The information and statistics set out in this section and other sections of this Document were extracted from the Frost & Sullivan Report, and from various official government publications and other publicly available publications. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [**REDACTED**]. *The information from official government sources has not been independently verified by us, the Joint Sponsors,* [**REDACTED**]*, any of their respective directors and advisors, or any other persons or parties involved in the* [**REDACTED**]*, and no representation is given as to its accuracy. For more details of the risks relating to our industry, see "Risk Factors" in this Document.*

OVERVIEW OF THE LBP MARKET

Introduction to LBPs

Live biotherapeutic products ("**LBPs**") are typically live microbial preparations composed of living microorganisms. In the U.S., the FDA clearly defines LBPs as "biological products, excluding vaccines, that contain live organisms (such as bacteria) and are applicable to the prevention, treatment, or cure of a disease or condition of human beings." In China, under the regulatory framework set out in the Administrative Measures for the Registration Classification and Submission Requirements of Biological Products issued by the NMPA in 2020, LBPs, which are classified as microbial products, are generally regulated as therapeutic biological products containing microorganisms, and are subject to the development, registration, and approval pathways applicable to biological products. LBPs represent the cutting-edge segment of the biopharmaceutical landscape focused on microbiome therapy. As a significant innovative branch, they signify a shift from drugs based on clearly defined active entities, such as antibodies and proteins, toward systemic therapies based on the regulation of the microbiome.

Intergenerational Development in the LBPs

According to Frost & Sullivan, the development of LBPs can be divided into two generations: (i) first-generation, representing the early exploratory phase prior to 2010, during which LBPs had been widely used but a unified regulatory definition had not yet been established. Most products remained at the level of traditional microecological preparations and were primarily applied empirically based on bacterial strains or genera without clear indication-driven use or systematic clinical validation. Clinical evidence was mostly derived from non-randomized controlled studies, and the CMC system was relatively underdeveloped, resulting in limited product consistency and reproducibility. Representative first-generation LBPs in China include combined bifidobacterium, lactobacillus, enterococcus and bacillus cereus tablets, live; and (ii) second-generation, centered on modern drug development systems, following the FDA first proposing in 2010 to incorporate such products into the pharmaceutical regulatory framework, and formally issuing relevant guidance in 2012 that established LBPs as a distinct category — followed by further revisions and updates in 2016 — the industry has gradually entered a more standardized stage of development. From the perspective of industry evolution, second-generation LBPs are characterized by well-defined mechanisms of action ("**MoA**"), robust clinical evidence, and controllable product quality. In addition, in recent years, the LBP industry has gradually evolved beyond live microorganisms toward broader therapeutic modalities, including inactivated microbial products, which may further expand the technological boundaries and clinical potential of LBPs. Representative second-generation LBPs globally include BIOMICTRA and REBYOTA.

From a generational perspective within the industry, second-generation LBPs are clearly defined by their well-established MoA, robust evidence base, and controllable quality. They can be distinguished primarily based on the following characteristics: (i) at the level of regulatory, LBPs are required to follow the IND application process and the marketing approval pathway applicable to pharmaceuticals; (ii) at the level of development targets, the focus has shifted from early-stage applications centered on microbial species or genera to a more precise development approach driven by specific functional strains. Representative products, such as SK08, demonstrate a clearer functional and indication-specific positioning, with a stronger emphasis on strain-level specificity rather than species-level classification,

thereby rendering their development paradigm aligned with that of pharmaceutical products in terms of scientific rigor; (iii) at the clinical level, emphasis is placed on demonstrating safety and efficacy through well-designed clinical trials. Clinical efficacy can only be considered established when it is confirmed by independent trials of acceptable quality, including those that are sufficiently powered, randomized, blinded, and placebo-controlled; and (iv) at the CMC level, a systematic control framework centered on "Quality by Design" (QbD) should be established to ensure reproducible manufacturing and batch-to-batch consistency based on a clear understanding of the target patient population, route of administration, distribution and colonization, and toxicological characteristics of the product.

Based on the timeline and classification outlined above, LBPs approved for marketing in China are first-generation products at present, all of which were approved prior to 2010. Since then, no second-generation LBPs have been approved for commercialization in China, according to Frost & Sullivan. Since 2010, the industry has begun to gradually align with the mainstream international regulatory and development frameworks for LBPs. In 2019, SK08 became the first oral second-generation LBP in China to initiate clinical trials, and in 2025, it also obtained approval in the U.S. to commence Phase II clinical trials. Meanwhile, SK10 obtained IND approval from the FDA for CID indication in 2022, marking a key milestone for domestic companies in aligning with standardized international LBP development pathways.

Indication Coverage

LBPs are used across multiple major therapeutic areas, the most significant of these is the field of diseases influenced by the gut microbiota. The gut microbiota, a collection of bacteria, archaea and fungi that colonize the intestine, plays a vital role in multiple physiological processes throughout the host's life cycle. It is involved in metabolic regulation, immune modulation, and neural signaling, and contributes to essential functions such as digestion and host immunity. Published literature have shown that the gut microbiota is closely associated with the onset and progression of a wide range of diseases, including gastrointestinal disorders, metabolic diseases, immune system disorders, and cancer, thereby providing important scientific foundation and direction for the development of LBPs.

Specifically, the clinical applications of LBPs span a range of key therapeutic areas. In the field of digestive system diseases, these primarily include *clostridioides difficile* infection ("**CDI**"), functional gastrointestinal disorders ("**FGIDs**"), and inflammatory bowel disease ("**IBD**"). Additionally, LBPs show significant efficacy in managing infectious diarrhea, such as rotavirus infection, by strengthening the intestinal barrier and modulating antiviral immune responses. In the area of metabolic diseases, the focus is on obesity and its associated metabolic disorders, providing long-term management strategies for chronic conditions. Regarding immune system diseases, LBPs demonstrate therapeutic potential for various immune-related disorders through the dynamic modulation of host immune functions and microbiota-host interactions. In oncology, LBPs not only improve the tumor microenvironment to enhance the efficacy of immunotherapies, such as PD-1/L1 inhibitors, but also play a critical role in supportive care. For complications like chemotherapy-induced diarrhea ("**CID**"), where traditional treatments often focus on symptomatic relief, LBPs provide a disease-modifying approach by repairing the intestinal mucosa, restoring microbial homeostasis, and regulating local immune activity.

