased long-term risk of developing colorectal cancer compared to the general population. In light of the substantial existing disease burden of UC in Western countries, and the rapidly increasing prevalence of UC globally, including in China, we are advancing clinical development of SK08 for UC in both China and the U.S. According to Frost & Sullivan, the number of UC patients was 5.3 million globally and 0.6 million in China in 2025 and is expected to increase to 6.2 million globally and 0.9 million in China by 2030, representing CAGRs of 3.3% and 7.3%, respectively. The global UC treatment market was USD9.7 billion in 2025 and is expected to reach USD13.2 billion by 2030.

In China and the U.S., UC treatment remains largely severity-based and step-up in nature, while existing therapies are subject to limitations such as inadequate response, relapse, steroid dependence and long-term safety concerns, creating unmet needs for differentiated therapies such as SK08. As of the Latest Practicable Date, there are seven clinical-stage LBP candidates for UC globally, of which SK08 is the only candidate led by a Chinese company and under development in China. For further details, see "Industry Overview — Ulcerative Colitis Drug Market."

SK08 for Advanced Solid Tumor (with anti-PD-1/L1 Monoclonal Antibodies): Market, Treatment and Competitive Landscape

According to Frost & Sullivan, the incidence of solid tumors in China increased from 4,429.0 thousand cases in 2020 to 4,916.0 thousand cases in 2025, representing a CAGR of 2.2%, and is expected to further increase to 5,487.0 thousand cases in 2030, representing a CAGR of 2.1% from 2025 to 2030. The growing patient population supports the continued demand for anti-tumor therapies in China. Frost & Sullivan further estimates that the China anti-tumor drug market increased from RMB197.5 billion in 2020 to RMB279.1 billion in 2025, representing a CAGR of 7.2%, and is expected to further increase to RMB504.0 billion in 2030, representing a CAGR of 12.5% from 2025 to 2030.

Although anti-PD-1/L1 monoclonal antibodies have become an important treatment option for various advanced solid tumors, a meaningful proportion of patients do not achieve durable clinical benefit, in part due to insufficient anti-tumor immune response rates, inter- and intra-patient variability, as well as resistance to anti-PD-1/L1 monoclonal antibodies. Combination therapies have therefore become an important strategy to enhance response rates and mitigate resistance associated with PD-1/PD-L1 inhibitors. In addition, from the perspective of microbiome-based or LBP-related therapies in oncology, the field remains at an early stage of development, with no approved products and only two clinical-stage candidates in China, which may provide market opportunities for differentiated product candidates such as SK08 in combination with PD-1/L1 inhibitors. For further details, see "Industry Overview — Advanced Solid Tumors (in Combination with anti-PD-1/L1 Monoclonal Antibodies) Drug Market."

Key Advantages

Novel Bacteroides fragilis Strain — Exclusive Cultivation and Core Technological Barriers

SK08 is an innovative LBP developed from a novel strain of *Bacteroides fragilis*. According to Frost & Sullivan, the biological functions and potential therapeutic value of *Bacteroides fragilis* across multiple diseases have been widely recognized in the academic community, and based on its unique mechanism, it is considered to address multiple pathophysiological features of intestinal diseases, including intestinal barrier repair, restoration of immune tolerance, and reduction of visceral hypersensitivity, offering a multimodal therapeutic approach distinct from traditional single-target drugs. However, the pharmaceutical development of *Bacteroides fragilis* is associated with significant challenges, including stringent anaerobic cultivation requirements, manufacturing and quality control difficulties, limited survival and functional stability following oral administration, genetic variability affecting consistency, and potential safety risks as an opportunistic pathogen.

Against this backdrop, we have not only successfully identified a pharmaceutically developable strain but also become the first and only company globally to advance a *Bacteroides fragilis*-based LBP into clinical trials, as of the Latest Practicable Date. In addition, as the second-generation LBP project supported under the National High-tech R&D Program of China (863 Program), SK08 reflects the national-level recognition of our ability to address key technical and safety evaluation challenges in exploring the development path for second-generation LBP candidates in China. Leveraging our research and development capabilities and CMC platform, we have established proprietary processes covering strain screening, anaerobic cultivation, large-scale fermentation, activity maintenance, formulation stability and quality control. These capabilities support the viable delivery, functional stability and product consistency of SK08. In addition, we have implemented safety evaluation and risk control measures throughout the development process to support its clinical development. As early as 2016, we completed a systematic safety evaluation of SK08 when directly comparable industry precedents were limited and generally accepted standards for the safety evaluation of second-generation LBPs were still evolving. Our related work was subsequently recognized as a representative study in *Frontiers* and have provided a reference for subsequent safety evaluation practices in the industry. Together, our rare bacterial strains, proprietary production processes and accumulated technical know-how have formed a robust technological moat and strengthened our position in the LBP therapeutics field.

Offering a More Comprehensive Clinical Efficacy for the Treatment of IBS-D

SK08's mechanism of action provides a differentiated biological rationale for treating IBS-D by targeting more upstream pathways and offering a more comprehensive and long-term benefit than conventional symptomatic therapies, and this rationale has been further reflected in its clinical performance.

For IBS, recurrent abdominal pain is a core symptom that affects patients' quality of life. Commonly used antispasmodics in clinical practice mainly provide symptomatic relief by reducing intestinal smooth muscle spasms, but do not directly address broader disease-related mechanisms of IBS. Certain antispasmodics may also be associated with anticholinergic effects, which may limit their suitability for long-term use in some patients. In contrast, SK08 not only targets more upstream pathways relevant to abdominal pain relief but also provides broader therapeutic effects, including long-term benefits, than antispasmodics by improving intestinal barrier function and regulating intestinal immune homeostasis. In addition, IBS-D, as a major subtype of IBS, is also characterized by diarrhea as another key clinical feature. Commonly used antidiarrheal agents, such as loperamide, primarily achieve antidiarrheal effects by slowing intestinal motility. As a result, they do not directly relieve abdominal pain and may, in some patients, worsen abdominal pain or constipation. Rifaximin, another commonly used antidiarrheal therapy, is a non-absorbed antibiotic that mainly inhibits the growth of relevant intestinal bacteria by suppressing bacterial RNA synthesis, and its effect on abdominal pain relief is also relatively limited.

SK08 not only demonstrated differentiated clinical benefits compared with the above symptomatic therapies, which generally target a single primary symptom, but also showed numerically superior efficacy outcomes in cross-trial comparisons with therapies intended to improve both abdominal pain and diarrhea. Eluxadoline is an FDA-approved drug used for IBS-D, designed to address both diarrhea and abdominal pain, but it has not been approved for marketing in China as of the Latest Practicable Date. Although no head-to-head clinical trial has been conducted between SK08 and eluxadoline, a cross-trial comparison of placebo-controlled clinical data from patient subgroups with similar baseline characteristics showed that the SK08 high-dose group achieved numerically more favorable primary efficacy endpoint results than those reported for eluxadoline. For further details, see "— Our Competitive Strengths" above in this section.

Favorable Safety and Sustained Efficacy Profile Supporting Long-term Disease Management

As IBS and UC are chronic and recurrent conditions that may require long-term disease management, and pediatric rotavirus diarrhea involves treatment in children, the safety and tolerability profile of therapies is particularly important.

Particularly, current treatment options for IBS are generally designed for relatively short treatment durations, such as two weeks or eight weeks, and there remains an unmet need for therapies suitable for long-term disease management. SK08 has demonstrated favorable safety and tolerability in clinical trials, with no apparent difference in the overall incidence of adverse events between the SK08 groups and the placebo group in the Phase II clinical trial (53.4% and 54.1% in the SK08 high-dose and low-dose groups, respectively, vs. 61.0% in the placebo group). No drug-related serious adverse events were reported, and no treatment-emergent adverse events led to treatment discontinuation, early withdrawal or death. SK08 also demonstrated a favorable sustained efficacy profile. Following the initial efficacy observed during Weeks 1 to 4 of treatment, the SK08 high-dose group showed more pronounced symptom improvement than the placebo group from Week 5 onwards, indicating a stable and sustained therapeutic effect over the treatment. This profile also supports SK08's potential advantages in the long-term management of IBS-D as a chronic condition. In light of its safety, tolerability and sustained efficacy profile, the Phase III clinical trial of SK08 adopts a 52-week treatment regimen, which, if successfully developed and approved, may support SK08's potential to provide a long-term treatment option for IBS. In addition, SK08 is derived from a non-toxic strain of *Bacteroides fragilis*, which is part of the human gut microbiota under normal physiological conditions; therefore, it may support its development for long-term administration. For further details, see "— Summary of Clinical Trials" below.

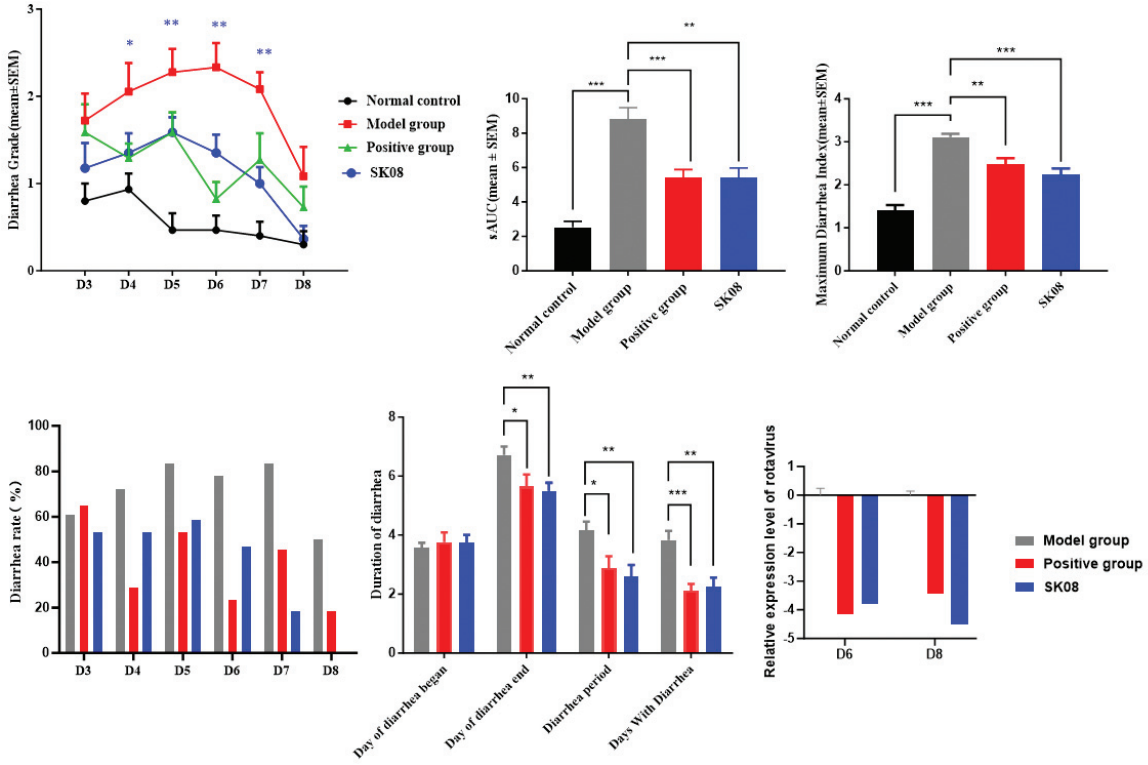
More Pronounced Clinical Benefits in Severe IBS-D Patients

SK08 high dose showed greater clinical benefits in patient subgroups with higher disease severity. Among patients, with weekly diarrhea days of ≥4, the eight-week composite weekly response rate in SK08 high-dose group achieved a response rate of 52.2%, compared with 35.6% in the placebo group. Among patients with IBS-SSS score>300, the eight-week composite weekly response rates were 57.1% and 30.0% in the SK08 high-dose group and placebo group, respectively. These results highlight SK08's potential clinical value in addressing the treatment needs of patients with severe IBS-D.

Potential for the Treatment of Multiple Diseases

In addition to IBS, our preclinical studies have shown that SK08 also has potential therapeutic value in multiple diseases, including pediatric rotavirus diarrhea, UC and tumors.

In a rotavirus-induced diarrhea model in suckling Lewis rats, which was used to assess pediatric virus-related diarrhea, SK08 improved multiple diarrhea-related parameters, including diarrhea scores, area under the diarrhea score curve, maximum diarrhea index, diarrhea rate, diarrhea duration and days with diarrhea, with a dose-dependent trend. In particular, the SK08 high-dose group reduced rotavirus positivity rates to 16.67% and 9.09% on Day 6 and Day 8, respectively, and reduced the relative viral expression level by approximately 10,000 to 100,000 times, indicating reduced viral burden in the model. SK08 also dose-dependently reduced the cytopathic effect induced by rotavirus in MA104 cells and increased cell viability, further supporting its antiviral-related activity *in vitro*.



Note: Normal control group refers to healthy animals that were not subjected to disease modeling or drug treatment. Model group refers to animals subjected to disease modeling without therapeutic intervention. Positive group refers to model animals treated with a positive control drug. SK08 group refers to model animals treated with SK08.

In UC animal models, including DNBS-induced Wistar rat colitis and DSS-induced C57BL/6 mouse colitis models, which are commonly used to evaluate intestinal inflammation and colitis-like pathological changes, SK08 showed pharmacodynamic effects on intestinal inflammation and tissue injury. These effects were reflected by improvements in colorectal injury scores (intestinal adhesion, intestinal wall thickening, etc.), ulcer area and histopathological scores, which are indicators used to assess the severity of intestinal inflammation and tissue damage.

In tumor models, SK08 in combination with anti-PD-1/L1 monoclonal antibodies showed enhanced antitumor activity in CT26 colorectal cancer, H22 liver cancer and B16F10 melanoma mouse models, as compared with anti-PD-1/L1 monoclonal antibodies monotherapy, suggesting its potential role in improving antitumor immune responses when used in combination with immune checkpoint inhibition.

Summary of Clinical Trials

As of the Latest Practicable Date, in China, we (i) have completed a Phase I clinical trial in healthy subjects and a Phase II clinical trial in patients with IBS-D; (ii) are conducting a Phase III clinical trial in patients with IBS-D; and (iii) plan to initiate (a) the Phase II clinical trial for pediatric rotavirus diarrhea in the third quarter of 2027, (b) the Phase II clinical trial for advanced solid tumor in combination with anti-PD-1/L1 monoclonal antibodies in the fourth quarter of 2028, and (c) the Phase II clinical trial for UC in the fourth quarter of 2027. In addition, we have also obtained the regulatory approval to initiate a Phase II clinical trial for UC in the U.S.

The table below sets forth an overview of all the completed and ongoing clinical trials for SK08:

Trial Number	Phase	Subjects	Country	Trial Design	Status	Initiation Date	Actual/Expected Completion Date
SK08-301	III	IBS-D Patients	China	Multicenter, Randomized, Double-Blind, Placebo-Controlled	Ongoing	March 2024	Primary efficacy endpoint assessment expected by the fourth quarter of 2027; full trial completion expected in 2028
ZHIYI202101 . . .	II	IBS-D Patients	China	Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group	Completed	August 2021	September 2022
2019-I-SK08-01 . .	I	Healthy Subjects	China	Single-center, Randomized, Double-Blind, Placebo-Controlled	Completed	May 2020	November 2020

Ongoing Phase III Clinical Trial of SK08 for IBS-D in China

This study is a multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial to evaluate the efficacy and safety of SK08 in the treatment of IBS-D. To preserve the integrity of the blind, the trial protocol did not pre-specify any interim analysis. The first patient was enrolled ("**FPI**") on March 16, 2024. As of the Latest Practicable Date, a total of 690 participants have been enrolled. We expect to complete patient enrollment by the third quarter of 2027 and primary efficacy endpoint assessment by the fourth quarter of 2027.

- **Enrollment and Dosing Regimen:** The study is planned to enroll 1298 participants aged 18 to 70 years old, who will be randomized in a 1:1 ratio to receive SK08 or placebo orally twice daily for 52 weeks.

- **Key Eligibility Criteria:** Eligible subjects were adults aged 18 to 70 years who met the Rome IV criteria for IBS-D. During the two-week run-in period, they had Bristol Stool Form Scale Type 6 or Type 7 stools on at least four days per week, an average daily worst abdominal pain NRS score of at least 3.0 on the relevant days, and a normal colonoscopy report within the past 12 months.

- **Primary Efficacy Endpoint:** The composite weekly response rate during Weeks 1 to 12.

- **Safety Evaluation:** Safety will be evaluated through monitoring of adverse events ("**AEs**") and serious adverse events ("**SAEs**"), physical examinations, vital signs, 12-lead ECGs, laboratory assessments.

Completed Phase II Clinical Trial of SK08 for IBS-D in China

Trial Status

This completed study is a randomized, double-blind, placebo-controlled, multicenter, Phase II clinical trial to evaluate the efficacy and safety of SK08 in the treatment of IBS-D. The FPI date was August 7, 2021; the last subject last visit ("**LSLV**") date was September 22, 2022; and the clinical study report ("**CSR**") was completed on March 10, 2023.

Trial Design

- **Enrollment and Dosing Regimen:** A total of 180 subjects were randomized in a 1:1:1 ratio to receive high-dose SK08, low-dose SK08 or placebo. Following a two-week run-in period, subjects received treatment twice daily for eight weeks.

- **Key Eligibility Criteria:** Eligible subjects were adults aged 18 to 70 years who met the Rome IV criteria for IBS-D. During the two-week run-in period, they had Bristol Stool Form Scale Type 6 or Type 7 stools on at least two days per week, an average daily worst abdominal pain NRS score of at least 3.0 on the relevant days, and a normal colonoscopy report within the past 12 months.

- **Primary and Secondary Endpoints:** The primary endpoint was the eight-week composite weekly response rate. Secondary endpoints included abdominal pain weekly response rate and stool consistency weekly response rate.

Efficacy Results

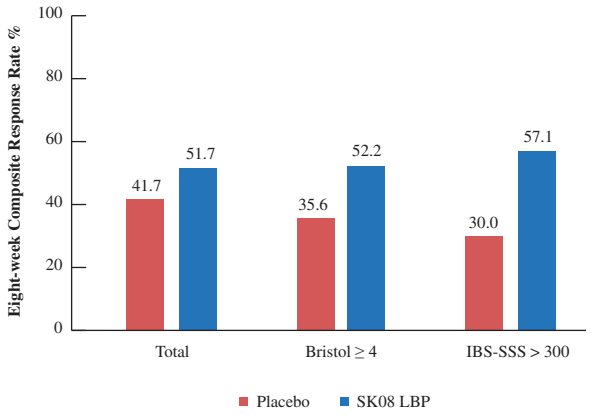
Efficacy was analyzed based on the full analysis set ("**FAS**", n=178) and the per protocol set ("**PPS**", n=162), with the FAS serving as the primary analysis set. Overall, the efficacy data showed a consistent numerical trend in favor of the high-dose group over the placebo group for the primary endpoint as well as the key secondary endpoints, with such a numerical trend becoming more apparent during Weeks 5 to 8.

- **Primary Efficacy Endpoint: Eight-week Composite Weekly Response Rate**

  In the FAS, the eight-week composite weekly response rate was 51.7% in the high-dose group, 30.0% in the low-dose group and 41.7% in the placebo group. In the PPS, the eight-week composite weekly response rate was 55.8% in the high-dose group, 30.4% in the low-dose group and 42.6% in the placebo group. In both the FAS and the PPS, the eight-week composite weekly response rate in the high-dose group was higher than that in the placebo group, with rate differences of 10.0% and 13.2%, respectively, while the SK08 low-dose group did not show superiority over the placebo group. Sensitivity analysis showed results generally consistent with the primary analysis.

Among patients with more severe disease, including those with Bristol ≥4 or IBS-SSS score >300, the eight-week composite weekly response rate in the high-dose group was substantially higher than that in the placebo group, while the low-dose group was comparable to the placebo group. For patients with Bristol ≥ 4, the rates were 52.2%, 29.3% and 35.6% in the high-dose, low-dose and placebo groups, respectively; for patients with an IBS-SSS score > 300, the rates were 57.1%, 31.3% and 30.0% in the high-dose, low-dose and placebo groups, respectively.

Primary Endpoint Results of High-Dose SK08 in the Overall Population and Severe Patient Subgroups

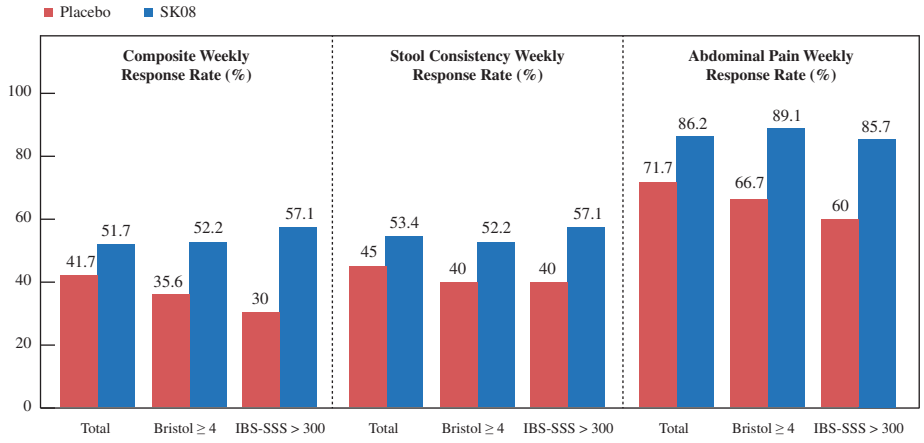


- **Secondary Efficacy Endpoints**

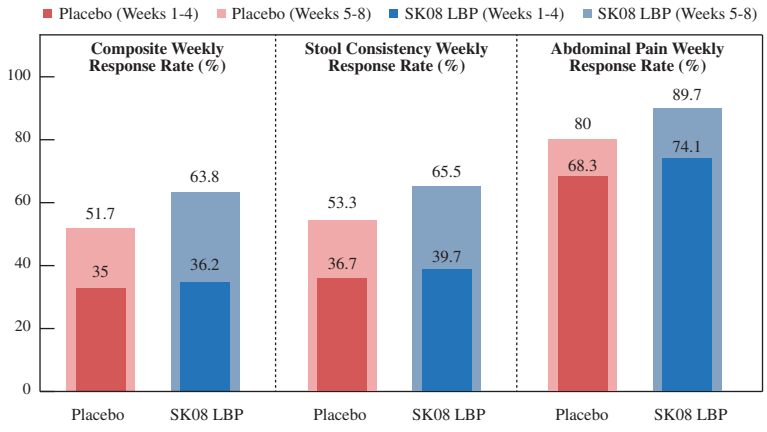
Abdominal Pain Weekly Response Rate: In the FAS, the high-dose group was numerically higher than both the low-dose group and the placebo group at each evaluated treatment period, with the low-dose group becoming superior to the placebo group starting from Week 4. During the entire treatment period of Weeks 1 to 8, the abdominal pain weekly response rate was 86.2%, 78.3% and 71.7% in the high-dose, low-dose and placebo groups, respectively. Particularly, the difference between the high-dose SK08 group and the placebo group reached 14.5 percentage points over Weeks 1 to 8. Among patients with Bristol ≥4, the difference further widened to 22.4 percentage points, which was statistically significant (p=0.010). During Weeks 1 to 4, the rates were 74.1%, 68.3% and 68.3% in the high-dose group, low-dose group and placebo group, respectively; during Weeks 5 to 8, the rates were 89.7%, 83.3% and 80.0%, respectively. As the treatment duration extended, the trend of superiority of the high-dose and low-dose groups over the placebo group became more apparent, and the slope of the dose-response curve increased.

Stool Consistency Weekly Response Rate: In the FAS, the high-dose group was numerically higher than the placebo group at each evaluated treatment period, while the low-dose group did not show superiority over the placebo group. During the entire treatment period of Weeks 1 to 8, the stool consistency weekly response rate was 53.4%, 30.0% and 45.0% in the high-dose, low-dose and placebo groups, respectively. During Weeks 1 to 4, the rates were 39.7%, 21.7% and 36.7%, respectively; during Weeks 5 to 8, the rates were 65.5%, 46.7% and 53.3%, respectively.

Results of High-Dose SK08 in the Overall Population and Severe Patient Subgroups During Weeks 1-8



Results of High-Dose SK08 During Weeks 1–4 and Weeks 5–8



Safety Results

Safety was evaluated based on the safety set ("**SS**", n=178). During this study, a total of 31 subjects (53.4%) in the SK08 high-dose group experienced 58 treatment-emergent adverse events ("**TEAEs**"), of whom 12 subjects (20.7%) experienced 17 drug-related TEAEs. In the low-dose group, 33 subjects (54.1%) experienced 56 TEAEs, of whom 12 subjects (19.7%) experienced 14 drug-related TEAEs. In the placebo group, 36 subjects (61.0%) experienced 51 TEAEs, of whom 11 subjects (18.6%) experienced 16 drug-related TEAEs. No apparent difference in overall adverse event incidence was observed among the three groups.

No TEAE leading to discontinuation, death or early withdrawal from the study was reported. No CTCAE Grade 3 or above drug-related TEAE was reported. A total of four SAEs were reported, including three cases of fascioliasis and one case of hemorrhoids, all of which were considered unrelated to the study drug by the investigators. The severity of all drug-related AEs was Grade 1 or Grade 2. Among drug-related TEAEs with an incidence of 5% or above, hyperuricemia was reported in three subjects (5.2%) in the high-dose group, none in the low-dose group, and three subjects (5.1%) in the placebo group, while hypertriglyceridemia was reported in three subjects (5.1%) in the placebo group.

Summary of AEs — Safety Analysis Set

	High-Dose Group (N=58)		Low-Dose Group (N=61)		Placebo Group (N=59)	
	n (%)	NE	n (%)	NE	n (%)	NE
Any TEAEs	31 (53.4)	58	33 (54.1)	56	36 (61.0)	51
Grade 1	26 (44.8)	42	25 (41.0)	40	34 (57.6)	47
Grade 2	8 (13.8)	12	10 (16.4)	15	4 (6.8)	4
Grade 3	4 (6.9)	4	1 (1.6)	1	0	0
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
TEAEs of Grade 3 or Higher Severity	4 (6.9)	4	1 (1.6)	1	0	0
TEAEs Leading to Drug Discontinuation	0	0	0	0	0	0
TEAEs Leading to Death	0	0	0	0	0	0
TEAEs Leading to Premature Withdrawal from Trial	0	0	0	0	0	0
TEAEs Related to Study Drug*	12 (20.7)	17	12 (19.7)	14	11 (18.6)	16
Grade 1	12 (20.7)	16	11 (18.0)	13	11 (18.6)	14
Grade 2	1 (1.7)	1	1 (1.6)	1	2 (3.4)	2
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Study Drug-Related TEAEs of Grade 3 or Higher Severity	0	0	0	0	0	0
Study Drug-Related TEAEs Leading to Drug Discontinuation	0	0	0	0	0	0
Study Drug-Related TEAEs Leading to Death	0	0	0	0	0	0
Study Drug-Related TEAEs Leading to Premature Withdrawal from Trial	0	0	0	0	0	0
Serious Adverse Events (SAEs)	3 (5.2)	3	1 (1.6)	1	0	0
Study Drug-Related SAEs	0	0	0	0	0	0

* Study Drug-related TEAE is defined as a TEAE "definitely related to" or "possibly related to" the study drug. TEAE with "unclassifiable" or missing causality was considered related to the study drug.

Overall, the Phase II clinical trial results support the further clinical development of SK08 in IBS-D. In terms of efficacy, the high-dose group showed higher response rates than the placebo group for the primary endpoint of eight-week composite weekly response rate and the key secondary endpoints of abdominal pain weekly response rate and stool consistency weekly response rate. In terms of safety, SK08 was generally safe and well tolerated in this study, with no apparent difference in the AEs incidence among the high-dose group, the low-dose group and the placebo group, and all drug-related AEs being Grade 1 or Grade 2 in severity.

Completed Phase I Clinical Trial of SK08 in China

This completed study was a single-center, randomized, double-blind, placebo-controlled Phase I clinical trial of SK08 in healthy subjects in China, consisting of a single-ascending-dose ("**SAD**") portion and a multiple-ascending-dose ("**MAD**") portion, to evaluate its initial safety and tolerability. The first subject was enrolled on May 18, 2020, and the CSR was completed on December 30, 2020.

- SAD Portion

  Trial Design: This trial evaluated the safety and tolerability of single ascending oral doses of SK08. Five dose levels were evaluated, namely 1/10×(1—25×10^8) CFU, 1×(1—25×10^8) CFU, 5×(1—25×10^8) CFU, 10×(1—25×10^8) CFU and 30×(1—25×10^8) CFU, with subjects randomized in a 3:1 ratio to receive SK08 or placebo.

  Key Eligibility Criteria: Eligible subjects were healthy Chinese male or female volunteers aged 18 to 45 years old with body weight and BMI within the protocol-specified ranges. Key exclusion criteria included clinically significant abnormalities, recent gastrointestinal abnormalities, recent use of drugs or probiotic products, significant hypersensitivity history, recent participation in other clinical trials, and pregnancy or lactation.

  Results: A total of 20 subjects were enrolled. A total of 17 AEs were reported in 10 subjects, including nine adverse drug reactions in seven subjects. No SAEs occurred, and no subject discontinued due to AEs. No statistically significant difference in AEs incidence was observed between the treatment and placebo groups. No clinically significant abnormalities were observed in vital signs, physical examinations or 12-lead ECGs.

- MAD Portion

  Trial Design: This was to evaluate the safety and tolerability of multiple ascending oral doses of SK08. Two dose levels were evaluated, namely 1×(1—25×10^8) CFU and 15×(1—25×10^8) CFU. Subjects were randomized in a 6:2 ratio to receive SK08 or placebo and dosed twice daily for 14 consecutive days.

  Key Eligibility Criteria: Eligible subjects were healthy Chinese male or female volunteers aged 18 to 45 years old with body weight and BMI within the protocol-specified ranges. Key exclusion criteria included clinically significant abnormalities, recent gastrointestinal abnormalities, recent use of drugs or probiotic products, significant hypersensitivity history, recent participation in other clinical trials, and pregnancy or lactation.

  Results: A total of 16 subjects were enrolled. A total of 22 AEs were reported in 12 subjects, including 13 adverse drug reactions in 10 subjects. No SAEs occurred, and no subject discontinued due to AEs. No statistically significant difference in AEs incidence was observed between the treatment and placebo groups. No clinically significant abnormalities were observed in vital signs, physical examinations or 12-lead ECGs.

Material Communications with Competent Authorities

We obtained IND approvals from the NMPA for SK08 to treat (i) IBS and UC in November 2019; (ii) advanced solid tumors in combination with anti-PD-1/L1 monoclonal antibodies in March 2022; and (iii) pediatric rotavirus diarrhea in September 2024. We also obtained IND approval from the FDA for SK08 to treat UC in January 2025.

For IBS and UC Indications

- In November 2019, we obtained the IND approval from the NMPA for the clinical development of SK08 in IBS and UC, covering the proposed Phase I, Phase II and Phase III clinical development plan. According to such IND approval, we are not required to submit a separate clinical trial application or conduct prior regulatory communication with the CDE solely for the initiation of the Phase II clinical trial. We are, however, required to communicate with the CDE after completion of Phase I and Phase II clinical trials and before initiation of Phase III clinical trials.

- In July 2023, in accordance with the regulatory requirements regarding the IND approval, we held an End-of-Phase II/Pre-Phase III meeting with the CDE to discuss the Phase III clinical development plan. During the meeting, the CDE confirmed the overall design of our pivotal Phase III clinical trial. We also reached a consensus with the CDE that the NDA submission would be based on the data from a statistical analysis conducted after all subjects had completed 12 weeks of treatment and at least 100 subjects had completed 52 weeks of treatment.

- 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.

- 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.

For Pediatric Rotavirus Diarrhea Indication

- 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.

For Advanced Solid Tumor (with anti-PD-1/L1 Monoclonal Antibodies) Indication

- In March 2022, we obtained the 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 based on the accumulated data generated from our completed clinical trials and non-clinical evaluation of SK08.

- We did not initiate the clinical trial for this indication after obtaining the relevant approval, due to our overall pipeline prioritization and development sequencing, as well as significant changes in the competitive landscape of marketed PD-1 inhibitors in recent years, and such IND approval lapsed in March 2025. 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. Subject to regulatory clearance, we plan to initiate the relevant clinical trial in the fourth quarter of 2028.

As of the Latest Practicable Date, we have not received any material objections to our clinical development plans for SK08 from the NMPA or FDA.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SK08 SUCCESSFULLY.

SK10, Our Key Product

Overview

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. As of the Latest Practicable Date, our patent portfolio relating to this product candidate comprised 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, covering, among others, its composition, formulation, method of use and manufacturing process. According to Frost & Sullivan, SK10 is the first LBP candidate based on *Bacteroides fragilis* approved by the FDA for clinical development and 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.

As of the Latest Practicable Date, we (i) have completed a Phase I clinical trial of SK10 in the U.S. in which 50% of the enrolled subjects were of Chinese descent; (ii) have received the Acceptance Notice from the CDE regarding our IND application for a Phase II clinical trial of SK10 in China in June and plan to commence this trial in the fourth quarter of 2026, if approved; and (iii) expect to commence a Phase II clinical trial in the U.S. in the first quarter of 2028.

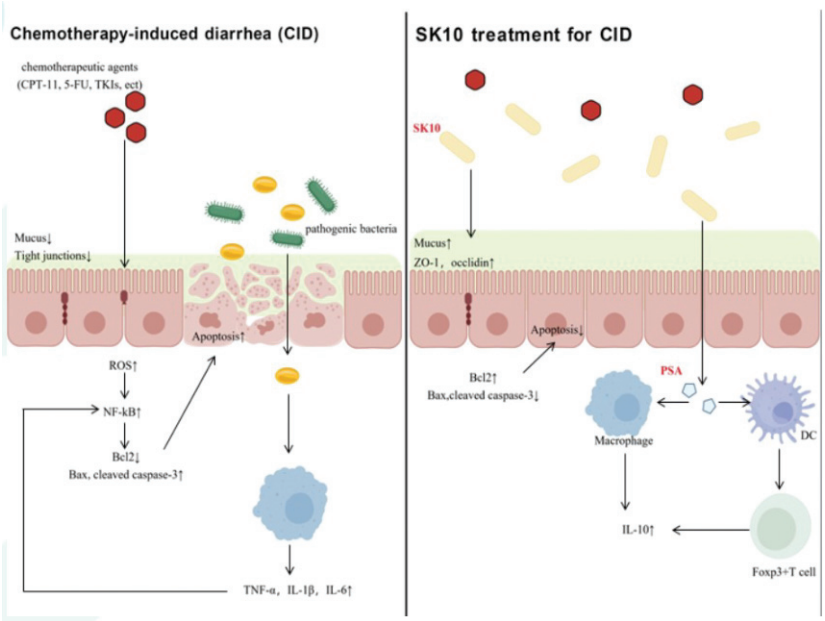
Drug Design and Mechanism of Action

CID is a common gastrointestinal adverse reaction to chemotherapy and is generally associated with chemotherapy-induced intestinal mechanical barrier and immune barrier impairment. SK10 is an inactivated bacterial product. Given that oncology patients undergoing chemotherapy often have substantially weakened immune function, the inactivated product form is considered more suitable for this indication. Based on published literature (Yan X., et al. *BMC Medicine*, 2025) and our research, SK10 is supposed to act mainly by (i) repairing chemotherapy drug-induced intestinal mechanical barrier damage by inhibiting intestinal epithelial cell apoptosis and increasing tight junction protein and mucin expression; and (ii) regulating local mucosal immune responses, thereby helping reduce intestinal mucosal injury associated with chemotherapy.

- **Repairing Mechanical Barrier Damage:** Chemotherapy causes the mucus layer to thin and damages the connections between intestinal epithelial cells, making the intestinal barrier more fragile. SK10 is supposed to help restore mechanical barrier integrity by (i) promoting mucin secretion; (ii) increasing the expression of key tight junction proteins (e.g., ZO-1 and occludin); and (iii) reducing intestinal epithelial cell apoptosis by regulating apoptosis-related protein expression (e.g., BCL2, BAX and cleaved caspase 3).

- **Enhancing Immune Barrier:** Chemotherapy often triggers a significant increase in pro-inflammatory cytokines, which impairs the immune barrier. SK10 effectively suppresses such pro-inflammatory cytokines (e.g., TNF-α, IL-1β, IL-6, and IL-8). In addition, similar to SK08, SK10 also contains PSA, which has been reported in various studies to induce macrophages and Foxp3+ T cells to secrete IL-10, an anti-inflammatory cytokine that helps maintain mucosal immune balance.

The following diagram illustrates the mechanism of action of SK10 in CID:



Source: the Company

Market Opportunity and Competition

Overview of the CID Market

As a common gastrointestinal adverse event in patients receiving chemotherapy, CID may impair patients' quality of life and treatment adherence, and in severe cases may lead to dose reduction, treatment delay or treatment discontinuation, thereby affecting overall treatment outcomes. According to Frost & Sullivan, in 2025, the incidence of patients with CID was 20.3 million globally, as compared to 5.6 million in China. Frost & Sullivan further estimates that 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. For further details, see "Industry Overview — Chemotherapy-Induced Diarrhea Drug Market."

Current Treatment Limitations

Current therapeutic options for CID remain limited and primarily focus on symptomatic management and supportive care. In addition, as of the Latest Practicable Date, there are currently no approved therapies available to effectively prevent the onset of CID or specifically for the treatment of CID. Existing therapies also have a number of limitations. For example, loperamide, a commonly used antidiarrheal agent, should generally not be used for more than 48 hours and carries a boxed warning for serious cardiac adverse effects. Octreotide is generally used in patients with refractory diarrhea after inadequate response to loperamide or in patients with Grade 3 to 4 diarrhea. As a result, current therapies generally focus on symptom control in selected settings and may be limited by restricted applicability, limited supporting evidence or safety considerations, highlighting the significant unmet medical need in CID management. For further details, see "Industry Overview — Chemotherapy-Induced Diarrhea Drug Market."

Competitive Landscape for the Treatment of CID

The competitive landscape of the treatment of CID is currently characterized by a limited number of treatment options, most of which are supportive or symptom-based therapies. As of the Latest Practicable Date, there are no approved products specifically for the treatment or prevention of CID, and only two clinical-stage LBP candidates globally targeting CID, including SK10 and KAL-002. Among them, SK10 had a substantially earlier public disclosure record and had completed a Phase I clinical trial in the U.S. as of the Latest Practicable Date. For further details, see "Industry Overview — Chemotherapy-Induced Diarrhea Drug Market."