Mechanism Advantages and Clinical Potential

LBPs participate in the construction of the microbiota-host interaction network by regulating the structure and function of the gut microbiota. They reshape host immune responses, metabolic pathways, and microecological balance, while the host's immune status and internal environment, in turn, influence the composition and function of the microbiota. Furthermore, through engineering approaches, targeted delivery and functional enhancement can be achieved, thereby systematically intervening in the onset and progression of diseases and establishing a novel therapeutic paradigm distinct from traditional drugs.

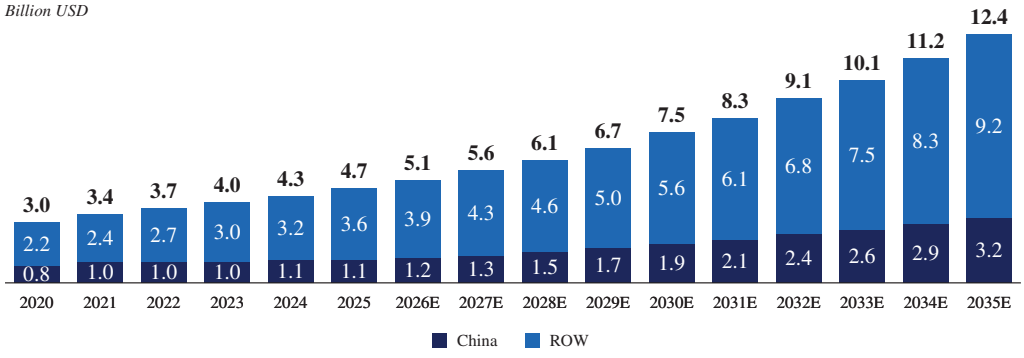
Based on strain composition and origin, LBPs can be classified into single-strain drugs, multi-strain drugs, fecal microbiota transplant ("**FMT**") products, and engineered microbial drugs. Different types of LBPs exhibit certain differences in their MoA, among these, the regulation of FMT in China has certain unique characteristics. According to the "Technical Specifications for National Medical Service Projects (2023 Edition)" issued in 2023 by the National Health Commission, the National Administration of Traditional Chinese Medicine, and the National Center for Disease Control and Prevention, FMT falls under the scope of medical technology management rather than being approved through the drug approval process. Products in this category primarily restore the homeostasis of the intestinal microbiome through comprehensive microbiota reconstitution. In the United States, FMT is still regulated as a biological product. However, FMT faces practical constraints in standardized manufacturing and large-scale production due to its donor-derived and highly heterogeneous nature. In contrast, single-strain drugs are more amenable to controlled, scalable manufacturing and therefore are not subject to the same production-related limitations. Single-strain drugs focus more on regulating the host's immune system, metabolic networks, or signaling pathways through specific bacterial components or metabolites. In comparison, single-strain drugs offer certain advantages in terms of the clarity of their MoA and the controllability of their functions, which helps enhance the predictability and consistency of their clinical outcomes and constitutes a core competitive advantage for the Company's products.

Global LBPs Market Size and Forecast, 2020-2035E

The global LBPs market increased from USD3.0 billion in 2020 to USD4.7 billion in 2025, representing a CAGR of 9.4% during the period. The market is expected to further grow to USD7.5 billion by 2030, at a CAGR of 9.8% from 2025 to 2030.

Global LBPs Market Size and Forecast, 2020-2035E

CAGR	Global	China	ROW
2020-2025	9.4%	5.8%	10.6%
2025-2030E	9.8%	11.6%	9.2%
2030E-2035E	10.7%	11.2%	10.5%



Notes:

1. *Measured at ex-manufacturer price level.*
2. *Due to differences in regulatory classification and audit coverage across jurisdictions, the market includes strictly approved LBPs and low-risk listed/complementary medicines.*

Source: Frost & Sullivan Analysis

Competitive Landscape of the Global and China Second-generation LBPs Markets

As of the Latest Practicable Date, there are only four approved second-generation LBPs globally, all of which are FMT-based therapies and no second-generation LBPs have yet been approved in China. There are nine products under late-stage development globally. Among these, SK08 is the only second-generation LBP for the treatment of IBS. The following tables provide an overview of the competitive landscape of second-generation LBPs, encompassing both marketed products and major late-stage clinical

candidates: (i) the marketed second-generation LBPs globally; (ii) the global late-stage (phase III and beyond) second-generation LBPs pipelines (primarily under the regulatory authority of the FDA and NMPA, as of the Latest Practicable Date) and (iii) the second-generation LBP pipelines in clinical stages in China:

Marketed Second-generation LBPs Globally

Drug	Company	Type of LBP	Administration route	Approval Time	Indication	Approving Regulatory Authority
BIOMICTRA	BiomeBank	FMT	Rectal	2022/09/22	recurrent CDI	TGA*
REBYOTA	Ferring Pharmaceuticals	FMT	Rectal	2022/11/30	recurrent CDI	FDA
				2025/03/06	recurrent CDI	Health Canada
VOWST	Seres Therapeutics & Nestlé Health Science	FMT	Oral	2023/04/26	recurrent CDI	FDA
EUTEGRA	Mikrobiomik	FMT	Oral	2026/02/17	CDI	ONT; CEi-SoHO*

Note: This table was last updated on June 13, 2026

**TGA refers to Therapeutic Goods Administration which is the medicine and therapeutic regulatory agency of the Australian Government; ONT refers to National Transplant Organization which is a national technical body, under Spain's Ministry of Health; CEi-SoHO refers to Innovation Evaluation Committee for Substances of Human Origin which was established by the Transplant Commission of the Interterritorial Council of the National Health System and coordinated by the ONT.*