Key Advantages

Differentiated and Pioneering Positioning in the LBP Landscape

SK10 has established a differentiated position in the LBP landscape through its strain basis, indication focus and product form. According to Frost & Sullivan, SK10 is the world's first *Bacteroides fragilis*-based LBP to receive FDA IND clearance and enter clinical development. It is also the first LBP candidate globally to be declared for CID, representing an early-mover position in this indication. In addition, according to Frost & Sullivan, we are the first company in China to advance an inactivated second-generation LBP product into the clinical stage. This reflects our capability to develop and clinically advance differentiated LBP product forms beyond conventional live bacterial approaches. These factors support SK10's differentiated competitive positioning within the emerging LBP field.

Favorable Safety Profile — Specifically Important for Patients Undergoing Chemotherapy

As an inactivated bacterial product, SK10 may minimize the potential infection risks associated with the administration of live bacteria, particularly in vulnerable patient populations such as patients undergoing chemotherapy. In our Phase I trial conducted in the U.S., SK10 was generally safe and well-tolerated. No deaths, SAEs, or TEAEs leading to study discontinuation were reported. No dose-dependent increase in the number of TEAEs was observed, nor was any significant change in severity levels as the dose escalated. For further details, see "— Summary of Clinical Trials" below.

Strong Logistical Efficiency and Cost-Effectiveness

SK10 can be stored and transported at room temperature, with relatively low reliance on cold-chain logistics or special storage conditions. This may help reduce warehousing, logistics and end-point distribution costs, while lowering the complexity of supply chain management during commercialization. Its favorable storage and transportation profile may also support broader distribution coverage, improve product accessibility across medical institutions and pharmacies, and facilitate future large-scale commercialization.

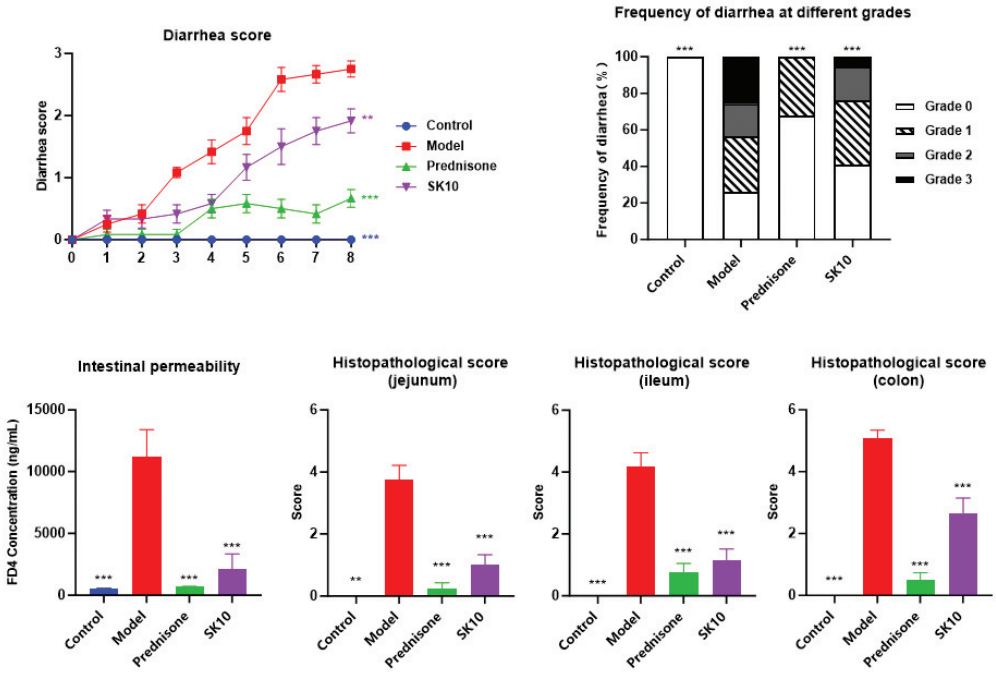
Mechanism-based Advantages in Addressing the Underlying Pathophysiology of CID

From a mechanistic perspective, SK10 is designed to address key pathophysiological changes underlying CID. As described in the section above on mechanism of action, SK10 is expected to exert its effects mainly by protecting intestinal barrier function, reducing intestinal permeability and modulating local mucosal immune responses, thereby alleviating intestinal tissue injury and diarrhea severity. These characteristics suggest that SK10 may offer a mechanism-based therapeutic approach for CID, with the potential to provide both symptom relief and protection against chemotherapy-related intestinal damage.

Demonstrated Preclinical Efficacy in Multiple CID Models

SK10 has demonstrated potent anti-diarrheal effects across multiple preclinical models related to CID. In CPT-11-induced BALB/c mouse CID models (as shown in the following figure), SK10 significantly reduced diarrhea severity and the frequency of severe diarrhea. In these models, SK10 was administered orally once daily starting from three days before CPT-11 induction and continued during and after CPT-11 treatment. This dosing regimen supports the evaluation of SK10's potential to prevent or reduce the development and severity of CID, in addition to alleviating diarrhea symptoms after CID induction. It also reduced intestinal permeability, which means it helped limit abnormal leakage across the intestinal lining, and lowered pathological scores in the jejunum, ileum and colon, indicating reduced intestinal tissue injury. Certain studies also showed a dose-dependent effect, meaning that higher dose levels were associated with greater efficacy. In addition, in afatinib-induced rat diarrhea and 5-FU-induced mouse CID models, SK10 also reduced diarrhea severity, and in the 5-FU model, further reduced the increase in intestinal permeability. The ability of SK10 to simultaneously reduce inflammatory cytokines while enhancing mucosal barrier function represents a dual mechanism of action that addresses both the

inflammatory and barrier-disruptive components of CID pathophysiology. Taken together, these results suggest that SK10 may have potential to prevent CID, relieve diarrhea symptoms and protect the intestine from treatment-related damage, supporting its further development for CID.



Notes: This figure compares the blank control group, the model group, the prednisone group and the SK10-treated groups with respect to diarrhea scores, grade 3 diarrhea incidence and intestinal injury-related parameters in CPT-11-induced BALB/c mouse CID models. The model group refers to animals with experimentally induced disease but without treatment. The prednisone serves as a positive control, as prednisone is a glucocorticoid commonly used to relieve disease symptoms and reduce inflammation. However, it has not been approved for CID. The SK10-treated groups refer to animals receiving SK10. The results showed that, compared with the model group, the SK10-treated groups showed improvement in diarrhea-related and intestinal injury-related parameters. "*" indicates statistically significant differences.

Summary of Clinical Trials

As of the Latest Practicable Date, we (i) have completed a Phase I clinical trial for SK10 for CID in the U.S.; (ii) received the Acceptance Notice from the CDE for a Phase II clinical trial in China on June 10, 2026, and plan to commence this trial in the fourth quarter of 2026; and (iii) expect to conduct a Phase II clinical trial in the U.S. in the first quarter of 2028. The table below sets forth an overview of the completed clinical trials of SK10 in the U.S and the clinical trial expected to be initiated in China in the near term:

Trial Number	Phase	Subjects	Country	Trial Design	Status	Actual/Expected Initiation Date	Actual/Expected Completion Date
SK10-101	I	Healthy Subjects	U.S.	Randomized, Double-blind, Placebo-controlled, Sequential Dose-escalation	Completed	August 2023	February 2024
SK10-201	II	High-risk CID Population	China	Randomized, Double-blind, Placebo-controlled, Dose-ranging	Received the Acceptance Notice on June 10, 2026	Expected in the fourth quarter of 2026, if approved	Expected in the fourth quarter of 2027, if approved

Completed Phase I Clinical Trial in the U.S.

Trial Status

This completed study was a randomized, double-blind, placebo-controlled, sequential dose-escalation clinical trial to evaluate the safety and tolerability of SK10 in healthy adult subjects. The FPI date was August 7, 2023, the LSLV date was February 11, 2024 and the CSR was completed on June 25, 2024.

Trial Design

- **Enrollment and Dosing Regimen:** A total of 24 subjects were enrolled in three sequential cohorts and randomized within each cohort in a 3:1 ratio to receive SK10 or placebo. Each cohort comprised six subjects receiving SK10 and two subjects receiving a placebo. Subjects received a single dose on Day 1, followed by multiple doses at the same dose level twice daily from Day 4 to Day 17. The three dose cohorts were: Cohort 1, (2—20) × 10^8 cells; Cohort 2, 5 × (2—20) × 10^9 cells; and Cohort 3, (2—20) × 10^11 cells. Sentinel dosing was applied in Cohort 1.

- **Key Eligibility Criteria:** Eligible subjects were healthy adults aged 18 to 55 years old with no clinically relevant abnormalities identified on screening, body weight and BMI within the protocol-specified ranges, and negative screening results for hepatitis B, hepatitis C and HIV. Female subjects were required to be non-pregnant and non-lactating, and subjects of childbearing potential were required to comply with contraception requirements. Key exclusion criteria included clinically significant systemic disease, recent gastrointestinal symptoms, hypersensitivity to SK10 or its excipients, recent use of medications or investigational products, recent intake of probiotic foods or health products, substance abuse, recent blood donation and recent vaccination.

- **Primary and Other Endpoints:** Primary endpoints included TEAEs and clinically significant changes from baseline in laboratory parameters and ECG parameters. Exploratory endpoints included changes in systemic cytokines, including TNF-α, IL-6, IL-1β, IL-4, IL-10 and IL-11, and changes in fecal calprotectin.

Results

This clinical trial demonstrated that SK10 was generally safe and well-tolerated across all tested dose levels.

- **TEAEs and Other AEs:** No deaths, SAEs or TEAEs leading to study discontinuation were reported. All reported TEAEs were classified as mild, and no moderate or severe TEAEs occurred during the study. No dose-dependent increase in the number of TEAEs or significant change in severity was observed with increasing doses. Among the 18 subjects in the SK10 dose groups, eight subjects (44.4%) experienced a total of 25 TEAEs. No significant difference was observed between the SK10 dose groups and the placebo group. The most common events by preferred term ("**PT**") were diarrhea (22.2%) and headache (11.1%).

Adverse Event Category	Cohort 1 (N = 6) n (%) E	Cohort 2 (N = 6) n (%) E	Cohort 3 (N = 6) n (%) E	Pooled Placebo (N = 6) n (%) E	Overall (N = 24) n (%) E
Any TEAE	2 (33.3) 4	2 (33.3) 3	4 (66.7) 18	4 (66.7) 7	12 (50.0) 32
TEAE Severity					
Mild	2 (33.3) 4	2 (33.3) 3	4 (66.7) 18	4 (66.7) 7	12 (50.0) 32
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
TEAE Causality					
Related	1 (16.7) 3	2 (33.3) 3	4 (66.7) 14	2 (33.3) 4	9 (37.5) 24
Not Related	1 (16.7) 1	0	1 (16.7) 4	3 (50.0) 3	5 (20.8) 8
Other significant AEs	1 (16.7) 1	0	1 (16.7) 2	1 (16.7) 1	3 (12.5) 4

Adverse Event Category	Cohort 1 (N = 6) n (%) E	Cohort 2 (N = 6) n (%) E	Cohort 3 (N = 6) n (%) E	Pooled Placebo (N = 6) n (%) E	Overall (N = 24) n (%) E
Withdrawal from study	0	0	0	0	0
Discontinuation of study treatment	0	0	0	0	0
Introduction of Interventions	1 (16.7) 1	0	1 (16.7) 2	1(16.7) 1	3 (12.5) 4
Dose Reduction	0	0	0	0	0
Any Serious TEAE	0	0	0	0	0

- **Other Safety and Exploratory Findings:** No subjects experienced clinically significant changes from baseline in laboratory values, vital signs, 12-lead ECG parameters, or physical examination findings. Exploratory evaluations of cytokines (including TNF-α, IL-6, and IL-10) and fecal calprotectin did not reveal any clinically relevant or dose-dependent changes.

Material Communications with Competent Authorities

In the U.S., for SK10, we received the IND approval from the FDA for CID indication in October 2022.

In China, based on the overseas Phase I data of SK10, we submitted an IND application to the NMPA for a Phase II clinical trial and then received the Acceptance Notice in June 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SK10 SUCCESSFULLY.

TP2

Overview

TP2 is an in-house-developed, preclinical-stage, high-molecular-weight polysaccharide drug candidate with a defined structure, which was extracted from our proprietary bacterial strain, and is being developed for the treatment of autoimmune diseases. To meet diverse clinical needs and improve administration convenience, we plan to develop three formulations for TP2, including an oral solution intended for gastrointestinal indications such as ulcerative colitis ("**UC**"), a cream intended for inflammatory skin conditions such as atopic dermatitis ("**AD**"), and a nasal drop formulation intended for upper airway indications such as allergic rhinitis ("**AR**"). As of the Latest Practicable Date, we have completed structural characterization, large-scale extraction and pilot pharmacodynamic studies, and we are preparing to submit the IND application to the NMPA and/or FDA in the fourth quarter of 2028.

Key Advantages and Market Opportunity

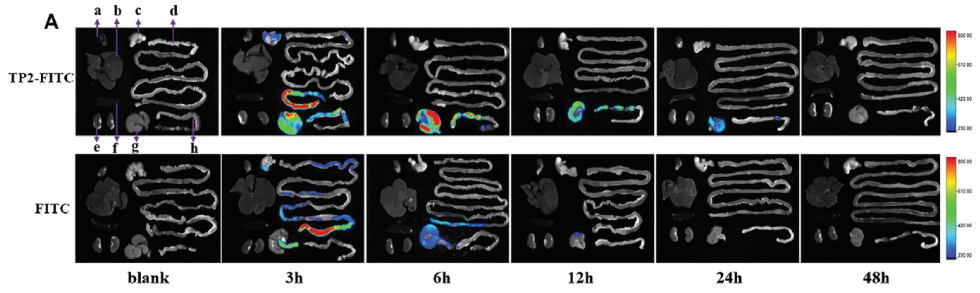
We believe TP2 has two core potential advantages, supported by preclinical pharmacokinetic and efficacy studies. Firstly, in our preclinical biodistribution studies, TP2 was primarily retained within the gastrointestinal tract following oral administration and was excreted via feces, with complete elimination observed within approximately 48 hours. These results suggest limited systemic exposure and a favorable local action profile, which is particularly relevant for chronic and recurrent autoimmune diseases that require long-term management, as reduced systemic exposure may help lower the risk of systemic adverse effects. Secondly, TP2 demonstrated potential therapeutic effects across multiple disease models in our preclinical studies, including UC, AD and AR. For further details, see "— Preclinical Studies" below.

TP2 targets inflammatory and autoimmune diseases involving the gastrointestinal tract, skin and mucosal tissues, which represent large and growing markets with significant unmet medical needs. According to Frost & Sullivan, in 2025, the number of patients with UC, AD and AR was approximately 5.3 million, 711.4 million and 1,386.3 million globally, respectively, and approximately 0.6 million, 74.1 million and 247.7 million in China, respectively. These diseases are generally chronic and recurrent, requiring long-term disease management. Current therapies, including anti-inflammatory drugs, immunosuppressants and biologics, may be limited by long-term safety, tolerability, route of administration and cost. However, based on TP2's preclinical profile, it may be positioned as a differentiated candidate with a more favorable safety profile and potential applications across multiple autoimmune indications.

Preclinical Studies

Biodistribution Study — Potential Local Action with Limited Systemic Exposure

In our preclinical biodistribution study, FITC-labeled TP2 was orally administered to mice to evaluate its distribution and elimination profile over time. As shown in the fluorescence imaging results below, TP2 signals were mainly observed in the gastrointestinal tract after administration and gradually decreased over time. By approximately 48 hours, no obvious fluorescence signal was observed, indicating that TP2 had been substantially eliminated from the body. These results suggest that TP2 was primarily retained in the gastrointestinal tract and excreted via feces, supporting its potential local action profile with limited systemic exposure.

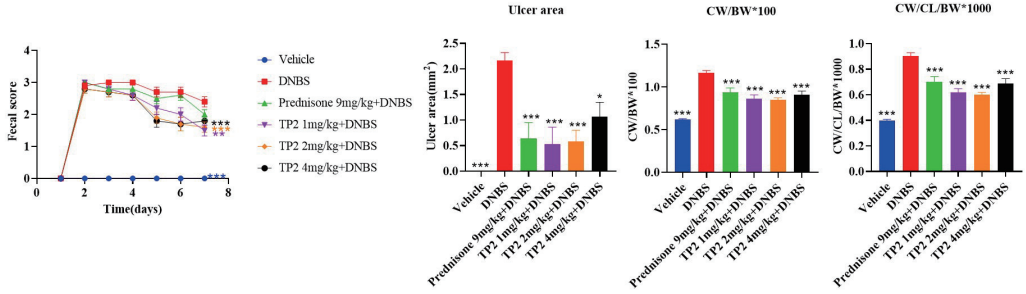


Notes: "FITC" refers to fluorescein isothiocyanate, a fluorescent label used to visualize TP2. The colored areas indicate fluorescence signals, with warmer colors representing stronger signals. The images show the distribution of FITC-labeled TP2 in major organs, at different time points after administration. The labels a to h indicate the heart, liver, stomach, small intestine, kidney, spleen, cecum and colorectum, respectively.

Efficacy Signals Across Multiple Preclinical Disease Models

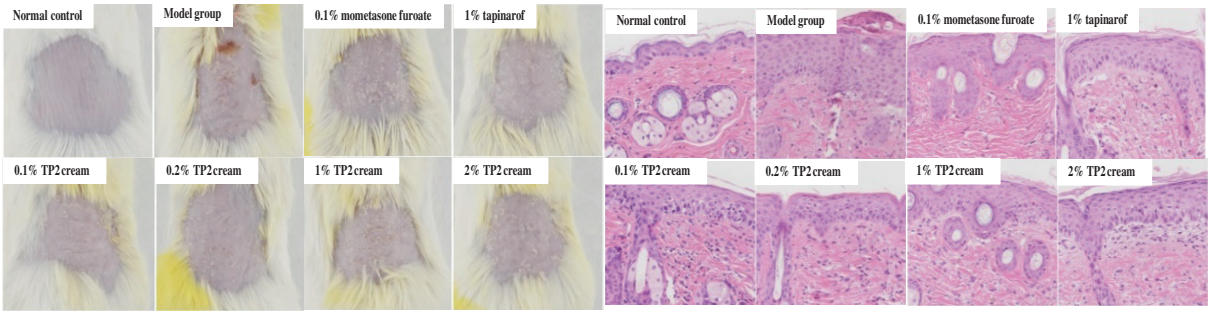
We evaluated TP2 in multiple preclinical inflammatory disease models, including UC, AD and AR, to assess its therapeutic potential across gastrointestinal, skin and airway mucosal conditions. These models were selected to reflect different tissue contexts and disease manifestations involving immune and inflammatory responses.

In the DNBS-induced rat UC model, TP2 reduced fecal scores and colon ulcer area, and decreased disease-related colon weight/body weight indicators, as shown in the following figure:

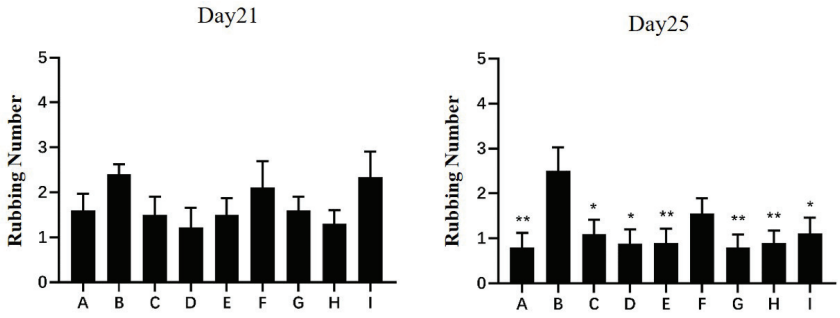


Notes: Fecal scores reflect stool condition and disease severity in the model. Colon ulcer area reflects the extent of colonic mucosal injury. CW/BW×100 and CW/CL/BW×1000 are colon weight/body weight-related indicators used to assess colonic inflammation and edema. Statistical significance is indicated as compared with the model group, where applicable.

In the mouse AD model, TP2 reduced skin lesion scores and improved dermatitis-related symptoms, including skin crusting and thickening of the stratum corneum and epidermis. In addition, the TP2 cream 2% group showed a significant reduction in plasma IL-4 level compared with the model group. The following chart shows representative skin appearance and histological images:



In a mouse AR model, TP2 reduced the frequency of nose rubbing, indicating its potential to alleviate typical symptoms of allergic rhinitis. In this model, mice were first sensitized by intraperitoneal injection of low-dose ovalbumin. Subsequently, from Day 21 to Day 25, mice in the model group and each treatment group were intranasally administered ovalbumin to induce local nasal challenge and trigger typical symptoms associated with allergic rhinitis. Mice in each treatment group were administered one dose at the designed dose level and by the designated route of administration approximately four hours before challenge, for five consecutive days. The figure below shows the effect of TP2 on nose-scratching frequency on Day 21 and Day 25:



Notes: Statistical significance is indicated as compared with the model group: *P < 0.05 and **P < 0.01. A: normal group; B: model group; C: TP2 low-dose oral group (1 mg/kg); D: TP2 medium-dose oral group (3 mg/kg); E: TP2 high-dose oral group (9 mg/kg); F: TP2 low-dose intranasal group (3 mg/mL); G: TP2 medium-dose intranasal group (10 mg/mL); H: TP2 high-dose intranasal group (30 mg/mL); and I: fluticasone propionate group (0.5 mg/mL).

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TP2 SUCCESSFULLY.

SK16

Overview

SK16 is an oral spray formulation being developed for the treatment of oral mucositis ("**OM**"). OM is a common and debilitating condition, particularly in patients receiving chemotherapy or radiotherapy, characterized by mucosal inflammation, ulceration and pain. Based on our preclinical studies, SK16 has been shown to inhibit cell apoptosis and cellular damage in epithelial cells induced by multiple chemotherapeutic agents. Accordingly, SK16 may alleviate oral mucositis by promoting mucosal healing, restoring mucosal barrier integrity.

We plan to submit the IND application to the NMPA and/or FDA for the treatment of OM in the fourth quarter of 2028.

Key Advantages and Market Opportunity

We believe SK16 has three potential core advantages. Firstly, as an oral spray formulation, SK16 is designed for direct application to affected mucosal areas, enabling localized action and convenient administration. Secondly, unlike conventional treatments that mainly provide symptomatic relief, SK16 is designed to combine anti-inflammatory effects with promotion of mucosal healing. Thirdly, SK16 may serve as a supportive care option in oncology settings, where OM is a common complication of chemotherapy and radiotherapy.

Current treatment approaches remain largely supportive and do not directly promote mucosal repair. Therefore, there remains a need for safe and effective therapies that can accelerate healing and reduce disease burden. SK16 is positioned to address this opportunity as a differentiated, locally administered therapy targeting both inflammation and tissue repair.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SK16 SUCCESSFULLY.

SK12

Overview

SK12 is a topical gel formulation being developed for inflammatory skin diseases, including atopic dermatitis ("**AD**") and psoriasis. Both AD and psoriasis are chronic and recurrent diseases characterized by immune dysregulation and skin barrier dysfunction. Based on our preclinical studies, SK12 may modulate the local skin immune microenvironment by inhibiting the overexpression of thymic stromal lymphopoietin ("**TSLP**"), an upstream epithelial-derived cytokine involved in initiating and amplifying inflammatory responses in AD. Based on our preclinical studies, we supposed that SK12 may alleviate skin inflammation and improve disease-related symptoms, through local immune modulation, improvement of epidermal barrier function.

We plan to submit the IND application to the NMPA and/or FDA in the fourth quarter of 2029.

Key Advantages and Market Opportunity

We believe SK12 has several potential core advantages. As a topical gel formulation, SK12 is designed for local administration, which may reduce systemic exposure and improve patient convenience. Unlike conventional therapies that primarily provide symptomatic relief or target single downstream pathways, SK12 is designed to act on upstream immune signaling and may offer a differentiated mechanism of action. In addition, SK12 is being developed for multiple dermatological indications, including AD and psoriasis, which may enable broader clinical applications.

AD and psoriasis represent large and growing markets with substantial unmet medical needs. Current topical therapies remain widely used but may face limitations in long-term use, tolerability and recurrence control. While biologics and small molecule therapies have improved outcomes in moderate-to-severe patients, their use may be limited by cost, route of administration and safety monitoring requirements. Therefore, there remains a need for safe, convenient and mechanism-differentiated topical therapies for long-term disease management. SK12 is positioned to address this opportunity.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SK12 SUCCESSFULLY.

ZY19

Overview

ZY19 is an in-house-developed, preclinical-stage product candidate based on a proprietary strain of *Akkermansia muciniphila* ("**AKK**") isolated from fecal samples of healthy human donors. We are currently developing ZY19 as a pharmaceutical candidate for the treatment of metabolic diseases, as we have observed improvements in blood glucose and lipid-related indicators in preclinical animal models of non-alcoholic fatty liver disease and glucose-lipid metabolic disorders.

We plan to submit the IND application to the NMPA and/or FDA in fourth quarter of 2029.

Key Advantages and Market Opportunity

The rapid growth of glucagon-like peptide-1 (GLP-1)-based therapies has validated the significant market demand for effective metabolic disease treatments and has expanded patient and physician awareness of long-term metabolic management. However, GLP-1 therapies are commonly administered by injection, and treatment discontinuation may be associated with weight regain and deterioration of metabolic indicators. These limitations create market opportunities for differentiated therapies that are convenient for long-term use and may support sustained metabolic control.

As an orally administered pharmaceutical candidate, ZY19 may offer a more convenient and patient-friendly treatment approach compared with injectable therapies. Based on our preclinical studies, ZY19 has demonstrated improvements in blood glucose and lipid-related indicators in animal models of non-alcoholic fatty liver disease and glucose-lipid metabolic disorders. In addition, AKK-based products may have potential as a long-term maintenance therapy, including for patients who have previously received GLP-1-based treatment, by helping to support metabolic stability after initial disease control. Given that metabolic diseases are chronic conditions requiring sustained management, the oral route of administration and potential long-term safety profile of AKK may support ZY19's development as a differentiated candidate in the metabolic disease market.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ZY19 SUCCESSFULLY.

OUR PROBIOTIC RAW MATERIALS PRODUCTS (NON-PHARMACEUTICAL PIPELINE)

Overview

In the commercial supply chain for probiotic products, probiotic strains are typically supplied as raw materials by upstream manufacturers and are further processed and incorporated by downstream manufacturers into finished consumer health products. Traditional probiotic raw materials mainly include commonly used strains such as *Lactobacillus* and *Bifidobacterium*. However, in recent years, the industry has gradually expanded toward next-generation probiotic ("**NGP**") raw materials with clearer functional characteristics and more specific application potential. Leveraging our long-established R&D capabilities in this field, we have expanded into the NGP raw materials market, where we develop and supply probiotic raw materials to downstream manufacturers.

AM06™, a proprietary *Akkermansia muciniphila* ("**AKK**") strain developed by us and derived from healthy human breast milk, is our principal NGP raw materials product. According to Frost & Sullivan, AKK is widely regarded as a representative NGP strain, and it has attracted increasing attention from both academia and industry due to its potential role in maintaining gut barrier function, supporting metabolic balance and regulating immune homeostasis. As the probiotic industry continues to shift from conventional strains toward more differentiated, higher-value strains, AKK has emerged as an important focus of research and product development, particularly in applications related to metabolic and gut health.

Based on our comprehensive assessment of 31 AKK isolates, including 30 fecal-derived isolates and one breast milk-derived isolate, AM06™ was identified with core characteristics including low toxicity, high genetic stability, and excellent pH and bile salt tolerance. According to Frost & Sullivan, AM06™ is among the few commercially available AKK strains derived from the breast milk of healthy women.

Market Opportunity and Competition

Market Size and Growth

According to Frost & Sullivan, the global probiotic raw materials market is expected to grow from USD1,977.8 million in 2025 to USD3,049.3 million by 2030, while the China probiotic raw materials market is expected to grow from USD296.5 million in 2025 to USD512.3 million by 2030. Such growth reflects the continued demand for probiotic raw materials in both the global and China markets, driven by the increasing adoption of probiotic ingredients in consumer health products and the growing market preference for functionally differentiated strains. In addition, according to Frost & Sullivan, the AKK market remains at an early stage of development but is expected to grow rapidly as regulatory recognition, consumer awareness and downstream product applications continue to develop. For further details, see "Industry Overview — Probiotic Raw Materials Market."

Competitive Landscape and Differentiated Positioning of AM06™

Competition in the NGP raw materials market is increasingly shifting from scale-based competition in conventional strains to technology- and evidence-based competition in differentiated strains. Compared with traditional probiotic raw materials, NGP raw materials, including AKK strains, generally require more stringent capabilities in strain sourcing and screening, functional and safety validation, process development, quality control and regulatory readiness, as downstream manufacturers typically place greater emphasis on scientific support, product stability and compliance when selecting high-value probiotic raw materials. According to Frost & Sullivan, China is among the global leaders in the field of NGPs, supported by its growing number of strains under development and continued progress in microbiome research.

We believe AM06™ is well-positioned to address these market requirements. AM06™ was identified following a comprehensive assessment of 31 AKK isolates and is differentiated by its healthy human breast milk origin. Its low toxicity, high genetic stability, and excellent pH and bile salt tolerance support its suitability for downstream consumer health applications. We have also developed PROFORCARE® Heat-InActivated technology to address the technical requirements for stable and controllable AKK raw material production. Together with our patent portfolio, third-party SGS quality testing and experience in strain development, CMC process development and quality control accumulated from the LBP field, these capabilities support the differentiated positioning of AM06™ in the NGP raw materials market.

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. In line with industry practice, we primarily conduct our R&D activities through our internal team and supported by external service providers where appropriate. More importantly, as a platform-based biopharmaceutical company, we have established ZYMIRS, our proprietary microbiome innovation research system that integrates strain discovery, functional validation, non-clinical evaluation, CMC development, manufacturing process development and quality control capabilities. This R&D system primarily supports the development of our own pipeline, while also allows us to extend our technical expertise to external projects within industry, by providing non-clinical CRO services and CDMO services. Such engagements allow us to broaden the application scenarios of our technologies, strengthen collaboration with industry participants and coordinate resources within industry.

Our research and development expenses amounted to RMB67.6 million and RMB61.9 million in 2024 and 2025, respectively, primarily reflecting our continued investment in the development of our pipeline throughout the Track Record Period. In 2024 and 2025, the research and development expenses attributable to our Core Product and key product amounted to RMB51.9 million and RMB49.4 million, respectively, representing 76.8% and 79.8% of our total research and development expenses for the corresponding years. 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. For further details, see "Financial Information — Description of Major Components of Our Results of Operations" and "Financial Information — Cash Operating Costs."

In-house R&D Team

We have established an integrated in-house R&D team comprising experienced personnel with expertise spanning medical affairs, early-stage discovery, pre-clinical research, CMC development and manufacturing operations. As of the Latest Practicable Date, under the strategic guidance of Dr. Zhi Fachao, we have established a dedicated in-house R&D team of 58 members, 20 of whom hold master's degrees or above. Our core R&D personnel play a critical role in supporting the continuous development of our Core Product and other product candidates. This team consists of eight members with expertise spanning the fields of novel drug R&D, clinical trials, and pharmaceutical microbiology technologies, and they have an average of over 14 years of experience working in the biopharmaceutical industry. Particularly, each of Dr. Wang Ye, 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). As of the Latest Practicable Date, the core R&D personnel involved in the development of our Core Product remained employed by us. In addition, all core R&D personnel are bound by non-compete agreements upon departure, and no prior non-compete restrictions apply to their current roles.

The following table sets forth the identities, positions, expertise of our core R&D personnel as of the Latest Practicable Date and their involvement and contributions to the R&D activities, including with respect to our Core Product, up to the same date:

Identity	Position and Role	Expertise	Involvement and contributions to the R&D activities, including with respect to our Core Product	Date of joining our Group
Dr. Wang Ye	General Manager; Co-founder; Director; Decision-making Manager	Over 20 years of experience in innovative drug R&D and commercialization, and more than 10 years of experience in corporate operations and management.	Responsible for the formulation and implementation of our R&D strategy, investment and financing matters, and the management and coordination of the business departments. At the early stage, established a comprehensive R&D system and commercialization platform, formulated and implemented the R&D strategy for our Core Product, built a stable and experienced core team, and led the Company to complete financing.	2013

Identity	Position and Role	Expertise	Involvement and contributions to the R&D activities, including with respect to our Core Product	Date of joining our Group
Dr. Liu Yangyang . .	Deputy General Manager; Co-founder; Head of Early-stage New Drug Discovery and Business Collaboration	15 years of experience in preclinical and clinical-stage R&D of LBP, and has promoted multiple business collaborations.	Responsible for early-stage drug discovery and external business development. Familiar with the product development and commercialization process in the fields of LBP and NGP. Has participated extensively in the preclinical and clinical research of SK08, and helped establish the collaboration and development platform for LBP.	2013
Dr. Li Ping	Deputy General Manager; responsible for coordinating CMC strategy, CMC team and Manufacturing Center	Over 15 years of experience in biologics and LBP development	Responsible for formulating the overall CMC R&D strategy, leading the coordination of key technical work between the CMC team and the production center, and coordinating the process development and industrialization implementation of product candidates, including our Core Product; served as deputy director of the Guangdong Engineering Technology Research Center for LBPs and participated in 10 national-, provincial- and municipal-level research projects.	2016
Ms. Wang Wei	Deputy General Manager; Head of Medical Affairs	Over 15 years of experience in clinical development, regulatory registration and compliance	Responsible for coordinating clinical development, drug registration and compliance-related matters, and leading the clinical development and registration filings of our product candidates, including our Core Product.	2021
Mr. Wu Jiaqi	General Manager of Puwei Junjian; Head of Manufacturing Center	Over 10 years of experience in pilot-scale manufacturing and commercial production of LBPs and NGP	Responsible for process scale-up, GMP-compliant production, and maintenance and operation of the GMP quality system, supporting manufacturing activities for our product candidates, including our Core Product.	2014
Ms. Zheng Lijun . . .	Head of NGP	Ten years of experience in isolation and discovery, mechanism research and preclinical development of NGP	Responsible for strain isolation, screening and identification, strain safety evaluation, early discovery and preclinical research of product candidates, and exploratory research on new technologies such as AI and synthetic biology	2016

Identity	Position and Role	Expertise	Involvement and contributions to the R&D activities, including with respect to our Core Product	Date of joining our Group
Mr. Kuang Gaobo . .	Head of CMC	Proficient in the full-chain process development and quality research of LBPs from laboratory-scale studies to pilot-scale studies	Leads the R&D of the CMC segment and coordinates the process development, process scale-up, quality research and technology transfer of product candidates, including the Core Product	2015
Mr. Ding Jingzhi . . .	Researcher of NGP	Proficient in microbiology R&D and bioinformatics analysis; holder of PMP certification	Previously responsible for establishing our microbial fermentation system, and subsequently participated in our early-stage microbiology research, responsible for microbial genome and omics analysis	2018

We had not experienced any material difficulties in our R&D activities, including the R&D of our Core Product, due to change of R&D personnel.

Early-Stage Drug Discovery and Development

Our NGP team serves as our early-stage discovery function and is primarily responsible for monitoring global scientific and R&D developments in our focus areas, evaluating potential project opportunities and conducting early-stage research. As of the Latest Practicable Date, our NGP team consisted of 10 members and was organized into a strain isolation team, a non-clinical team and a bioinformatics team. Members of the NGP team generally hold bachelor's degrees or above, and more than 50.0% of them hold master's degrees. The team is primarily responsible for activities spanning early-stage discovery, developability assessment and non-clinical research. It also supports our innovative pipeline through the systematic discovery, screening and validation of live biotherapeutic candidate strains with therapeutic potential, thereby supporting subsequent development and industrialization.

Clinical Development

We have established an in-house medical affairs team to support the clinical development of our product candidates. As of the Latest Practicable Date, our medical affairs team consisted of six members. Over 60.0% of the team had nearly 10 years of clinical research experience, and the project manager had more than eight years of project management experience. The team is primarily responsible for advancing the conduct of clinical trials, facilitating subject enrollment, follow-up and clinical data collection, analyzing and interpreting clinical data, preparing IND- and NDA-related materials, and evaluating clinical needs and development feasibility for potential indications. Through this medical affairs team, we have developed in-house capabilities in clinical strategy, trial management and clinical data analysis, which, together with our collaborations with clinical trial sites, principal investigators ("**PIs**"), CROs and SMOs, support the continued advancement of our clinical development activities.

Collaborations with Clinical Trial Sites

In China, drug clinical trials are required to be conducted at clinical trial institutions that meet the relevant requirements and have completed the required filing procedures, in accordance with the applicable PRC laws and regulations, including the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) and the Good Clinical Practice for Pharmaceutical Products (2020 Revision) (《藥物臨床試驗質量管理規範(2020年修訂)》) ("**GCP**"). In selecting clinical trial sites, we typically consider factors such as the site's expertise in the relevant therapeutic area, patient resources, research capabilities, clinical trial experience, equipment and facilities, and the qualifications of the relevant investigators.

For each clinical trial, we typically enter into agreements with the participating sites setting out, among other things, the parties' responsibilities, study conduct requirements, payment arrangements and intellectual property ownership. Clinical trial protocols, informed consent forms and other required documents are submitted to the ethics committee of each participating site for review, and the trial is conducted in accordance with the approved protocol and the applicable GCP requirements. The participating sites are responsible for conducting the trial, collecting trial data and preparing relevant study records in accordance with the protocol, while we make milestone-based or scheduled payments in accordance with the relevant agreements.

We also conduct internal screening, evaluation and approval procedures for clinical suppliers and service providers pursuant to our internal standard operating procedures (SOP). Through such collaborations and the implementation of internal control measures, we seek to ensure that our clinical trials are conducted in a compliant, efficient and quality-controlled manner, thereby supporting the clinical development and potential registration of our product candidates.

Relationships with PIs

In addition to our collaborations with clinical trial institutions, we maintain ongoing communication with PIs and clinical experts in relevant therapeutic areas and keep them informed of our latest R&D progress. When selecting PIs, we generally take into account their academic influence in the relevant field, the clinical resources and research capabilities of their affiliated hospitals, and their ability to facilitate relevant clinical development efforts. Based on these considerations, the PIs and clinical experts with whom we collaborate are senior physicians from leading Class III hospitals and are responsible for the implementation, quality control and safety management of clinical trials.

In 2025, we collaborated with 55 PIs during the clinical development of our product candidates. These PIs and clinical experts not only provide important feedback on clinical needs, trial design and patient management, but also help us better advance the clinical development of our product candidates. In addition, we continue to engage with PIs and clinical experts through industry and academic conferences, where our latest R&D progress is presented and discussed, thereby facilitating academic exchange and supporting our R&D efforts.