Source: FDA, TGA, Health Canada, ONT, Frost & Sullivan Analysis

Global Late-stage (Phase III and Beyond) Second-generation LBP Pipelines

Drug Code	Company	Type of LBP	Administration Route	Highest Phase of Trial	Indications	First Posted Date	Regulatory Authority
Live double combined lactobacillus	Guangdong Longchuangji Pharmaceutical	Multi-strain	Intravaginal	NDA	Bacterial vaginitis	2025/12/10	NMPA
Live lactobacillus for vagina-Lc262-1	Suzhou OSAI Biopharma	Single-strain	Intravaginal	NDA	Bacterial vaginitis	2025/11/01	NMPA
MaaT013	MaaT Pharma	FMT	Rectal	NDA	Acute Graft-versus-Host Disease	2025/06/02	EMA*
SK08	Guangzhou Zhiyi Biotechnology Co., Ltd.	Single-strain	Oral	Phase III	IBS	2023/11/24	NMPA
IBP-9414	Infant Bacterial Therapeutics	Single-strain	Oral	Phase III	Necrotizing Enterocolitis	2019/03/21	FDA
VE303	Vedanta Biosciences	Multi-strain	Oral	Phase III	CDI	2024/02/01	FDA
XLF-055	Zhejiang Xinlifei Biotech; Hangzhou H-power Xinjian	Multi-strain	Intravaginal	Phase III	Recurrence of bacterial vaginosis	2021/11/1	NMPA
KAL-001	Sichuan Anaerobic Biotech; Inner Mongolia Shuangqi Pharmaceutical	Multi-strain	Intravaginal	Phase III	Bacterial vaginitis	2026/03/01	NMPA
TARA-002	Protara Therapeutics	Single-strain	Intravesical	Phase III	Non-muscle Invasive Bladder Cancer	2026/03/18	Not Disclosed

Note: This table was last updated on June 13, 2026

** EMA refers to European Medicines Agency*

Source: Clinical Trials, Frost & Sullivan Analysis

Second-generation LBP Pipelines in Clinical Stages in China

Drug Code	Company	Type of LBP	Administration Route	Highest Phase of Trial	Indications	First Posted Date
Live double combined lactobacillus	Guangdong Longchuangji Pharmaceutical	Multi-strain	Intravaginal	NDA	Bacterial vaginitis	2025/12/10
Live lactobacillus for vagina-Lc262-1	Suzhou OSAI Biopharma	Single-strain	Intravaginal	NDA	Bacterial vaginitis	2025/11/01
SK08	Guangzhou Zhiyi Biotechnology Co., Ltd.	Single-strain	Oral	Phase III	IBS	2023/11/24
XLF-055	Zhejiang Xinlifei Biotech; Hangzhou H-power Xinjian	Multi-strain	Intravaginal	Phase III	Recurrence of bacterial vaginosis	2021/11/1
KAL-001	Sichuan Anaerobic Biotech; Inner Mongolia Shuangqi Pharmaceutical	Multi-strain	Intravaginal	Phase III	Bacterial vaginitis	2026/03/01
BPR-101	Chengdu Beite & Chengdu Xinke	–	Intravaginal	Phase II	Bacterial vaginosis	2024-09-20
WST01	Shanghai Pharmaceuticals & SPH Sine	Single-strain	Oral	Phase II	Obesity & Type 2 Diabetes	2021-03-15
KAL-002	Sichuan Anaerobic Biotech	Multi-strain	Oral	Phase I	Radiation enteritis & Diarrhea caused by chemotherapy	2025-08-18
MNC-168	Moon Biotech	Single-strain	Oral	Phase I	Colorectal cancer & Solid tumor	2022-05-20
WST03	SPH Sine	–	Oral	Phase I	Bacterial vaginosis	2025-01-22
WST04	SPH Sine	–	Oral	Phase I	Solid tumor	2024-11-11
LBP-ShC4	Fosun Pharmaceutical	Single-strain	Topical	IND	Androgenetic alopecia	2026-03-13
IBNI617	Ibiome Biology	Single-strain	Oral	IND	Depression	2025-12-19
GK-01	Zhejiang Mayata Bacterial Testing Intelligent Technology	–	Oral	IND	Allergic rhinitis	2026-03-04
MNO-863	Moon Biotech	Single-strain	Oral	IND	Obesity	2025-03-19
AUP-16	Aurealis Therapeutics; Shenzhen Xbiome	Engineered LBP	Topical	IND	Diabetic foot ulcer	2023-11-13

Note: This table was last updated on June 13, 2026

Source: NMPA, Frost & Sullivan Analysis

As of the Latest Practicable Date, a total of 16 second-generation LBP pipelines are in clinical development in China. Among them, SK08 is the most advanced orally administered candidate and is currently undergoing Phase III clinical trials for the treatment of irritable bowel syndrome ("**IBS**").

Industry Barriers, Growth Drivers and Future Trends of the LBP Market

Industry Barriers

R&D Barrier. The development of LBPs encompasses stages such as strain screening, mechanism-of-action research, and preclinical evaluation, placing high demands on strain safety, functional characterization, efficacy validation, and development capabilities. The screening of natural strains is highly exploratory, and it is challenging to identify candidate strains with well-defined functions and stable activity. Once the development phase begins, it is necessary to comprehensively assess the impact of production processes, formulation matrices, and storage conditions on strain activity and stability to ensure the product's consistent efficacy. Therefore, safety evaluation, selection of non-clinical models, biodistribution studies, and CMC research also present significant technical challenges. Overall, since LBPs remain an emerging field with a relatively limited number of products, and development varies significantly across different bacterial species, the relevant evaluation systems are still undergoing continuous refinement.

Barriers to Industrialization and Commercialization. The industrialization of LBPs requires the completion of process development, large-scale fermentation, formulation stability control, and quality system establishment. Given the lengthy technological chain and the high demands on companies' R&D translation and industrialization capabilities, the barriers to entry in this industry are relatively high. At the same time, their clinical application and commercialization also face certain challenges, including stringent storage and transportation requirements for certain live-organism formulations, which rely on cold-chain logistics, as well as the need for ongoing efforts to enhance physician awareness and medical education, given that LBPs remain an emerging therapeutic modality.

Clinical and Regulatory Pathway Barriers. Compared to traditional chemical drugs and biological products, LBPs, as an emerging form of therapy, are still in the process of refining their clinical evaluation systems and regulatory pathways. Their MoAs involve the gut microbiome and immune modulation, and their efficacy is easily influenced by individual microbiota, diet, and lifestyle, which increases the complexity of clinical trial design and efficacy evaluation. During the registration process, LBP must focus on CMC requirements specific to live microorganisms within the framework of biological products, such as control of microbial parameters, genetic stability, and control of exogenous factors, which impose higher standards on production and GMP systems. At the same time, as global regulatory frameworks are still being established, companies must comprehensively meet requirements across multiple areas, including strain safety, stability, biodistribution, and quality control.

Growth Drivers

Clinical Demand. Chronic diseases, represented by IBS, still lack effective curative therapies. Conventional treatments primarily focus on symptom management, such as antispasmodics can relax the smooth muscles of the gastrointestinal tract and reduce the colon's response to food intake and stress, they are used to relieve abdominal pain. However, the persistent and unpredictable nature of these symptoms often imposes a heavy psychological and social burden, significantly compromising patients' daily functioning and overall quality of life. These conventional therapies have limitations in terms of long-term management and addressing the underlying causes. LBP, as represented by SK08, can intervene in the disease process at the mechanistic level by regulating intestinal immune homeostasis. Ulcerative colitis ("**UC**") is characterized by its chronic, relapsing nature, often requiring patients to undergo repeated induction and long-term maintenance therapies. Currently, a subset of patients continues to face challenges such as inadequate response, waning efficacy, or long-term safety concerns. LBPs mitigate inflammatory responses and promote the repair of the intestinal barrier, offering a promising new intervention pathway for patients with suboptimal responses or refractory conditions. In the management of CID, where conventional treatments focus on symptom control, LBPs are expected to function by repairing the intestinal barrier and modulating immune responses. For infectious diseases such as rotavirus infection, LBPs can also reduce viral load and alleviate diarrheal symptoms by strengthening the intestinal barrier

and regulating antiviral immune responses. In the field of oncology, the overall response rate ("**ORR**") of immune checkpoint inhibitors ("**ICIs**") remains limited, particularly in "cold tumors." Recent studies have demonstrated that LBPs show significant synergistic potential with immunotherapy in the preclinical stage.

Increased Acceptance among Doctors and Patients. In recent years, as LBPs have progressively undergone systematic R&D following the regulatory pathways for biological products, the industry has increasingly aligned with international standards in terms of clinical trial design, endpoint selection, and efficacy validation. The continuous accumulation of evidence-based medical data is driving the industry's transition toward a standardized, evidence-driven phase of development. These advancements are instrumental in enhancing clinicians' understanding of LBP mechanisms and therapeutic effects, thereby increasing their willingness to incorporate these products into clinical practice. Furthermore, standardized product modalities (such as single-strain preparations) and precise indications help strengthen patient awareness and alleviate concerns regarding their use. This clarity is expected to drive improvements in patient compliance and facilitate broader market acceptance of LBPs.

Driven by Technological Maturity. As the bidirectional regulatory mechanisms between gut microbiota and host immunity, metabolism, and systemic health are increasingly elucidated, the academic understanding of the "microbiota-host-disease" axis has continued to deepen. This progress has established a robust scientific foundation for the development of LBPs. In contrast to the human genome, the microbiome exhibits significantly greater plasticity, rendering it an ideal target for therapeutic intervention. Consequently, LBPs interact with host biological systems through multifaceted MoA, offering a systemic and precisely tunable therapeutic paradigm that is fundamentally distinct from conventional pharmaceuticals.

Regulatory and Policy Drivers. In recent years, several LBPs have successfully secured regulatory approvals globally. The regulatory framework governing LBPs continues to mature, with technical standards, quality control requirements, and clinical evaluation pathways becoming increasingly well-defined. This evolution is propelling the industry's transition from an exploratory phase toward a stage of standardized development. The clarification of the regulatory landscape not only mitigates R&D uncertainties but also establishes a predictable trajectory for clinical development and commercialization. Consequently, these developments are expected to accelerate the clinical translation of LBPs and catalyze the overall growth of the industry.

Future Trends

Indications and Applications Continue to Expand. Currently, while approved LBPs focus on gastrointestinal diseases (CDI), deeper insights into the microbiome-host axis (immunity, metabolism, CNS) are transforming the microbiome into a systemic target, expanding pipelines into oncology, metabolic, and neurological disorders. For example, LBPs have already entered clinical evaluation in pancreatic cancer and demonstrated encouraging clinical outcomes. Simultaneously, enhanced safety and stability are driving next-generation LBPs beyond clinical prescriptions into the out-of-hospital management market, boosting overall penetration.

Evolution Toward Precision and Platform-based Approaches. Shifting from empirical FMT to precise interventions, the industry now leverages multi-omics and bioinformatics to deploy single-strain or defined multi-strain consortia for targeted mechanisms, improving reproducibility. Consequently, the competitive landscape has shifted from individual product R&D to integrated platform capabilities (screening, functional regulation, and delivery systems).

Improvements to Regulatory and Manufacturing Systems. In recent years, the establishment of standardized production systems, the continuous refinement of GMP standards, and the ongoing upgrades in cold-chain logistics and formulation technologies have significantly bolstered industrialization capabilities. These advancements have, in turn, fueled a rapid increase in the demand for specialized Contract Development and Manufacturing Organizations (CDMOs). Concurrently, regulatory agencies worldwide have progressively clarified the regulatory classification of LBPs as biological products, while

continuously refining requirements for clinical development and CMC. Driven by the synergy between a maturing regulatory framework and an evolving industrial value chain, LBPs are accelerating their transition from the R&D phase toward full-scale commercialization.