Collaborations with CROs and SMOs for Our Clinical Trials

We collaborate with CROs and SMOs to support the execution of our clinical trials. CROs generally provide specialized clinical development services, such as project management, clinical monitoring, data management, statistical analysis, medical writing and pharmacovigilance, while SMOs generally provide site-level operational support. In selecting CROs, we generally focus on service providers with established SOP, strong execution capabilities, broad personnel coverage and a well-established industry reputation. For larger clinical projects, we typically invite multiple CROs to participate in the selection process and make our decision after internal evaluation and comparison of, among other things, their service capabilities, relevant project experience and proposed fees. We mainly determine the service fees paid to the CROs and SMOs in accordance with market prices of similar services, the number of enrolled patients, the duration of the clinical trials, and the quality and contents of the services provided. In both 2024 and 2025, we engaged a total number of 11 and two CROs and SMOs, respectively.

During our clinical trials, we also engage independent third-party auditors to conduct inspections, and our internal personnel conduct on-site checks at study centers, in each case with a view to strengthen quality control and protecting subjects' rights and safety. Through such collaborations and the implementation of internal control measures, we seek to support the compliant, efficient and quality-controlled conduct of our clinical trials.

Key terms of the agreements that we typically enter into with our CROs and SMOs are set forth below:

Services. The CROs and SMOs provide clinical trial services as set out in the relevant agreement or work order. CROs generally provide project and site management, monitoring, data management, biostatistics, medical writing and monitoring, pharmacovigilance, and regulatory and ethics support. SMOs generally provide clinical research coordination, including clinical research coordinator (CRC) site management, administrative support to investigators, patient enrollment and follow-up, electronic data capture (EDC) entry, sample shipment, subject diary follow-up and data query responses.

Term. The CROs and SMOs must perform within the agreed service period or the timeline and milestones in the relevant agreement or work order, which may be adjusted by mutual agreement based on trial progress.

Payments. We pay the CROs and SMOs per the agreed schedule, which may be tied to project progress, subject enrollment, subject visits, database lock, deliverable submission, regulatory review or other milestones.

IP rights. We own the IP, data, results, records and other deliverables generated within the agreed scope of work.

Confidentiality. The CROs and SMOs may not disclose confidential information obtained from the projects, including but not limited to, scientific, technical, business and financial information, trial data, research records, project documents and subject privacy information.

Termination. The agreements may be terminated per their terms, including upon mutual agreement, material breach, delayed or non-conforming services, changes to our development strategy or trial plan, or other specified circumstances.

Regulatory Affairs

Our registration and compliance team is responsible for the regulatory approval process of our product candidates. The team manages the regulatory submission process, which requires that filings be made to, and approved by, the relevant authorities prior to the initiation of clinical trials or commercialization. In this capacity, the registration and compliance team prepares and manages regulatory filings by coordinating relevant teams in drafting filing dossiers, coordinating the preparation of responses to regulatory requests, and conducting CMC and GMP readiness assessments for our product candidates.

Early Support from Guangdong Zhiguang

During the establishment and incubation stage of our Company, Guangdong Zhiguang, one of our founding Shareholders, provided support to us. Certain early-stage R&D projects were applied with Guangdong Zhiguang as the applicant, and certain intellectual property rights were also registered in the name of Guangdong Zhiguang. Following the establishment of our Company, Guangdong Zhiguang entered into a series of technology transfer agreements and patent transfer agreements with us, pursuant to which all the relevant technologies and intellectual property rights registered under Guangdong Zhiguang's name (including patents, patent applications, trade secrets, technical materials, etc.) were transferred to our Company.

We do not regard these arrangements as license-in arrangements. Guangdong Zhiguang is our founding Shareholder, not an external licensor; it was an equity investment platform and did not conduct any R&D on its own. It had never owned any technologies (or any associated intellectual property rights) other than those technologies developed by our core R&D personnel and subsequently transferred to us after our establishment. We do not rely on any continuing authorization or license from Guangdong Zhiguang for the development, manufacturing or commercialization of our Core Product and other product candidates. Guangdong Zhiguang did not retain any commercialization rights, license rights, royalty-sharing rights or other rights that would restrict the development or commercialization of our Core Product or other product candidates.

Before and after the relevant technologies and intellectual property rights had been transferred to us, our core R&D team has continuously conducted systematic R&D activities, including strain verification, pharmacodynamic mechanism studies, CMC development, preclinical studies, clinical development, regulatory submissions and global intellectual property portfolio development. These efforts have formed the basis of our existing core technology system. In particular, all the clinical trials in relation to our Core Product and other product candidates were initiated by us after the relevant technologies and intellectual property rights had been transferred to us.

During the Track Record Period and up to the Latest Practicable Date, there had been no dispute between our Company, Guangdong Zhiguang, its shareholders, our Shareholders (then or current) or our core R&D personnel in relation to the ownership of the relevant technologies and intellectual property rights.

Collaborations with Nanfang Hospital and Southern Medical University

We and our core R&D team have maintained an amiable collaborative relationship with Nanfang Hospital, Southern Medical University (南方醫科大學南方醫院) and Southern Medical University (南方醫科大學). Our collaborations with them included, among others, (i) SK08-related research under a research task of the National High-tech R&D Program of China (國家863計劃), (ii) subsequent project-based collaborations under provincial and/or municipal science and technology programs (such as the Guangzhou industry-university-research collaborative project (廣州市產學研協同重大專項資金)) relating to MoA studies and pharmacodynamic evaluation, and (iii) a Guangdong Provincial Major Special Program for New Drug Innovation and Development (廣東省重大新藥創製專項) project for the Phase I/II clinical research of SK08.

These collaborations enabled us to leverage Dr. Zhi's long-standing clinical and academic expertise in gastroenterology, as well as Nanfang Hospital's clinical research experience in intestinal microecology. The relevant collaborations were primarily research, academic and project-based arrangements, and supported certain non-clinical and clinical-stage R&D activities relating to SK08, including MoA studies, pharmacodynamic evaluation, clinical trial protocol development, clinical trial implementation and study summary. They did not constitute license-in arrangements in respect of our Core Product or other product candidates.

Pursuant to the relevant agreements between Nanfang Hospital, Southern Medical University and us, all the material technologies, research results and intellectual property rights resulting from our collaborations that are necessary for the development and commercialization of SK08 and our other product candidates are owned by us. Nanfang Hospital and Southern Medical University did not retain any commercialization rights, license rights, royalty-sharing rights, milestone payment rights, reversion rights or other rights that would restrict our development or commercialization of SK08 or any other product candidates. Any rights retained by Nanfang Hospital or Southern Medical University under the relevant arrangements were limited to academic publication, project reporting, authorship or inventor attribution and other non-commercial academic or administrative rights.

During the Track Record Period and up to the Latest Practicable Date, there had been no dispute between our Company, Nanfang Hospital, Southern Medical University, our Shareholders or our core R&D personnel in relation to the ownership of the relevant technologies and intellectual property rights.

CMC AND MANUFACTURING

Our CMC Team

As of the Latest Practicable Date, we had a total of 45 personnel engaged in pharmaceutical research and manufacturing. Our CMC team is mainly responsible for (i) fermentation lyophilization process development and optimization; (ii) formulation process development and optimization; (iii) analytical method development and validation; and (iv) technology transfer of manufacturing processes and quality standards to our manufacturing team. Our manufacturing team is primarily responsible for process scale-up, GMP-compliant manufacturing, and quality system operations.

As maintaining and building up our talent pool is one of our key success factors, we have implemented training and development programs to equip our manufacturing team with the capabilities necessary to support our commercialization and expansion objectives. Our training programs cover three areas: (i) onboarding training for new employees, which includes induction in the Company's policies, GMP fundamentals, and occupational health and safety; (ii) role-specific skills training, which includes standard operating procedures and individual job responsibilities; and (iii) continuing education for existing employees, such as periodic refresher courses, skills updates, and external training programs. Training effectiveness is assessed through skill assessments.

In terms of talent development, we have established three functional career tracks, namely technical, R&D, and management, with 11 graded levels from M1/P1 to M11/P11. Advancement across levels is determined by performance appraisal results, ensuring a continuous pipeline of qualified talent to support our commercialization and expansion. Our CMC team is led by Mr. Kuang Gaobo, the head of our CMC team, who has over 10 years of experience in LBP pharmaceutical research; and our manufacturing team is led by Mr. Wu Jiaqi, the head of our manufacturing team, who has over 10 years of experience in LBP manufacturing and NGP production.

Manufacturing Facilities

We have established an LBP pilot manufacturing base in the PRC, which is located in Huangpu District, Guangzhou, Guangdong Province. Our manufacturing base comprises two pilot plants with a combined floor area of 4,894.8 sq.m. Our manufacturing facilities are collectively equipped with two 5,000-liter fermentation tank bacteria powder production lines and two powder formulation production lines each employing an eight-lane powder filler. Plant No. 1 has a floor area of 2,633.6 sq.m. and it is equipped with a 5,000-liter fermentation tank supporting both anaerobic and aerobic fermentation processes, enabling the production of live bacterial and inactivated bacterial products.

In addition, Plant No. 2 has a floor area of 2,261.2 sq.m. and is equipped with a 5,000-liter fermentation tank. Both plants are designed to GMP/cGMP standards and can support clinical trial drug candidate manufacturing for IND through Phase III clinical trials in both the PRC and the U.S. Following future technical upgrades, the plants are expected to support regulatory submissions at the NDA/BLA filing stage. For our pharmaceutical products, our manufacturing facilities will be subject to the on-site inspection process conducted in connection with NDA submission, which comprises: (i) registration verification, (ii) pre-approval GMP inspection, and (iii) registration testing.

Currently, our LBP drug candidates (including our Core Product, SK08, and our key product, SK10) remain at the clinical research stage, and none of such products entered scaled mass production during the Track Record Period. Our manufacturing facilities are 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) production of the NGP raw material AKK AM06™, which also remains at an early stage of business development, with a relatively small output scale. The table below sets forth the utilization rates of our manufacturing facilities during the Track Record Period:

Production Lines	Gross Floor Area (sq.m.)	Principal Use	Utilization Rate[1] [2]	
			2024	2025
Plant No. 1 and Plant No. 2, comprising two fermentation tank bacteria powder production lines and two powder formulation production lines	4,894.8	– Process development; – Production of materials used in clinical trials; – CRO/CDMO services; and – Production of AKK AM06™	56.6%[3]	71.8%[3]

Notes:

1. The utilization rate is calculated by dividing (i) the number of days during the relevant year on which our production facility was actually in operation for the execution of various R&D and production projects (including actual production, necessary cleaning steps, equipment maintenance and validation, audits, and line-sharing together with the related cleaning and validation assessments) by (ii) the total number of available working days for the corresponding year after deducting public holidays (calculated on the basis of 250 working days per plant, or 500 working days in aggregate for the two plants). In 2024 and 2025, the aggregate number of days of actual operation of Plant No. 1 and Plant No. 2 was 283 days and 359 days, respectively.

2. At the current stage, our LBP drug candidates and CRO/CDMO services primarily involve R&D-oriented, small-batch and multi-product production activities. For projects at the early-stage clinical development phase, the quantity of biologics required to produce a single batch varies significantly depending on the circumstances and progress of our customers' clinical trials, and the output of a single batch may not be at full capacity; nevertheless, during the production period, the relevant production facility is occupied by such project and cannot be used simultaneously to produce another product under development. Accordingly, calculating the utilization rate by dividing the actual output of a specific product by the theoretical maximum annual production capacity would not accurately reflect the actual occupancy and use of our production facilities. In view of the foregoing, for such businesses, the utilization rates of our production facilities were calculated following the method set forth in note 1 above, which we believe can more appropriately and comparably reflect our actual use of the production facility at the current stage.

   By contrast, the output of the NGP raw material AKK AM06™ can be measured by weight (in kilograms), and its per-batch output is relatively standardized, thereby making the conventional "output divided by capacity" calculation method slightly more reasonable. The actual output of AKK AM06™ in 2024 and 2025 was approximately 486.2 kilograms and 234.8 kilograms, respectively, and the theoretical maximum annual production capacity of our production facilities was 10,000.0 kilograms for AKK AM06™. Therefore, with respect to the production of AKK AM06™, the utilization rates of our production facilities calculated following the conventional method was approximately 4.9% and 2.3% for 2024 and 2025, respectively. However, as this business remains at an early stage of commercialization with a relatively small output, and for consistency with our LBP and CRO/CDMO business as well as to facilitate overall comparison, we have also presented AKK AM06™ under the operating-days-based facility utilization rate described above.

3. The utilization rate increased during the Track Record Period, primarily due to the advancement of our LBP pipeline projects and the increase in clinical-batch production, as well as the increase in the number of CRO/CDMO projects undertaken, which correspondingly increased the number of operating days of the production facility.

We plan to commence technical renovation of the existing manufacturing facilities in 2027 to satisfy the requirements for the NDA application and drug manufacturing license application of our self-developed powder of our Core Product SK08 ("**Live SK08 Powder**"). After the renovation, the original two bacteria powder production lines and two formulation production lines will be reduced to one bacteria powder production line and one formulation production line, with the storage, outer-packaging, and other functional areas expanded simultaneously to match the needs of commercial-scale production and quality-system upgrades.

LBP Drug Candidates

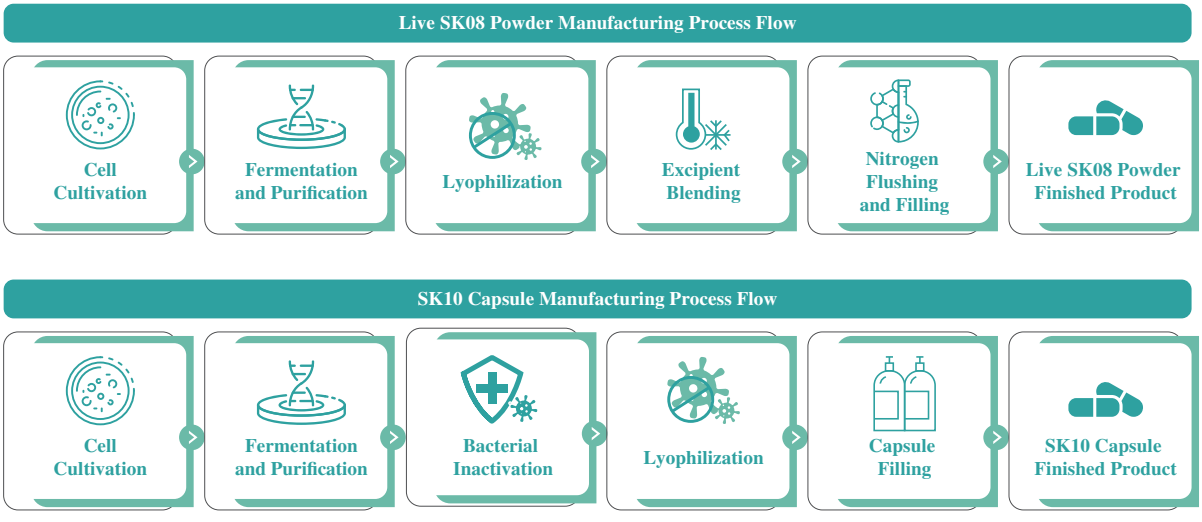
During the Track Record Period and up to the Latest Practicable Date, we successfully completed approximately 405,116 production packets/capsules of clinical trial samples supporting our preclinical studies and Phase I, II, and III clinical trials. The table below sets forth key production details of our key LBP drug candidates during the Track Record Period and up to the Latest Practicable Date:

Pipeline Products	Dosage form	Total packets/ capsules produced	Packets/ capsules for clinical use	Packets/ capsules for non-clinical use	Product release success rate
		'000	*'000*	*'000*	
SK08 (IBS-D, UC, pediatric rotavirus diarrhea, and advanced solid tumors (in combination with anti-PD-1/L1 monoclonal antibodies))	Powder	381	381	0	100%
SK10 (CID)	Capsule	24	24	0	100%
Total		**405**	**405**	**0**	**100%**

Our SK08 and SK10 production lines employ an LBP-specific anaerobic manufacturing process that seamlessly integrates all stages from seed culture expansion through lyophilization to final drug product. The process begins with the expansion of the working seed of *Bacteroides fragilis*, and is subsequently scaled up to 5,000-liter anaerobic fermentation. Following fermentation, the broth is subjected to centrifugation to harvest bacterial cells. The separated bacterial cells are then washed, re-centrifuged for collection, mixed with lyoprotectants, and lyophilized. The resulting lyophilized cake is then milled into bacterial powder, blended with pharmaceutical excipients, and filled into the final drug product form. The fermentation and lyophilization process represents the most technically complex stage of our manufacturing operations, and we possess technical know-how and intellectual property covering our fermentation formulation and process control parameters. For SK10, an additional inactivation step is conducted after fermentation.

At the current state of process technology, Plant 2 has an estimated annual production capacity of approximately five million packets for SK08. We plan to upgrade Plant 2 to prepare for commercialization, after which its capacity is expected to increase to 15 million packets. We intend to invest in new commercial-scale manufacturing facilities following NDA approval of our Core Product and key product.

The following diagram illustrates the production process of our SK08 and SK10:



Our CMC Research Capabilities

CMC encompasses the activities that define manufacturing processes, product testing and release specifications, and product storage conditions, all of which are essential to ensuring that a pharmaceutical product is safe, effective, and consistent across batches. The specialized nature of LBP manufacturing, characterized by high-density fermentation of live bacterial strains, lyophilization of live bacteria, and stringent control of viable bacterial counts, requires CMC capabilities that are distinct from those applicable to conventional small-molecule or biologic drugs. We have built an LBP CMC research and manufacturing platform in the PRC, underpinned by over 10 years of accumulated experience in this field. Our CMC capabilities comprise the following key functions:

Process Development. Our process development team focuses on developing and optimizing the fermentation and lyophilization processes for our LBP candidates and NGP raw materials. The key steps in the production of our LBP products involve seed culture expansion, fermentation at scale (up to 5,000 liters), centrifugal separation of bacterial cells, addition of lyoprotectants and lyophilization to obtain bacteria powder, mixing with excipients and dispensing into the final drug product form. For SK10, an additional post-fermentation inactivation step and associated quality control are required to confirm complete inactivation of biological activity while preserving the therapeutic properties of the bacterial components. We hold know-how and intellectual property rights covering our fermentation formulations and process control parameters.

Manufacturing Facilities. We have established pilot manufacturing capabilities to support our clinical development programs, as described above under "— Manufacturing Facilities." Our two pilot plants, which are designed to GMP/cGMP standards, currently serve as our primary manufacturing bases. We plan to apply for a Drug Manufacturing License and complete GMP compliance inspection upon NDA submission. Once a production run is initiated, the process must be completed in full without interruption. Accordingly, we maintain stable utilities supply arrangements and conduct planned maintenance during scheduled shutdown periods. All principal manufacturing equipment is owned by us, subject to regular maintenance by our production team and annual servicing in collaboration with equipment manufacturers. We intend to establish dedicated commercial-scale manufacturing facilities upon NDA/BLA approval of our Core Product and key product.

Analytical Sciences. Our analytical science capabilities implement a science-driven approach to the development and application of analytical techniques throughout the lifecycle of each of our LBP candidates. These capabilities include analytical method development and validation for drug substance API and drug product, technical transfer of process and analytical methods, establishment of product specifications, and batch testing and release. Given the inherent biological characteristics of LBP products, our analytical methods are designed to assess critical quality attributes including potency (content), identity (strain authentication), purity, and safety parameters such as the absence of contaminants and adventitious agents.

Quality Control and Quality Assurance. With a well-documented and comprehensive quality management system, our quality control and quality assurance function is responsible for testing and verifying product quality against release specifications at every stage, from incoming raw material inspection through to final batch release. See "— Quality Control and Assurance" below for further details.