IRRITABLE BOWEL SYNDROME DRUG MARKET

Overview of IBS

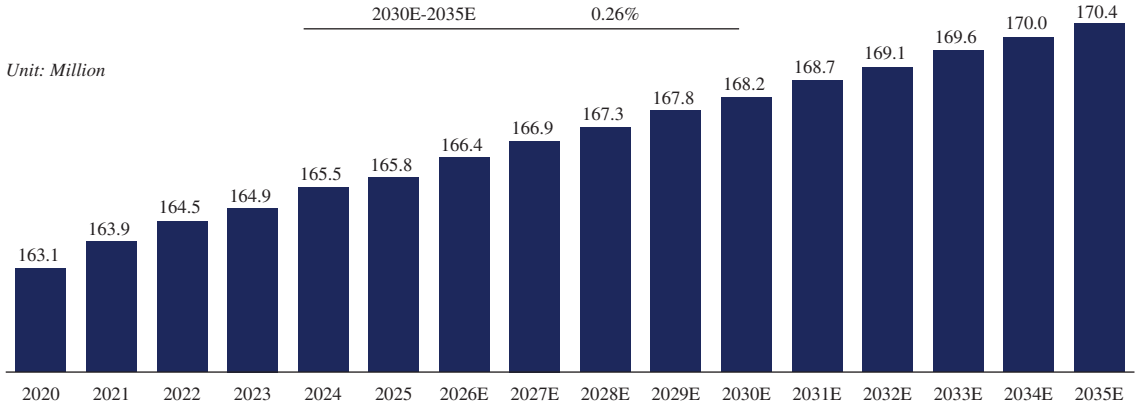
IBS is a chronic, relapsing FGID characterized by core symptoms including abdominal pain and bloating accompanied by changes in bowel habits. It is one of the most prevalent gastrointestinal diseases both globally and in China. Unlike organic GI diseases, IBS is primarily a symptom-based diagnosis guided by Rome IV criteria, and in line with current expert consensus, its diagnosis relies predominantly on clinical assessment of patient-reported symptoms. IBS is classified into four primary subtypes based on stool consistency: diarrhea-predominant ("**IBS-D**"), constipation-predominant ("**IBS-C**"), mixed-type ("**IBS-M**"), and unsubtyped ("**IBS-U**"). Among them, IBS-D accounts for approximately 70.0% of the patient population in China. Pathophysiologically, IBS is considered a "biopsychosocial" disorder where various factors, including visceral hypersensitivity, intestinal dysbiosis, altered gut permeability, and low-grade mucosal inflammation, interacting to trigger the gut-brain axis. Dietary habits, cultural customs, geographic distribution, and demographic characteristics are all important factors influencing the prevalence of this disease, resulting in regional variations in global prevalence.

Prevalence of IBS in China, 2020-2035E

According to Frost & Sullivan analysis, the prevalence rate of IBS in China was 11.8% in 2025, corresponding to approximately 165.8 million patients, with a diagnosis rate of around 25.0%. Driven by factors such as accelerating urbanization, the westernization of dietary patterns, a faster pace of life, and increasing psychological stress, the prevalence of IBS in China is expected to continue to rise moderately over the next decade. The number of IBS patients in China is projected to reach approximately 168.2 million by 2030 and further increase to 170.4 million by 2035. According to expert consensus, IBS-D is recognized as one of the predominant IBS subtypes in China, accounting for approximately 70.0% of the overall IBS patient population.

Prevalence of IBS in China, 2020–2035E

Period	CAGR
2020-2025	0.33%
2025-2030E	0.30%
2030E-2035E	0.26%



Source: Frost & Sullivan Analysis

Current Treatment

As of the Latest Practicable Date, the diagnosis and treatment of IBS in China primarily follow the Chinese Expert Consensus on IBS and relevant clinical guidelines. The clinical pathway typically adopts a stepped treatment approach. Initial management focuses on lifestyle modifications and dietary interventions such as a low FODMAP diet. Regarding pharmacological treatment, current guideline-recommended treatment strategies are primarily aimed at symptomatic relief. For example, antispasmodics, such as pinaverium bromide, acting on specific ion channels in intestinal smooth muscle to alleviate spasms; antidiarrheal agents, such as loperamide and diosmectite (smectite), can effectively improve diarrhea symptoms in IBS-D patients; non-absorbable antibiotics, such as rifaximin, can improve overall symptoms in non-IBS-C patients, as well as alleviate bloating and diarrhea; and osmotic laxatives, such as polyethylene glycol, can increase bowel movement frequency and improve stool consistency in IBS-C patients. Furthermore, neuromodulators are recommended for use with caution only in patients with IBS who present with psychological or psychiatric symptoms (including depression, anxiety, and somatization), as well as in patients with refractory IBS who have not responded well to standard gastroenterological treatment. However, most existing medications primarily focus on alleviating end-point symptoms and have significant limitations regarding long-term safety (e.g., risk of antibiotic resistance) and sustained efficacy (e.g., high relapse rates after discontinuation). Clinical evidence suggests that approximately 40.0%-50.0% of patients experience symptom recurrence after stopping treatment. Clinicians are increasingly seeking innovative approaches that balance long-term safety with pathophysiological intervention.

In current clinical practice in China, combination therapy strategies are also commonly considered for patients with IBS-D. Such regimens may include either intestinal antibiotics or probiotics, in combination with antispasmodic agents for alleviating intestinal hypersensitivity (such as trimebutine or pinaverium bromide), anti-anxiety or neuromodulatory therapies (such as sulpiride, fluoxetine, or sertraline), as well as traditional Chinese medicines, depending on individual patient conditions and symptom profiles. The following table shows safety and efficacy analysis of IBS treatment.

Safety and Efficacy Analysis of IBS Treatment

Treatment	Mechanism	Efficacy	Safety
Antispasmodics	• target gut muscle contractions to relieve abdominal pain and spasms	• Mebeverine, otilonium bromide, alverine citrate/simethicone, pinaverium bromide, phloroglucinol, drotaverine hydrochloride, and peppermint oil, have shown effectiveness in relieving IBS symptom • For example, in the Zheng et al. double -blind, placebo-controlled study: Symptom score analysis of Pinaverium vs Placebo/Control: 60% vs 34% (P < 0.001)	• Nausea and dizziness were the main adverse events. • For example, in the study by Zheng et al., commonly reported side effects included mild occurrences of nausea (3.7%), dizziness (3.2%), and elevated blood pressure (2.3%).
Antidiarrheals (For IBS-D)	• Loperamide/Eluxadoline reduces the release of acetylcholine, promotes the intestinal absorption of water and electrolytes, and alleviates fecal incontinence.	• In pooled randomized, double-blind, placebo-controlled studies (12 weeks): Composite response (abdominal pain and stool consistency) of Eluxadoline 75 mg / 100 mg vs Placebo: 26.2% / 27.0% vs 16.7% (p < 0.001 for both vs placebo)	• Most common adverse events with eluxadoline : constipation (8.0%), nausea (7.7%), and abdominal pain (6.5%) • Common side effects of Loperamide include constipation, abdominal cramping and nausea.
Osmotic Laxatives (For IBS-C)	• By creating a hyperosmotic environment in the intestinal lumen, it promotes intestinal secretion, thereby softening stools and accelerating intestinal transit.	• In a randomized clinical trial (week 4): PEG 3350+E vs Placebo—mean weekly number of SBMs (± s.d.): 4.40 ± 2.58 vs 3.11 ± 1.94 (95% CI: 1.17–1.95; P < 0.0001); additional endpoints (SCBMs, responder rates, stool consistency, and straining severity) also showed superior improvement with PEG 3350+E.	• Most common treatment-emergent adverse events with PEG 3350+E: abdominal pain (4.5%) and diarrhoea (4.5%).
Secretagogues (For IBS-C)	• By activating ion channels in intestinal epithelial cells, it enhances epithelial secretion, thereby softening stools and alleviating constipation symptoms.	• A meta-analysis including 8,462 patients with IBS-C treated with secretagogues (including guanylate cyclase-C agonists and selective chloride channel activators) demonstrated that these agents were significantly more effective than placebo in improving constipation symptoms. • Guanylate cyclase-C agonists (e.g., linaclotide) may also modulate visceral sensation in patients with IBS-C.	• In the registration trial by Johanson et al.,. Reported adverse events such as nausea, vomiting, and diarrhea were common (incidence rate, 2-75%)
Non-absorbable antibiotics (For non IBS-C)	• Improve intestinal dysbiosis, modulate intestinal inflammation, and enhance intestinal mucosal barrier function.	• Multiple large-scale randomized controlled trials have demonstrated that short-term use of rifaximin can improve bloating and overall symptoms in non-IBS-C patients, and some studies have also shown that rifaximin is effective in alleviating abdominal pain and diarrhea.	• A 2016 study reported one case of *clostridioides difficile* infection in a patient undergoing repeated rifaximin treatment, which warrants attention.

Source: Literature Review, Frost & Sullivan Analysis

Clinical Needs

Although IBS is not life-threatening, it imposes a substantial multi-dimensional disease burden that remains inadequately addressed by existing treatment options, particularly among patients with severe or treatment-refractory disease. IBS patients may experience significantly impaired health-related quality of life, with impairment comparable to chronic conditions such as diabetes or end-stage renal disease, and severe treatment-refractory IBS patients reported an average of approximately 145.0 days of activity restriction per year and pain throughout most of each month. IBS is also associated with psychological comorbidities and meaningful disruption to daily life, social activities and work productivity, with approximately 76.0% of patients reporting interference with daily life, 87.0% reporting reduced productivity, nearly 14.0 hours of productivity loss per week and an approximately 21.0% reduction in effective work output. In addition, IBS results in meaningful economic burden, 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 25.0% of total costs, highlighting continuing clinical needs in the management of IBS.

Furthermore, clinical need is also evident in diagnostic precision and the management of underlying pathophysiology. Current medications lack sufficient efficacy in addressing visceral hypersensitivity and repairing the physical intestinal barrier, leaving a large number of patients in a state of "living with disease" while experiencing diminishing therapeutic benefits. 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. Although IBS is not highly fatal, it imposes a significant overall disease burden. Published literature further indicates that the impact of IBS on patients extends beyond a decline in quality of life to include increased psychological distress and ongoing losses in social productivity associated with disease management. Consequently, there is a real and clear market need for more effective treatment options. Given the high heterogeneity of IBS, there is a clear market demand for a transition toward mechanism-driven and precision-based therapies. As a novel therapeutic modality, LBPs offer the potential to address the disease's root causes by restoring microbiota homeostasis, modulating host immune responses, and promoting intestinal barrier repair. By moving away from a "one-size-fits-all" paradigm, LBPs enable a more targeted approach tailored to an individual's specific dysbiosis profile. This innovative pathway provides a promising alternative for patients with suboptimal responses to conventional therapies, demonstrating its potential for market penetration.

Competitive Landscape of IBS Drugs Globally and in China

As of the Latest Practicable Date, a total of three approved products for IBS indications had been approved in China. Among them, *Saccharomyces boulardii* is categorized as a first-generation LBP, was approved by the NMPA in July 2004 for the treatment of IBS. As of the Latest Practicable Date, no drugs have been approved in China specifically for the treatment of IBS-D. The following table provides an overview of the approved products for IBS in China:

Approved Products for IBS in China

Drug	Company	Type	Route of Administration	IBS Subtype	Approved Time
Linaclotide	AstraZeneca	Peptide Drugs	Oral	IBS-C	2019/01/15
Saccharomyces boulardii	Laboratoires Biocodex	First-generation LBP	Oral	IBS	2004/07/27
Tegaserod*	Novartis	Chemical Drug	Oral	IBS-C	2003/04/01