QUALITY CONTROL AND ASSURANCE

Quality control and quality assurance are critical to our continued success, and are particularly important for LBP products given the inherent sensitivity of live bacterial strains to process deviations and environmental variables. We are committed to ensuring the quality of our operations through a comprehensive quality management system covering all key stages of our R&D and manufacturing processes, established in accordance with GMP requirements of the NMPA and cGMP requirements of the U.S. FDA. We closely monitor evolving GMP standards and regulatory developments, continuously updating our internal procedures to adhere to applicable standards for patient safety and regulatory compliance.

Our quality management team comprises 16 dedicated personnel as of the Latest Practicable Date. All team members possess work experience and qualifications commensurate with their roles and the requirements of our quality management activities.

We have established comprehensive quality control and assurance procedures covering the following key areas:

Incoming Material Control. All incoming raw materials, excipients, and packaging materials must be inspected upon arrival and accepted only after passing inspection. Upon acceptance, materials are submitted for an inspection request, with our quality control team conducting sampling and testing. For items which we do not yet have in-house testing capabilities, qualified third-party testing institutions are engaged to perform independent testing, and an inspection report is issued upon passing. Materials that fail to meet our quality standards are subject to return and no disputes have arisen from such returns to date. We maintain a qualified supplier list and conduct periodic supplier evaluations focusing on product quality, the validity of production licenses, and CDE registration status.

In-process Control and Deviation Management. The primary quality control challenge in LBP manufacturing is the risk of microbial contamination, particularly the introduction of adventitious microorganisms into fermentation vessels. We address this through strict operational protocols, rigorous incoming material controls, personnel hygiene requirements, and regular equipment maintenance. In the event that contamination is detected during fermentation, our deviation management procedures require immediate termination of the affected batch, inactivation and discharge of the contaminated material, root cause analysis, and the preparation of a full deviation report in accordance with GMP requirements, and the formulation of corrective and preventive measures. Contamination events have occurred on limited occasions during the Track Record Period and all were managed in accordance with our deviation management procedures without material adverse consequence.

Analytical Testing and Release Standards. We have established product release specifications for each of our LBP drug candidates and AKK AM06™. Each production batch must satisfy release criteria, covering potency (content), identity, purity, and safety attributes, before it may be deployed in clinical trials or distributed to customers.

During the Track Record Period, we did not experience any quality incidents resulting in regulatory sanctions, product recalls, or material adverse impact on our operations.

COMMERCIALIZATION

As of the Latest Practicable Date, none of our LBP candidates have been approved for commercial sale. Nonetheless, we have been building our commercial planning and portfolio management capabilities since our pipeline candidates entered clinical development.

As our LBP candidates advance towards NDA or BLA filing, we intend to adopt a CSO model for the initial commercialization of SK08 and SK10. This approach will allow us to leverage the established market access networks of experienced commercialization partners to achieve faster market penetration, facilitate listing on the NRDL, and support future conversion to OTC status. Based on the experience of comparable LBPs in the PRC market, we expect OTC pharmacy sales to be a key channel for our products at a later stage. In parallel, we intend to build in-house medical affairs capabilities focusing on Key Opinion Leaders' engagement and medical education to support our clinical adoption. Furthermore, we intend to strengthen our internal capabilities, including market access, channel management, and commercial operations, to drive the implementation and refinement of our overall commercialization strategy.

We also intend to pursue strategic collaboration opportunities to support the commercialization of our LBP candidates in the PRC and potentially in international markets. In particular, we may selectively license out our LBP candidates, establish joint ventures, or enter into other forms of partnerships with leading biopharmaceutical companies for the purposes of executing late-stage clinical trials and/or commercializing our LBP candidates in the relevant markets.

Pricing

LBP Candidates

When our LBP candidates, including our Core Product and key product, progress to commercialization, we will determine their prices based on a number of factors, including (i) our costs of production; (ii) the prices of competing therapies (if applicable); (iii) the clinical differentiation and therapeutic benefits of our LBP candidates relative to existing treatments; (iv) health economics and outcomes data; (v) market trends; and (vi) changes in the levels of supply and demand. Given that our pipeline spans multiple therapeutic areas, including oncology, gastroenterology, and metabolic diseases, our pricing strategy will be tailored to the specific patient population, treatment setting, and competitive landscape of each indication. We plan to develop a detailed pricing strategy for each LBP candidate as it progresses towards commercialization.

As of the Latest Practicable Date, there was no pricing guidance or centralized procurement requirement set by the PRC government applicable to our LBP candidates. We intend to seek inclusion of our Core Product, key product and other LBP candidates into the NRDL and other reimbursement programs through active negotiations with the relevant authorities, as we believe such inclusion would significantly enhance our market access and patient affordability. However, inclusion into the NRDL is evaluated and determined by the relevant government authorities at their discretion, and we cannot assure you that any of our LBP candidates will be successfully included. See "Risk Factors — Risks Relating to Manufacturing and Commercialization of Our Drug Candidates — The commercialization of our LBP candidates, if approved, may be subject to uncertainties from national, provincial or other third-party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business" for further details.

Research and Development services

Our pricing for research and development services is determined on a project-by-project basis using a combination of cost-plus and value-based pricing strategies. Under our service agreements, we receive fees in the form of upfront payments, regular research period payments and milestone payments. The specific terms are negotiated on a project-by-project basis taking into account the scope of work, the stage of development, and the resources required.

NGP Raw Materials

Our pricing policies for our NGP raw material, namely AKK AM06™, are determined based on production costs, market positioning, and the terms negotiated with our distribution partners in the relevant territories. To maintain our price competitiveness relative to other products in the industry, we continuously strive to reduce our production costs through ongoing optimization of our fermentation process and downstream post-processing workflows. We believe our cost reduction efforts enable us to sustain a competitive pricing advantage while preserving healthy margins as we scale up our commercial operations.

SALES AND MARKETING

Sales

Since our establishment, we have always been primarily focused on the R&D of our Core Product. However, the development of innovative second-generation LBP products requires substantial investment in terms of capital, time, personnel, and other resources, and as of the Latest Practicable Date, none of our LBP product candidates have been approved for commercial sale. In order to generate some revenue and cash flows to support the continuing R&D of our Core Product and other product candidates, during the Track Record Period, we leveraged certain technologies that we developed during the process of developing our LBP product candidates, and conducted limited sales activities related to our two existing revenue-generating business lines: (i) our NGP raw material business, under which we sell our proprietary

AKK AM06™ strain to distributors and direct customers; 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.

NGP Raw Materials — AKK AM06™

Distributors

During the Track Record Period and up to the Latest Practicable Date, we sell AKK AM06™, our proprietary *Akkermansia muciniphila* strain raw material, to one independent third-party distributor incorporated in the PRC, which is responsible for the sale and distribution of the NGP raw material AKK AM06™ in the PRC, the U.S., Canada, Japan, South Korea, Thailand, Indonesia, and Malaysia. The revenue generated from such distributor is recognized when control of the goods is transferred to the distributor, generally upon receipt of the goods. By leveraging its established distribution channels and existing customer networks, we are able to access these international markets for our NGP raw material products efficiently. We selected this distributor based on its business qualifications and marketing capabilities, such as distribution network coverage, quality, number of personnel, cash flow conditions, creditworthiness, logistics, compliance standard and past performance, and customer management capacity. As of the Latest Practicable Date, we were not aware of any potential abuses or improper use of our name by our distributor which could adversely affect our reputation, business operation or financial condition.

We have entered into a distributorship agreement with our distributor. The principal terms are set forth as below:

Key Terms	Descriptions
Duration	Two years, with expected renewal upon expiry.
Designated distribution area	The PRC, the U.S., Canada, Japan, South Korea, Thailand, Indonesia, and Malaysia.
Payment	Payment before delivery.
Minimum purchase amount	One kilogram per order.
Trademark and patent license	We authorize the distributor to use our AM06™ trademark and patents for promotional purposes.
Sub-distributors	The distributor may engage sub-distributors. We provide standard form sub-distribution agreement templates and retain the right to request disclosure of the sub-distributor list, but we do not directly manage sub-distributors.
Price control	Sub-distributors are prohibited from selling below our supply price to the distributor.
Return of products	We generally do not allow product returns except for defective products, which is in line with the industry practice; no returns have occurred to date.
Compliance with law	The distributor's performance under the agreement shall be in compliance in all material respects with all the applicable laws, regulations and other legal and administrative requirements in the designated distribution territory. The distributor shall also ensure that the procurement and production activities of its customers in the PRC do not violate any applicable laws, regulations or industry requirements.

Direct Sales

We have also commenced the direct sales of our NGP raw material AKK AM06™ to domestic brand owners and functional health product manufacturers in the PRC, primarily through industry conferences, trade exhibitions, and direct client engagement. These customer relationships are managed by our in-house sales personnel. We did not generate any direct sales revenue from the NGP raw material AKK AM06™ in 2024. In 2025, our direct sales of the NGP raw material AKK AM06™ accounted for 32.0% of our total revenue from the NGP raw material AKK AM06™.

Research and Development Services

We provide CRO/CDMO services directly to clients on a project-by-project basis, without engaging distributors or agents. Our clients include large pharmaceutical companies, biotechnology companies and academic and research institutions. We source clients primarily through industry conferences, proactive outreach, and referrals, with clients concentrated in the PRC. In 2025, we entered into our first overseas CRO service engagement with a renowned Swedish research institution, marking an initial step in our international expansion.

Our services cover a broad scope, including strain safety evaluation, pharmacology and toxicology studies, CMC research, clinical trial material manufacturing, and regulatory filing support for IND applications in the PRC and the U.S. Fee arrangements vary by project in the form of upfront payments, regular research period payments and milestone payments. During the Track Record Period and up to the Latest Practicable Date, we served 29 clients for our research and development services. The aggregate value of our orders in backlog for research and development services amounted to RMB59.1 million as of the Latest Practicable Date.

Marketing

NGP Raw Materials

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. We promote AKK AM06™ to international brand owners and manufacturers through our distribution network and participation in international industry exhibitions, online promotion through our official website and social media channels, as well as direct client outreach.

Research and Development Services

Our business development function for CRO/CDMO services is led by our Deputy General Manager, who also oversees our R&D team, with support from our early research, manufacturing and CMC teams. Our business development activities include participation in industry conferences, proactive client outreach, and follow-up on inbound inquiries from the scientific and pharmaceutical community.

LBP Drug Candidates

As of the Latest Practicable Date, we have not commenced marketing activities for our LBP drug candidates, all of which remain in clinical development. As our LBP candidates advance toward NDA or BLA filing, we intend to establish an in-house medical affairs and commercial team. See "Business — Commercialization" in this Document for further details.

OUR SUPPLIERS AND RAW MATERIALS

Our 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. Our procurement activities cover three main categories: (i) CRO services including pre-clinical and clinical development activities; (ii) procurement of specialized culture media, fermentation ingredients, pharmaceutical-grade raw materials and consumables; and (iii) technical services, including outsourced testing, instrument calibration and other engineering-related technical services.

As of the Latest Practicable Date, we had a total of 438 suppliers. During the Track Record Period, 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. We believe that we maintain strong and stable relationships with our major suppliers.

The table below sets forth the salient terms of a typical agreement with our key suppliers:

Key Terms	Descriptions
Services	CRO and/or SMO technical services in connection with our LBP drug development programs, primarily covering Phase I to Phase III clinical trial services including site management, clinical research coordination, regulatory filing support (including IND applications in the PRC and the U.S.), and related technical and laboratory services. Specific services are set out in work orders or project-specific appendices executed under the applicable master service agreement.
Duration	Typically project-based, with terms aligned with the projected clinical study timeline (generally ranging from two to four years, subject to extension upon mutual agreement). For master service agreements, the agreement is open-ended with individual work orders governing specific projects and timelines.
Payment and credit terms	Payment is generally due within 30 days upon receipt of a valid VAT-compliant invoice from the supplier. For project-based agreements, payments are structured in accordance with the agreed payment schedule or milestone plan set out in the relevant work order. Late payment may incur a penalty at a rate of 0.5% per month on the outstanding amount.
Confidentiality	Each party undertakes to keep the other party's confidential information strictly confidential and not to disclose it to any third party without prior written consent. Confidentiality obligations are mutual and survive the termination or expiry of the agreement, remaining in force until the relevant information enters the public domain through no fault of the receiving party.
Intellectual property rights	We retain ownership of all deliverables, study data, and rights to the study drugs and/or investigational products upon full payment of all amounts due. Suppliers retain ownership of their pre-existing intellectual property, proprietary methodologies, tools, and systems. Both parties warrant that the services and materials provided will not infringe any third-party intellectual property rights, and each party shall indemnify the other for actual losses arising from a breach of such warranty.

Key Terms	Descriptions
Medical liabilities	For agreements involving the deployment of clinical research coordinators (CRCs) or other personnel stationed at clinical trial sites, the supplier acts as the employer and is solely responsible for all obligations in respect of such personnel, including salaries, employee benefits, social insurance contributions, and any workplace accidents or injuries occurring during the service period. We bear no liability for employment-related claims brought by such personnel.
Liabilities and termination	Either party may terminate the agreement for cause, including material breach, insolvency, regulatory risk, or prolonged project suspension. We may terminate without cause upon giving 30 to 120 days' advance written notice (depending on the specific agreement), and are required to pay for all services rendered and irreversible costs incurred up to the termination date. Neither party is liable for indirect, punitive, or consequential losses.

The following tables set forth details of our five largest suppliers in each year during the Track Record Period:

Suppliers	Background	Services/products provided to us	Year of commencement of business relationship with us	Credit term/ Payment method	Purchase amount by us	Percentage of the total purchase
					(RMB'000)	*(%)*
For the Year Ended December 31, 2024						
Supplier A	A company primarily engaged in innovation community operations and technology services, providing operating lease and power supply solutions to enterprises.	Property leasing and electricity resale services	2016	Payment due by the 10th/15th of each month/Bank transfer	6,795	17.1
Supplier B	A company primarily engaged in providing professional management and human resources services to the pharmaceutical and healthcare sector.	Clinical research service – CRO	2020	Installment payments within 30 days of each milestone completion/Bank transfer	4,745	12.0
Supplier C*(Note 1)*	A globally leading CRO primarily engaged in providing biopharmaceutical product development and outsourcing services.	Clinical research service – CRO	2022	Installment payments within 30 days of each milestone completion/Bank transfer	2,535	6.4
Supplier D	A company primarily engaged in providing professional technical services focused on clinical research and the medical field.	Clinical research service – SMO	2023	Installment payments within 30 days of each milestone completion/Bank transfer	1,550	3.9

Suppliers	Background	Services/products provided to us	Year of commencement of business relationship with us	Credit term/ Payment method	Purchase amount by us	Percentage of the total purchase
					(RMB'000)	*(%)*
Supplier E	A company primarily engaged in providing business and management consulting services to enterprises.	Consulting service	2024	Within 30 business days after completion of transaction closing/Bank transfer	1,287	3.3
Total					**16,912**	**42.7**
For the Year Ended December 31, 2025						
Supplier A	A company primarily engaged in innovation community operations and technology services, providing operating lease and power supply solutions to enterprises.	Property leasing and electricity resale services	2016	Payment due by the 10th/15th of each month/Bank transfer	6,687	17.3
Supplier B	A company primarily engaged in providing professional management and human resources services to the pharmaceutical and healthcare sector.	Clinical research service – CRO	2020	Installment payments within 20 days of each milestone completion/Bank transfer	5,211	13.5
Supplier F	A leading CRO in the PRC primarily engaged in providing clinical trial services.	Clinical research service – SMO	2021	Installment payments within 20 days of each milestone completion/Bank transfer	1,626	4.2
Supplier D	A company primarily engaged in providing professional technical services focused on clinical research and the medical field.	Clinical research service – SMO	2023	Installment payments within 30 days of each milestone completion/Bank transfer	1,311	3.4
Supplier G[(Note 2)]	An A-share listed company primarily engaged in providing one-stop outsourcing (CRO) services for the whole-process R&D and production of drugs and medical devices.	Consulting, registration services and China-US dual filing service	2025	Installment payments within 10 days of each milestone completion/Bank transfer	1,211	3.1
Total					**16,046**	**41.5**

Notes:

1 Including transactions with a company incorporated in the U.S. of RMB2.5 million and a domestic company of RMB27,300, which are under common control of Supplier C and are deemed as one supplier.

2 Including transactions with a company incorporated in Hong Kong of RMB0.7 million and a domestic consulting company of RMB0.5 million, which are under common control of Supplier G and are deemed as one supplier.

To the best of our knowledge, the top five largest suppliers in each year during the Track Record Period are Independent Third Parties. None of our Directors, their close associates, or any Shareholder who, to the best knowledge of our Directors, owns more than 5% of the issued share capital of our Company as of the Latest Practicable Date had any interest in any of our five largest suppliers for each year during the Track Record Period.

Raw Materials

The principal raw materials that we used include specialized culture media, excipients, and pharmaceutical-grade raw and auxiliary materials, which are primarily sourced from suppliers in the PRC. We adopt stringent supplier selection procedures tailored to each procurement category. For GMP-regulated suppliers, we require valid production licenses, quality management system certifications, and CDE registration status, with preference given to suppliers holding a Category "A" CDE registration status. For R&D material suppliers, we require product inspection reports (such as valid inspection reports) demonstrating compliance with our quality requirements. Our suppliers are required to possess all licenses necessary for their operations.

Our principal raw materials are generally readily available in the market through a number of suppliers. Our principal raw materials typically have two to three qualified suppliers, and for certain commodity materials, the number of qualified suppliers may be higher. For one of our key culture media products, we currently source from a limited number of international suppliers; however, we have completed process validation studies for alternative suppliers and intend to maintain at least three qualified supplier options upon NDA/BLA approval. Moreover, we generally maintain approximately three months of inventory for our principal raw materials. We believe we have alternative sources for our principal raw materials with comparable quality and pricing.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any material shortage or delay in the supply of raw materials, and we did not experience any significant increases in the prices of our major raw materials or fluctuations in raw material costs which had a material adverse impact on our results of operations or gross profit margins. Our procurement costs have remained broadly stable during the Track Record Period, with a moderate declining trend attributable to the progressive substitution of certain imported materials with domestically-sourced alternatives and the introduction of additional competing suppliers. See "Risk Factors — Risks Relating to Our Reliance on Third Parties — We rely on a stable supply of high-quality culture media and specialized raw materials for LBPs, as well as the availability of combination therapy drugs, and any interruptions of such supply could have an adverse impact on our business."

OUR CUSTOMERS

In 2024 and 2025, our revenue was generated from various customers across our research and development service (including CRO/CDMO services) business and our NGP raw material business. For our research and development services, payment terms are generally linked to project milestones, with settlement typically completed within approximately 15 working days following confirmation of each milestone. For our sales of NGP raw material AKK AM06™, we generally adopt a payment-before-delivery policy.

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.