Note: This table was last updated on June 13, 2026

**Tegaserod was historically approved in China for the treatment of IBS-C. However, in June 2007, the NMPA ordered the suspension of its production, sale and clinical use in the Chinese market.*

Source: NMPA, Frost & Sullivan analysis

As of the Latest Practicable Date, there are seven active clinical-stage pipelines for IBS in China, of which two have advanced to Phase III clinical trials. SK08 is one of the two Phase III candidates and the only biologic therapy that has reached this stage. The following table provides an overview of the competitive landscape of clinical-stage IBS pipelines in China:

Clinical-Stage IBS Pipelines in China

Drug Code	Company	Type of Drug	Route of Administration	Highest Phase of Trial	IBS Subtype	First Posted Date
SK08	Guangzhou Zhiyi Biotechnology Co., Ltd.	LBP	Oral	Phase III	IBS-D	2023/11/24
Changkang	Tasly Pharmaceutical	TCM	Oral	Phase III	IBS-D	2024/11/27
Brenipatide	Eli Lilly	Peptide	Subcutaneous	Phase II	IBS-D	2026/04/22
Rifaquizinone capsules	TenNor Therapeutics	Chemical drug	Oral	Phase I	IBS-D	2025/09/13
SMP-100	Chengdu Xilingyuan Pharmaceutical	Chemical drug	Oral	Phase I	IBS	2022/05/23
Tenapanor	Fosun Pharmaceutical	Chemical drug	Oral	Phase I	IBS-C	2020/09/09
AP-2202	Hangzhou Anprime Biopharma	Chemical drug	Oral	IND	IBS-D	2026/01/19

Note: This table was last updated on June 13, 2026

Source: NMPA, Frost & Sullivan Analysis

As of the Latest Practicable Date, there were 18 clinical-stage pipelines globally for the treatment of IBS-D, among which two investigational drug candidates had advanced to Phase III clinical development or later stages. SK08 is one of these two Phase III clinical-stage candidates and is also the only biologic therapy to have advanced to this stage globally. The following table shows the overview of global late-stage (phase III and beyond) IBS-D pipelines:

Global Late-Stage (Phase III and Beyond) IBS-D Pipelines

Drug Code	Company	Type of Drug	Route of Administration	Highest Phase of Trial	First Posted Date	Regulatory Authority
SK08	Guangzhou Zhiyi Biotechnology Co., Ltd.	LBP	Oral	Phase III	2023/11/24	NMPA
Changkang	Tasly Pharmaceutical	TCM	Oral	Phase III	2024/11/27	NMPA

Note: This table was last updated on June 13, 2026

Source: NMPA, Frost & Sullivan Analysis

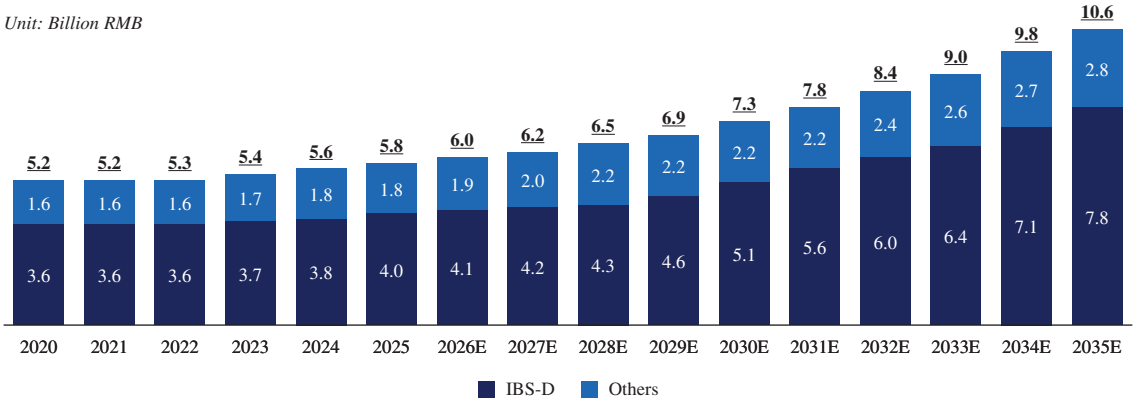
Market Size of IBS Drugs in China, 2020-2035E

The China IBS drug market increased from RMB5.2 billion in 2020 to RMB5.8 billion in 2025, representing a CAGR of 2.2% from 2020 to 2025. Driven by the emergence and increasing availability of innovative therapeutic approaches, rising disease awareness among IBS patients in China, and growing demand for symptom management and long-term disease control, the market is expected to further expand to RMB10.6 billion by 2035, representing a CAGR of 7.8% from 2030 to 2035.

The China IBS-D drug market increased from RMB3.6 billion in 2020 to RMB4.0 billion in 2025, representing a CAGR of 2.3% from 2020 to 2025, and is expected to reach RMB5.1 billion by 2030. Given the large patient population, the introduction of novel precision therapies may support further market development. The limited number of advanced-stage pipeline candidates addressing IBS-D also suggests that there remains room for new treatment options. From 2030 to 2035, the market is expected to further expand to RMB7.8 billion, representing a CAGR of 8.9%, as a subtype of IBS, its CAGR is higher than IBS. This is primarily driven by innovative therapy adoption, improved diagnosis, rising long-term management needs, and greater physician recognition of IBS-D.

China IBS Drug Market Size, 2020-2035E

	Total	IBS-D	Others
2020-2025	2.2%	2.3%	2.0%
2025-2030E	4.8%	5.0%	4.3%
2030E-2035E	7.8%	8.9%	4.9%



Note: China IBS-D drug market includes both prescription and over-the-counter (OTC) drugs.