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

Customers	Background	Services/products purchased	Year of commencement of business relationship with us	Credit term/Payment method	Revenue contribution	Percentage of total revenue
					(RMB'000)	*(%)*
For the Year Ended December 31, 2024						
Customer A	A company primarily engaged in providing full-service health product supply chain solutions.	AKK AM06™ raw material	2024	Payment before delivery/Bank transfer	330	45.8
Customer B	A company primarily engaged in pharmaceutical R&D, manufacturing, and sales.	CRO service	2024	Payment in three installments: 60% prepayment; 1/3 upon receipt of testing report; rest upon receipt of inspection report/Bank transfer	264	36.6

Customers	Background	Services/products purchased	Year of commencement of business relationship with us	Credit term/Payment method	Revenue contribution	Percentage of total revenue
					(RMB'000)	*(%)*
Customer C	A company primarily engaged in providing third-party testing and scientific research analysis services.	CRO service	2024	50% prepayment within 15 business days of contract signing; balance within 15 business days of delivery/Bank transfer	38	5.2
Customer D	A comprehensive research university.	CRO service	2023	Payment in two installments: initial payment upon completion of 1L-scale parameters; balance upon acceptance of second batch/Bank transfer	28	3.9
Customer E	A Grade-A tertiary general hospital.	CRO service	2023	Full payment within 10 business days of contract signing/Bank transfer	25	3.4
Total					**685**	**94.9**
For the Year Ended December 31, 2025						
Customer F	A company primarily engaged in microbiome drug research and development in the biopharmaceutical field.	CRO service	2024	50% prepayment upon contract signing; balance in two installments, each within 15 business days of delivery of the respective reports/Bank transfer	611	25.4
Customer A*(Note 1)*	A company primarily engaged in raw material supply, formulation services and ODM/OEM production of health and functional food products; and its subsidiary is primarily engaged in the R&D and technical services of TCM extracts, cosmetic raw materials and natural active ingredients.	AKK AM06™ raw material; CRO service	2024	Payment before delivery; 30% prepayment upon contract signing; 40% within 2 weeks of preliminary screening results; 30% within 30 days of final report/Bank transfer	594	24.7

Customers	Background	Services/products purchased	Year of commencement of business relationship with us	Credit term/Payment method	Revenue contribution	Percentage of total revenue
					(RMB'000)	*(%)*
Customer B	A company primarily engaged in pharmaceutical R&D, manufacturing, and sales.	CRO service	2024	Payment in three installments: 60% prepayment; 1/3 upon receipt of testing report; rest upon receipt of inspection report/Bank transfer	500	20.8
Customer G	A biotechnology company primarily focused on the field of individual microbiome.	CRO service	2025	52.1% prepayment within 5 business days of contract signing, balance within 5 business days of delivery; or full payment within 5 business days of delivery (depending on the contract)/Bank transfer	306	12.7
Customer H	A company primarily engaged in the manufacturing of health food (tablets, capsules, etc.) and food products (beverages, herbal tea substitutes, etc.)	AKK AM06™ raw material	2025	Payment before delivery/Bank transfer	106	4.4
Total					**2,117**	**88.0**

Note:

1 Including transactions with Customer A of RMB0.4 million and its domestic subsidiary of RMB0.2 million, which are deemed as one customer.

To the best of our knowledge, the top five largest customers in each year during the Track Record Period are Independent Third Parties. Save for Customer G, none of our Directors, their close associates, or any Shareholder who, to the best knowledge of our Directors, owns more than 5% of the issued share capital of our Company as of the Latest Practicable Date had any interest in any of our five largest customers for each year during the Track Record Period.

Historical Collaborative Development Arrangement

Background of the Collaboration

In May 2022, we entered into a new drug variety co-development agreement (the "**Collaboration Agreement**") with an Independent Third Party (the "**Collaboration Partner**") in respect of the research and development of an early-stage LBP candidate. The collaboration commenced in May 2022, prior to the Track Record Period, and was structured in two phases: (i) completing pre-clinical work to support IND approval and entry into clinical trials; and (ii) advancing the first indication of the candidate to marketing approval in the PRC.

Key Rights and Obligations of the Parties

Under the Collaboration Agreement, the parties agreed on the allocation of development responsibilities and interests in the candidate, principally including:

Lead Party for Development and Registration: The Collaboration Partner was responsible for the overall development, registration and clinical strategy of the candidate (including drug efficacy and toxicology studies, clinical protocol design, and the preparation and submission of registration dossiers, other than the parts undertaken by us), and held the clinical trial application rights, the new drug certificate and the marketing approval.

Our Responsibilities: We were responsible for pre-clinical strain safety evaluation, distribution and colonization studies, the full course of CMC research and the manufacture of drug substance for Phase I clinical trials, and were designated as the manufacturer for clinical supply and, upon NDA/BLA, for commercial manufacturing.

Allocation of Interests: We were entitled to a minority economic interest in the first indication of the candidate, with the majority interest held by the Collaboration Partner; any future commercialization income, or proceeds from the licensing or transfer of the candidate to third parties, was to be shared between the parties in the same agreed proportions, the majority to the Collaboration Partner and the balance to us. Each party bore its own research and development costs for the work allocated to it.

Intellectual Property: Intellectual property generated jointly during the collaboration could be jointly applied for as patents upon mutual agreement; inventions arising from our proprietary technology (including CMC, quality research and formulation processes) belonged to us, with the Collaboration Partner granted a right of use. Neither party was permitted to dispose of the technology, data or results of the candidate to any third party without the other party's consent.

Termination: Neither party could unilaterally terminate the collaboration; the agreement could be terminated by mutual agreement only where the candidate suffered a material setback (for example, clinical results demonstrating an insurmountable obstacle, or regulatory or market changes rendering the candidate unviable).

Dispute Resolution: Disputes arising from the agreement were to be resolved through friendly negotiation, failing which through litigation before the competent court at the plaintiff's domicile. The agreement was governed by PRC law.

Transfer of Our Interests

In January 2026, we and the Collaboration Partner entered into a supplementary agreement to the Collaboration Agreement, under which we transferred to the Collaboration Partner all of our rights and interests in the candidate (including all related intellectual property, know-how, data and results), in consideration of a cash amount payable by the Collaboration Partner to us in instalments, failing which the arrangement may not proceed. Following the transfer, and subject to performance of the supplementary agreement, we ceased to hold any interest in, or to bear any further obligation in respect of, the candidate, and would no longer be entitled to the economic interest described above. Subject to the foregoing, the candidate has since been advanced independently by the Collaboration Partner, and we do not currently participate in its subsequent development.

OVERLAPPING OF CUSTOMERS AND SUPPLIERS

During the Track Record Period, one of our five largest customers in 2024 also served as a clinical trial center for certain of our LBP drug candidates and is therefore also one of our suppliers ("**Overlapping Customer and Supplier**"). Such overlap is attributable to the nature of our clinical development operations, whereby certain hospital partners that engage us for CRO service also serve as clinical trial centers for our LBP drug candidates in their capacity as a supplier of clinical trial services. Such commercial relationship as a customer and clinical trial activities as a supplier involved different departments and personnel within the hospital respectively.

Our revenue generated from such Overlapping Customer and Supplier amounted to RMB24,717.0 and RMB17,358.5 in 2024 and 2025, respectively, representing 3.4% and 0.7% of our total revenue in the respective years. Our purchases from such Overlapping Customer and Supplier amounted to RMB0.3 million and RMB0.3 million in 2024 and 2025, respectively, representing 0.6% and 0.9% of our total purchases in the respective years. The gross profit attributable to our transactions with such Overlapping Customer and Supplier in 2024 amounted to RMB8,141.7, representing a gross profit margin of 33.0%. In 2025, we recorded a gross loss of RMB41,003.3 attributable to our transactions with such Overlapping Customer and Supplier, representing a gross loss margin of 236.2%. The gross loss recorded in 2025 was primarily attributable to a shift in our revenue mix in 2025, with CRO services accounting for an increasing proportion of our revenue. As we were in the early stage of business development, we strategically accepted orders with relatively small individual sizes and lower gross profit margins in order to develop customers and expand our market reach, and had not yet achieved economies of scale.

All of our purchases from and sales to such customer-supplier were conducted in the ordinary course of business and on an arm's length basis, and were neither inter-connected nor inter-conditional. We have maintained good and long business relationship with our Overlapping Customers and Suppliers and did not have any disputes with them during the Track Record Period. Save for the foregoing, to the best of our knowledge, none of our five largest customers in each year during the Track Record Period is also a supplier to us.

INTELLECTUAL PROPERTY ("IP")

Intellectual property, including patents, trade secrets and trademarks, is critical to our business. Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates, novel discoveries, product development technologies, inventions and know-how. Our success also depends in part on our ability to defend and enforce our patents including patents that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of other parties.

We have adopted a strategy to develop a global portfolio of patents to protect our drug candidates and know-how. 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. All material patents in relation to our Core Product and key product are owned by our Group. For more details in relation to granted patents and patent applications material to our business operations, see "Appendix IV — Statutory and General Information" in this Document. The following table summarizes the details of all our material patents and patent applications in connection with our Core Product and key product as of the Latest Practicable Date:

Product	Patent/ Application Number	Patent Type	Patent Protection Scope	Patentee	Jurisdiction	Filing/ Registration Date	Patent Status	Patent Expiration
SK08, SK10	ZL 201510459407.5	Invention	Use of Bacteroides fragilis in animal breeding (脆弱擬桿菌在動物養殖中的應用)	the Company	PRC	November 2020	Granted	July 2035
SK08	ZL 201510728725.7	Invention	Use of a strain of Bacteroides fragilis in preventing and/or treating inflammatory bowel disease (一種脆弱擬桿菌在預防和/或治療炎症性腸病中的應用)	the Company	PRC	February 2019	Granted	October 2035
SK08, SK10	ZL 202110977532.0	Invention	Use of Bacteroides fragilis and its extract in preparing medicine for preventing and treating irritable bowel syndrome (脆弱擬桿菌及其提取物在製備防治腸易激綜合徵的藥物中的應用)	the Company	PRC	October 2022	Granted	September 2037
SK08, SK10	ZL 202210968927.9	Invention	Use of Bacteroides fragilis in preparing medicine for preventing and treating irritable bowel syndrome (脆弱擬桿菌在製備防治腸易激綜合徵的藥物中的應用)	the Company	PRC	September 2025	Granted	September 2037
SK08	ZL 202110728771.2	Invention	Culture medium, preparation method thereof and method for culturing Bacteroides fragilis using same (培養基及其製備方法、用其培養脆弱擬桿菌的方法)	the Company	PRC	March 2023	Granted	June 2041

Product	Patent/ Application Number	Patent Type	Patent Protection Scope	Patentee	Jurisdiction	Filing/ Registration Date	Patent Status	Patent Expiration
SK10	2021111889739	Invention	An inactivated Bacteroides fragilis powder and preparation method thereof (一種脆弱擬桿菌滅活菌粉及其製備方法)	the Company	PRC	October 2021	Pending	N/A
SK08, SK10 .	202111188989X	Invention	Use of Bacteroides fragilis in preventing and treating cancer-related diarrhea (脆弱擬桿菌在防治癌症相關腹瀉中的應用)	the Company	PRC	October 2021	Pending	N/A
SK08, SK10 .	2024103528427	Invention	Use of Bacteroides fragilis in preparing medicine for treating oral mucosal diseases (脆弱擬桿菌在製備治療口腔黏膜病的藥物中的應用)	the Company	PRC	June 2022	Pending	N/A
SK08, SK10 .	202211339890X	Invention	Use of Bacteroides fragilis in improving and treating diarrhea (脆弱擬桿菌在改善和治療腹瀉中的應用)	the Company	PRC	October 2022	Allowed	N/A
SK08, SK10 .	US18/700,420	Invention	Use of Bacteroides fragilis in prevention and treatment of cancer-related diarrhea (脆弱擬桿菌在防治癌症相關腹瀉中的應用)	the Company	U.S.	September 2022	Pending	N/A
SK08, SK10 .	EP22880094.2	Invention	Use of Bacteroides fragilis in prevention and treatment of cancer-related diarrhea (脆弱擬桿菌在防治癌症相關腹瀉中的應用)	the Company	Europe	September 2022	Pending	N/A
SK08, SK10 .	US18/833,059	Invention	Use of Bacteroides fragilis in improvement and treatment of diarrhea (脆弱擬桿菌在改善和治療腹瀉中的應用)	the Company	U.S.	December 2022	Pending	N/A
SK08, SK10 .	EP22923662.5	Invention	Use of Bacteroides fragilis in improvement and treatment of diarrhea (脆弱擬桿菌在改善和治療腹瀉中的應用)	the Company	Europe	December 2022	Pending	N/A
SK08, SK10 .	AU2022436554	Invention	Use of Bacteroides fragilis in improvement and treatment of diarrhea (脆弱擬桿菌在改善和治療腹瀉中的應用)	the Company	Australia	December 2022	Pending	N/A

During the establishment and incubation stage of our Company, certain early-stage patent applications in relation to our technologies were initially filed under the name of Guangdong Zhiguang, one of our founding shareholders. All such intellectual property rights previously held by Guangdong Zhiguang were subsequently transferred to us, and Guangdong Zhiguang did not retain any commercialization rights, license rights, royalty-sharing rights or other rights that would restrict the development or commercialization of our Core Product or other product candidates. See "— Research and Development — Early Support from Guangdong Zhiguang." The intellectual property rights transferred from Guangdong Zhiguang related to early-stage research results. By contrast, all material patents and patent applications set forth in the table above were independently applied for by us.

Our IP Counsel has conducted freedom to operate analysis ("**FTO Analysis**") in Chinese Mainland and the U.S. in relation to our Core Product and key product. No material infringement risk against valid and enforceable patents of any third party issued in Chinese Mainland and the U.S. had been identified from the FTO Analysis in relation to the bacteria used in, or indications currently under clinical stage of, our Core Product and key product. However, we cannot provide any assurance that all relevant third party patents were identified or that conflicting patents will not be issued in the future.

The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends on various factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular jurisdiction, and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug candidates and methods of manufacturing the same. For a detailed description of risks related to our intellectual property, see "Risk Factors — Risks Relating to Our Intellectual Property Rights."

Intellectual Property Protection Measures

In addition to patent protection, we maintain the confidentiality and proprietary nature of our intellectual property through a combination of contractual, technical and administrative measures, including:

Confidentiality and Intellectual Property Agreements: we enter into confidentiality and intellectual property agreements (the "**IP Agreement**") with all employees upon joining. Under the IP Agreement, all inventions, technical achievements, and related rights created or developed by employees in the course of their employment with us are assigned unconditionally to us or any entity designated by us. Employees are also required to cooperate with us in completing all formalities necessary for the protection of the relevant intellectual property rights. Prior to onboarding, we also conduct reviews of new employees' prior employment history to identify any potential conflicts with our intellectual property;

Employee IP Incentive Policies: we have established policies under which inventors are entitled to receive awards calculated by reference to their contribution to each patent filed and granted, settled on a semi-annual or annual basis;

Data Security Controls: we have implemented an internal document management and access control system under which all outbound documents require approval prior to transmission, and our server infrastructure is subject to strict permission controls limiting access to core technical data; and

Non-competition Arrangements: we have entered into non-competition agreements with our senior management and key R&D personnel to prevent the misappropriation of trade secrets and commercially sensitive information.

Intellectual Property Disputes

During the Track Record Period and up to the Latest Practicable Date, (i) we were not involved in any legal, arbitral or administrative proceedings in respect of, and we had not received notice of any material claims of infringement, misappropriation or other violations of third-party intellectual property; and (ii) we were not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on the R&D for any of our drug candidates in which we may be a claimant or a respondent.

All annual maintenance fees in respect of our intellectual property have been paid on a timely basis. None of our intellectual property rights is subject to any mortgage, pledge, lien, seizure, freeze or attachment.

COMPETITION

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition and a strong emphasis on proprietary drugs. 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, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions.

We focus on leveraging our industry experience and established R&D capabilities for the in-house discovery and development of differentiated therapeutics in the fields of oncology, gastroenterology, infectious diseases and immunology across our LBP drug pipeline. According to Frost & Sullivan, we are the only company globally to advance a *Bacteroides fragilis*-based LBP product into clinical trials, as of the Latest Practicable Date. Moreover, our Core Product 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. According to Frost & Sullivan, SK10, our key product, is the first inactivated LBP in the PRC to obtain IND approval from the U.S. FDA. 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.

We expect the competition will intensify in the future as additional players enter into these segments. Any drug candidates that we successfully develop and commercialize will compete with existing drugs or any new drugs that may become available in the future. For more information on the competitive landscape of our drug candidates, see "— Our Product Pipelines (Pharmaceutical Pipelines)" and "— Our Probiotic Raw Materials Products (Non-Pharmaceutical Pipelines)" in this section and "Industry Overview" in this Document.

DATA SECURITY AND PRIVACY

In our pharmaceutical research, preclinical research, drug registration filings, and drug manufacturing activities, we do not collect or process personal information. As the clinical trial sponsor, we collect and process personal information of subjects during clinical research activities; the personal information collected is limited to what is necessary for the clinical trials, and its use is restricted to the clinical trials. In addition, during the course of our clinical trials, we access and store personal information of personnel of cooperative institutions (such as clinical trial institutions, CROs and SMOs) for the purpose of verifying their identities and qualifications.

We have established strict personal information protection policies and adopted various measures to ensure that the collection, use, storage, and processing of personal information comply with the applicable laws and regulations. In our clinical trials, the collection of personal information of subjects is primarily performed by the clinical trial institutions. The basic personal profile and personal identity information of

subjects collected and processed by us as the clinical trial sponsor is de-identified; such personal information is provided to us by the clinical trial institutions in the form of subject identification codes. The correspondence tables between the subject identification codes and the subjects' actual identities are held by the clinical trial institutions and are not held or replicated by us. We have established a minimum-authorization control strategy in accordance with the clinical data management workflows and require all internal employees, as well as clinical trial institutions, CROs, SMOs and other third parties involved in our clinical trials, to adhere to strict confidentiality obligations.

We do not transfer or store personal information of subjects collected and generated in our domestic operations outside the PRC, nor have we granted any channel or authorization to any institution, organization, or individual outside the PRC to access or retrieve such personal information.

During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any administrative penalty, investigation, inquiry or warning from any cyberspace, telecommunications, public security or other governmental authorities in respect of cybersecurity, data security or personal information protection, nor had we experienced any data leakage or other cybersecurity, data security or personal information protection related incidents.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our principal insurance policies cover adverse events in clinical trials. We also maintain social insurance for our employees in accordance with relevant PRC laws and regulations, and purchase additional commercial accident insurance for our employees. However, we did not purchase property insurance against property loss and we did not maintain insurance for environmental liability. See "Risk Factors — Risks Relating to Our Business Operations — We have limited insurance coverage, and any claims beyond our coverage may result in substantial costs and a diversion of resources" in this Document.

We consider that the coverage from the insurance policies maintained by us is adequate to cover our key assets, facilities, and liabilities and in line with the industry practice in the PRC. During the Track Record Period, we had not made or been the subject of any material insurance claims.

EMPLOYEES

As of the Latest Practicable Date, we had 83 employees and all of them were in the PRC. The following table sets forth the number of our employees categorized by functions as of the Latest Practicable Date:

Function	Number of employees	As a percentage of our total number of employees
		(%)
R&D	58	69.9
Manufacturing	8	9.6
Finance and Legal	6	7.2
Human Resources, Administration and Others	11	13.3
Total	**83**	**100.0**

Employment Agreements and Recruitment

We enter into individual employment agreements with our employees covering salaries, bonuses, employee benefits, workplace safety, and grounds for termination. We also enter into separate confidentiality agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information of our business.

We recruit and retain highly engaged, motivated team players who align with our commitment and are eager to contribute to our development leveraging their extensive experience. The success of our endeavors relies significantly on the efforts and expertise of all employees, who form an integral part of our business. We adopt high standards and strict procedures in our recruitment to ensure the quality of new hiring and use various methods for our recruitment, including internal recommendation, social recruitment and recruiting through headhunters, to satisfy our demands for different types of talent.

Employee Training

To maintain our workforce's quality, knowledge, and skill levels, we also provide trainings based on the needs of our employees across different teams. Our training framework consists of both onboarding training for new hires and ongoing role-specific trainings for existing employees. New hires complete an onboarding orientation covering our Company's policies, safety protocols, and our quality management system. Following onboarding, employees receive team-specific trainings tailored to their roles, covering areas such as laboratory techniques, manufacturing procedures, quality control protocols, and project execution. Training sessions are regularly organized and conducted by senior internal staff or, where appropriate, third-party consultants.

In addition, we facilitate external training opportunities for our employees, including attendance at industry conferences, academic seminars, and technical workshops. These external engagements allow our employees to stay abreast of the latest scientific advancements, regulatory changes, and industry best practices.

Employee Benefits

We are dedicated to ensuring that working conditions across our business network are safe and that employees are treated with care and respect. We believe in providing our employees with competitive compensation packages, reflecting our stakeholder-centric ethos, which we believe fosters sustainable and enduring growth. In accordance with the PRC regulations, we participate in various government-mandated employee benefit plans, including social insurance such as pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing funds. Under PRC law, we are obliged to make contributions to these employee benefit plans at specified percentages of salaries, bonuses, and certain allowances, up to maximum amounts specified by local government regulations.

We strive to create an equitable, inclusive, and diverse workplace while fostering positive working relationships with our employees. As of the Latest Practicable Date, we have not encountered any major labor disputes that led to disruptions in our operations.

PROPERTIES

To support our business operations, including R&D, manufacturing, and administration, we leased properties in four cities across Chinese Mainland, including Guangzhou, Qingyuan, Shanghai, and Shijiazhuang. Our principal executive office is located in Guangzhou, Guangdong Province. We currently do not own any land use rights or properties. As of the Latest Practicable Date, we are leasing seven properties with an aggregate GFA of approximately 7,632.9 sq.m., which are primarily used for office, R&D, and manufacturing purposes. As of the Latest Practicable Date, three of our leased properties had not been registered with the relevant PRC authorities. As advised by our PRC Legal Advisor, such non-registration will not affect the validity of the lease agreement, but the relevant local housing administrative authorities may require us to complete registrations within a specified timeframe and we may be subject to a fine of between RMB1,000 and RMB10,000. Our Directors believe that such registration defect does not and will not materially impact our ability to use the properties, as the leases remain valid, and sufficient alternative premises are available in the market should relocation become necessary. We will continue to liaise with the respective lessors to complete the registrations where feasible.

In the event that any of our leases expire after the end of their respective lease term, we would need to seek alternative premises and incur relocation costs. We believe that there are alternative properties at comparable rental rates available on the market, the use of which would not materially and adversely affect our business operations, and we thus do not rely on the existing leases for our business operations.

As of the Latest Practicable Date, none of the properties leased by us had a carrying amount of 15% or more of our total assets. According to section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this Document is exempt from the requirements of section 342(1)(b) of the Companies (Winding up and Miscellaneous Provisions) Ordinance to include all interests in land or buildings in a valuation report as described under paragraph 34(2) of the Third Schedule to the Companies (Winding up and Miscellaneous Provisions) Ordinance.

AWARDS AND RECOGNITION

The table below sets forth the major awards and recognition we received as of December 31, 2025:

Year of Grant	Project/Entity	Award/Recognition	Issuing Authority
2025	Zhiyi Biotech	14th China Innovation and Entrepreneurship Competition (Guangdong • Guangzhou Division) and 2025 Guangzhou Technology Innovation and Entrepreneurship Competition Industry Track — Growth Group First Prize (第十四屆中國創新創業大賽(廣東 • 廣州賽區)暨2025年廣州科技創新創業大賽行業賽-成長組一等獎)	Guangzhou Municipal Bureau of Science and Technology (廣州市科學技術局)
2025	Zhiyi Biotech	Innovative Enterprise of the Year for Investment Value (2025) (投資價值年度創新企業(2025))	BioCon China Expo Organizing Committee (BioCon China Expo組委會)
2024	Zhiyi Biotech	"Specialized, Sophisticated, Distinctive and Innovative" Small and Medium-Sized Enterprise ("專精特新"中小企業)	Guangdong Provincial Department of Industry and Information Technology (廣東省工業和信息化廳)
2024	Zhiyi Biotech	Outstanding Synthetic Biology Enterprise (2024) (合成生物學傑出企業 (2024))	Synbio China Organizing Committee (Synbio China 組委會)
2023	Zhiyi Biotech	First Guangdong Provincial Outstanding Pharmaceutical Achievement (廣東省首屆優秀醫藥成果)	Guangdong Medical Association (廣東省醫學會)

ENVIRONMENTAL, SOCIAL AND GOVERNANCE ("ESG") MATTERS

ESG Governance

We seek to conduct our business in a responsible and sustainable manner and to maintain transparency and accountability to our stakeholders, including employees. Given the nature of our operations, our key environmental aspects are primarily associated with office and laboratory activities. We seek to comply with applicable PRC environmental laws and regulations, including requirements relating to hazardous waste and wastewater generated from laboratory operations. We monitor relevant regulatory developments and, where appropriate, maintain communication with relevant regulators to support compliance. To support our long-term sustainability strategy, we have established ESG-related policies and periodically review our ESG management framework with a view to aligning it with evolving regulatory expectations and industry practices.

We have established an Environmental, Social and Governance Working Group (the "**ESG Working Group**"), comprising management representatives and led by the Board of Directors, to coordinate our ESG-related matters. The ESG Working Group assists in identifying, analyzing, monitoring and reporting ESG-related risks. It also assists in formulating and reviewing policies, targets and key performance indicators ("**KPIs**"), and corresponding action plans having regard to our operational circumstances. The ESG Working Group reports to the Board on our ESG performance at least annually.

We have established environmental management policies and procedures, including, among others, the Environmental Protection Management Procedures (《環境保護管理規程》), the Hazardous Waste Standardized Environmental Management Policy (《危險廢物規範化環境管理制度》) and the Hazardous Waste-related Environmental Emergency Contingency Plan (《危險廢物相關單位環境應急預案》). These documents set out general requirements and responsibilities for environmental management, including hazardous waste handling and emergency response arrangements, as applicable.

Identification and Assessment of Potential ESG-related Risks

In identifying, assessing and prioritizing material ESG topics and related potential risks, we take into account our business strategy, national policies, industry characteristics and stakeholder expectations. Based on stakeholder engagement and our review of the relevant industry practices, we have identified ESG issues that are most relevant to our operations. The table below sets out the material ESG-related issues identified, their potential risks and impacts and the corresponding strategies:

Material ESG-related Issues	Potential Risks and Impacts	Our Strategies
Greenhouse Gas ("GHG") Emissions	GHG emissions may arise from our operations, which may give rise to climate-related risks.	We monitor our emissions profile and implements measures to manage and control emissions.
Resource Management	Ineffective resource management may lead to higher energy and/or water consumption and increased operating costs.	We implement resource management measures and promotes conservation practices.
Climate Change	Physical and transition risks associated with climate change may disrupt operations and/or increase compliance and operating costs.	We monitor ESG-related regulatory requirements and evaluates response measures where appropriate.

Material ESG-related Issues	Potential Risks and Impacts	Our Strategies
Employee Management	Non-compliance with labor-related laws may result in regulatory action, disputes and costs. Insufficient training and development may increase turnover and reduce capability.	We maintain policies and procedures to support compliance and provide benefits and development opportunities.
Product Safety and Quality	Given the nature of our business, product safety and quality are key considerations for us. Any deficiencies in product safety or quality may result in regulatory actions and additional compliance or rectification costs, and may also lead to product-related claims, operational disruption (including delays or suspension of certain activities) and reputational impact.	We have established quality management arrangements and procedures to identify and manage product quality-related risks across relevant activities. In this regard, we have obtained a compliance audit certificate of Good Manufacturing Practices for Drug in respect of pharmaceutical products for clinical trials (trial), with the audit scope covering specified biological product(s).
Business Ethics	Lapses in ethical conduct may result in regulatory penalties, financial losses, reputational damage and stakeholder disengagement.	We require integrity and compliance in operations and maintains governance and compliance controls.

Climate-related Risks

We monitor potential climate change impacts on our operations. In terms of physical risk, extreme weather events (such as heavy rainfall and flooding) may disrupt operations. In such circumstances, we may implement contingency arrangements and take actions in response to relevant government notices to support employee safety. In terms of transition risk, regulatory changes (including carbon emissions requirements and ESG disclosure requirements) may increase compliance costs. We will continue to monitor evolving ESG standards, regulatory developments and industry trends and assess response measures in light of our operations.

Environmental Protection

We strictly comply with the applicable PRC environment-related laws and regulations by assessing and managing environmental impacts arising from our business activities. We have implemented environmental policies and procedures and adopted measures in our daily operations to support environmental management and compliance. In particular, we have established the environmental protection management procedure, which covers the management of "three wastes" (waste gas, wastewater and solid waste), including assigning relevant responsibilities, integrating environmental protection requirements into day-to-day operations, and maintaining relevant records.

Under Environmental Protection Management Procedures (《環境保護管理規程》), we carry out environmental monitoring activities having regard to our discharge profile and address any exceedance identified, as applicable. The procedure also requires that hazardous waste disposal be entrusted to qualified service providers.

Metrics and Targets

GHG Emissions

We measure GHG emissions arising from our daily operations where applicable. As we do not operate company-owned vehicles or canteen facilities, we do not generate direct Scope 1 greenhouse gas emissions. Scope 2 emissions are indirect emissions arising from the consumption of purchased electricity, which constitute the primary source of our operational emissions. The following table presents our emissions during the Track Record Period:

		For the Years Ended December 31,	
GHG Emissions[1] Key Performance Indicator	**Unit**	**2024**	**2025**
Energy indirect (Scope 2) GHG emissions	tCO_2e	1,861.27	1,858.79
Total GHG emissions	tCO_2e	1,861.27	1,858.79

Note:

1. GHG emission data are presented in terms of carbon dioxide equivalent and are based on, including but not limited to (i) "The Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standards" issued by the World Resources Institute and the World Business Council for Sustainable Development; (ii) "How to prepare an ESG Report — Appendix 2: Reporting Guidance on Environmental KPIs" issued by the Stock Exchange; (iii) the relevant PRC electricity carbon footprint factor; and (iv) the "Global Warming Potential Values" from the IPCC Sixth Assessment Report.

Waste Management

We engage qualified and licensed waste collectors to handle hazardous waste generated from laboratory operations in accordance with the applicable requirements, including, where applicable, hazardous laboratory waste liquids (including spent solutions) and hazardous laboratory solid waste.

Due to the nature of our operations, we may involve the use of chemical materials and hazardous waste may be produced. Hazardous waste generated is handed over to qualified third parties in accordance with applicable requirements for disposal. General waste is placed at designated locations to be handled by municipal authorities. We maintain procedures addressing hazardous waste handling requirements in different operational environments, including but not limited to the Hazardous Waste Standardized Environmental Management Policy (《危險廢物規範化環境管理制度》) and the Hazardous Waste-related Environmental Emergency Contingency Plan (《危險廢物相關單位環境應急預案》). We maintain records of hazardous waste generated, with a view to managing potential environmental impacts arising from our operations.

		For the Years Ended December 31,	
Waste Key Performance Indicator	**Unit**	**2024**	**2025**
Hazardous waste	kg	1,057.0	1,105.0

Resource Management

We monitor resource consumption such as electricity and have implemented measures to enhance resource efficiency. For example, we prioritize energy-saving lighting equipment in offices and common areas and require employees to switch off idle lighting systems and electronic appliances where practicable.

		For the Years Ended December 31,	
Use of Resources Key Performance Indicator	**Unit**	**2024**	**2025**
Indirect energy consumption – Purchased electricity	MWh	2,999.6	2,995.6
Total energy consumption	MWh	2,999.6	2,995.6

Environmental Targets

We have set various goals to reduce environmental impact and continue to take steps towards achieving them:

GHG Emissions. We aim to reduce our GHG emissions and support national "carbon peaking and carbon neutrality" goals. This may be achieved through the adoption of energy-efficient equipment where feasible.

Energy Consumption. We monitor our electricity consumption patterns. Looking ahead, we aim to further promote energy-saving practices in the workplace and increase the share of low-carbon energy usage in daily operations where suitable.

Hazardous Waste Management. For hazardous waste generated from operations, we engage certified third-party service providers to support compliant disposal. Looking ahead, we aim to continue reviewing and optimizing processes to avoid unnecessary hazardous waste generation where practicable.

Social Matters

Employment

We operate in compliance with the Labor Law of the PRC (《中華人民共和國勞動法》), the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), the Provisions on Prohibition of Using Child Labor (《禁止使用童工規定》) and other relevant laws and regulations. We have developed and implemented internal employment policies and procedures such as the Recruitment Management Policy (《招聘管理制度》), the Remuneration and Compensation Policy (《薪酬福利管理制度》) and the staff handbook. These documents set out our employment management framework, covering areas including recruitment and onboarding, employment administration, employee conduct and disciplinary measures, working hours, compensation and benefits, performance evaluation, leave entitlements, and resignation and termination processes. We strive to provide equal opportunities in recruitment, promotion, remuneration and career advancement. In addition, we provide training and development initiatives to support employee capability and operational needs.

Occupational Health and Safety

We have established and implemented occupational health and safety policies and procedures, including the Production Safety Operation Management Standards (《生產安全操作管理規程》), Laboratory safety management (《實驗室的安全管理》) and relevant emergency plans. Our occupational health and safety management arrangements are established in line with the applicable legal requirements. Where necessary, we provide appropriate safety equipment and conduct safety education, training and drills to support a safe working environment for employees.

Product Quality and Safety

Given the nature of our operations, product safety and quality are important to our business and compliance profile. We maintain quality management arrangements and procedures designed to identify and manage product quality-related risks across relevant activities. In this regard, we have obtained a GMP compliance audit certificate in respect of pharmaceutical products for clinical trials (trial), with the audit scope covering specified biological product(s).

Business Ethics

We operate with a commitment to integrity and compliance in business dealings. We have established confidentiality and information management arrangements and expects employees to comply with confidentiality obligations. Internal policies and measures regarding anti-corruption and anti-bribery have also been implemented to prevent corrupt practices and support our commitment to ethical conduct.

PERMITS, LICENSES AND APPROVALS

As of the Latest Practicable Date, as advised by our PRC Legal Advisor, we had obtained all material licenses and permits required for our business operations in the PRC, and such business licenses had remained in full effect. For more details regarding the laws and regulations to which we are subject, see "Regulatory Overview." We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. During the Track Record Period and up to the Latest Practicable Date, no material unexpected or adverse changes that could adversely affect the maintenance and renewal of our material licenses, permits, approvals and certificates had occurred since the dates of issue of the relevant regulatory approvals for our business operation.

Set forth below are the details of selected material licenses and permits held by us as of the Latest Practicable Date:

License/Permit	Holder	Issuing Authority	Date of Grant	Expiry Date
Customs Registration of Consignors and Consignees of Import and Export Goods	Zhiyi Biotech	Suidong Customs of the PRC	April 7, 2023	N/A[1]
Customs Registration of Consignors and Consignees of Import and Export Goods	Guangzhou Puwei Junjian	Suidong Customs of the PRC	December 30, 2024	N/A[1]

Note:

1. "N/A" means that the relevant license, permit or certification does not have an expiration date (i.e. valid indefinitely as long as business activities are continued).

As of the Latest Practicable Date, our Core Product SK08 and key product SK10 have received notice for approval of clinical trials (臨床試驗通知書) issued by the NMPA. The following table sets forth details of the clinical trial approvals obtained by us as of the Latest Practicable Date:

Approval Authority	Acceptance Number	Product Name	Licensed Content	Approval Date
NMPA	CXSL1800114	Live SK08 Powder	Approved to conduct Phase I, IIa, II and III clinical trials for IBS and UC	November 19, 2019
NMPA	CXSB2000056	Live SK08 Powder	Approved to conduct clinical trials using samples manufactured with the newly-established seed bank, production raw materials and manufacturing process	November 27, 2020
NMPA	CXSL2200001	Live SK08 Powder	Approved to conduct Phase Ib/II clinical trial in combination with immune checkpoint inhibitors for the treatment of advanced solid tumors	March 10, 2022
U.S. FDA	IND 028841	SK10 Powder	Approved to conduct clinical trials for CID	October 17, 2022
NMPA	CXSB2300085	Live SK08 Powder	Approved to conduct further clinical trials for Live SK08 Powder	October 31, 2023
NMPA	CXSL2400440	Live SK08 Powder	Approved to conduct Phase II clinical trial for pediatric rotavirus diarrhea	September 14, 2024
U.S. FDA	IND 031169	Live SK08 Powder	Approved to conduct clinical trials for UC	January 17, 2025

LEGAL PROCEEDINGS AND COMPLIANCE

Legal Proceedings

We may from time to time be involved in contractual disputes or legal proceedings arising out of the ordinary course of business or pursuant to governmental or regulatory enforcement actions. Litigation or any other legal or administrative proceeding, regardless of the outcome, is likely to result in substantial cost and diversion of our resources, including our management's time and attention. See "Risk Factors — Risks Relating to Our Business Operations — If we face litigations, government investigations, or administrative actions, our management's focus could be shifted, leading to significant costs and liabilities for us."

During the Track Record Period and up to the Latest Practicable Date, neither we nor any of our Directors were involved in or subject to any litigations, arbitrations, administrative proceedings, claims, damages or losses which would have a material adverse effect on our business, financial position or results of operations as a whole. As of the Latest Practicable Date, we were not aware of any pending or threatened material litigations, arbitrations or administrative proceedings against us or any of our Directors, which individually or as a whole would have a material adverse effect on our business, financial position or results of operations. We had complied, in all material respects, with the relevant PRC laws and regulations in the jurisdictions we operate in, and no material administrative penalties were imposed on us.

Compliance

During the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that have led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition and results of operations.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations and we recognize that risk management is critical to our success. For a discussion of various operational risks and uncertainties we face, see " Risk Factors — Risks Relating to Our Business Operations — Failure to maintain an effective internal control system could lead to inaccurate financial reporting, loss of investors' confidence, limited access to capital, and a decline in our stock price." We have adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up, mitigated and rectified by us.

The following key principles outline our approach to risk management:

- Our Audit Committee will oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Group.

- Our Board will be responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) reviewing and approving major risk management issues of our Group; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our Company; (v) reviewing the relevant departments' reporting on key risks and providing feedbacks; (vi) supervising the implementation of our risk management measures by the relevant departments; and (vii) ensuring that the appropriate structure, processes and competencies are in place across our Group.

- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could

potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group's internal control.

Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as confidentiality management, IT security and protection of intellectual property.

- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the [**REDACTED**].

- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Group.

- We plan to provide various and continuing trainings to update our Directors, senior management, and relevant employees on the latest laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.

- We have established a comprehensive Anti-Bribery and Anti-Corruption Policy that sets out clear guidelines prohibiting any form of bribery, corruption, extortion and improper advantage, which applies to all Directors, employees and third-party representatives acting on behalf of our Group. We provide regular trainings and awareness programs to our Directors, senior management and employees on anti-bribery and anti-corruption laws and regulations, as well as our internal policies. We have also implemented a whistleblowing policy that allows employees to report suspected misconduct or breaches of our anti-bribery policy in a confidential and anonymous manner, without fear of retaliation.

- Our Directors believe that compliance creates value for us and are dedicated to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behavior across the organization, we regularly conduct internal compliance checks and inspections, adopt strict internal accountability and conduct compliance trainings.

- We conduct periodic reviews and updates of our policies to ensure they remain aligned with the latest regulatory requirements and industry best practices.

During the Track Record Period, we had regularly reviewed and enhanced our risk management system and internal control system. We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with our risk management and internal control.