Source: Frost & Sullivan analysis

PEDIATRIC ROTAVIRUS DIARRHEA DRUG MARKET

Overview of Pediatric Rotavirus Diarrhea

Pediatric rotavirus diarrhea is a global public health challenge that seriously threatens the health of children under the age of five. Pediatric rotavirus diarrhea typically presents with an acute onset of nausea, vomiting, and diarrhea, often accompanied by fever. Severe cases can lead to dehydration, electrolyte disturbances, acid-base imbalances, multi-system complications, and even death. The primary triggers of pediatric rotavirus diarrhea include the ingestion of rotavirus particles via the fecal-oral route, often through contaminated hands, toys, or water. Its rapid spread is further driven by the virus's high environmental stability and the extremely low infectious dose required to cause severe illness in children. In particular, infants and young children have immature immune systems and limited capacity for fluid regulation, as a result, they are more prone to complications such as dehydration and electrolyte imbalance following infection, leading to a relatively high disease burden. Rotavirus is a major cause of hospitalization and severe cases of acute gastroenteritis in children under 5, and it is a major cause of death from diarrhea in infants and young children.

Incidence of Pediatric Rotavirus Diarrhea in China, 2020-2035E

According to Frost & Sullivan, the incidence of pediatric rotavirus diarrhea in China declined gradually from 20.3 million cases in 2020 to 19.0 million cases in 2025, and is projected to increase further to 21.2 million cases by 2035. Following the gradual implementation of the universal two-child policy

since 2016 and subsequent fertility support measures, China's birth population structure is expected to improve to some extent. Against the backdrop of supportive demographic policies and population structure adjustments, the population of children aged 0–5 years is expected to remain relatively stable and gradually increase over the forecast period. In addition, continued improvements in pediatric healthcare capacity at primary healthcare institutions, the broader adoption of molecular diagnostic technologies, increased coverage of etiological testing for viral diarrhea, and enhanced healthcare-seeking awareness among parents are expected to facilitate the identification and diagnosis of pediatric rotavirus diarrhea cases.

According to Frost & Sullivan, pediatric rotavirus diarrhea accounts for approximately 30.0% of diarrhea cases among children under five years of age in China, indicating a disease burden in this population. The healthcare-seeking rate for pediatric rotavirus diarrhea was 61.8% in 2025 and is projected to increase to approximately 75.0% by 2035. This growth is expected to be driven by rising public awareness of pediatric infectious diseases, improving access to healthcare services, and continued enhancements in diagnostic and disease surveillance capabilities, resulting in a greater proportion of patients being identified and treated.

Current Treatment

According to the Expert Consensus on Immunoprophylaxis of Childhood Rotavirus Gastroenteritis (2024), pediatric rotavirus diarrhea in China remains a major threat to children's health. Clinical diagnosis relies on characteristic watery or "scrambled-egg-like" stools, confirmed by stool antigen or nucleic acid tests. In terms of treatment, the core strategy focuses on rehydration therapy and symptomatic supportive care to prevent and correct dehydration. Among these, oral rehydration therapy (ORS III) for mild-to-moderate dehydration, and intravenous fluids for severe cases. To further shorten the duration of illness and alleviate symptoms, the clinical pathway also incorporates various adjunctive therapies including smectite powder, zinc, and probiotics. Combined with dietary management and vaccination, these form a comprehensive prevention and care system.

However, despite clear clinical pathways, the treatment of pediatric rotavirus diarrhea still faces significant challenges. Currently, no specific antiviral drugs targeting rotavirus have been approved, and virus clearance remains largely dependent on the patient's own immune system. The only approved pharmacological interventions remain preventive vaccines rather than therapeutic agents. Although rotavirus vaccines have demonstrated favorable safety profiles in pediatric populations, certain adverse events may occur following vaccination. Common adverse reactions include irritability, diarrhea, and vomiting. In addition, an increased risk of intussusception has been reported, primarily within the first week after administration of the first or second vaccine dose. The development of pediatric antiviral drugs faces extremely high barriers to entry, requiring not only excellent medication adherence but also passing extremely rigorous safety evaluations and ethical reviews. Constrained by difficulties in recruiting pediatric patients and lengthy follow-up periods, the field of pediatric antiviral drugs has long been characterized by extended development cycles and a scarcity of effective treatments. Clinically, there is an urgent need for innovative drugs that balance safety with targeted, etiology-based interventions.

Clinical Needs

Prevention Gap. While rotavirus is a major cause of under-five pediatric diarrhea in China, the coverage of rotavirus vaccine remains low. A key challenge is the out-of-pocket payment requirement associated with the vaccine's non-National Immunization Program (non-NIP) status, which has contributed to regional immunization disparities and limited population-level disease control. In addition, limited public awareness and the need to complete a multi-dose vaccination schedule within a defined immunization window, have resulted in low completion rates among eligible children. According to the Expert Consensus on Immunoprophylaxis of Pediatric Rotavirus Gastroenteritis, a cross-sectional survey conducted across ten provinces in China in 2019 reported that the coverage rate for the first dose of rotavirus vaccine was 20.3%, while the coverage rate for the third dose was only 1.8%.

Lack of Specific Antiviral Therapies. Current management relies solely on supportive care and rehydration, lacking specific antiviral therapies. This therapeutic gap prolongs viral shedding and disease duration, increasing risks for vulnerable children. Furthermore, pediatric rotavirus diarrhea causes gut dysbiosis (reducing microbial diversity and driving inflammation), an underlying pathology that conventional treatments fail to address.

R&D Barriers & The LBP Solution. Developing pediatric medicines faces high hurdles due to stringent safety standards, palatability requirements, and difficult clinical recruitment. In this context, LBPs represent a promising therapeutic avenue. By utilizing multi-targeted mechanisms, such as competitively blocking viral entry, inducing host production of antiviral interferons and restoring microbiota homeostasis, LBPs are expected to fill the current void in specific treatments. Such an intervention could significantly shorten the viral shedding period and disease course, ultimately reducing both the family caregiving burden and overall healthcare expenditures.

Competitive Landscape of Pediatric Rotavirus Diarrhea Globally and in China

As of the Latest Practicable Date, a total of four products had been approved in China for pediatric rotavirus diarrhea, all of which are prophylactic vaccines. The following table shows marketed products of pediatric rotavirus diarrhea in China:

Marketed Products of Prophylactic Vaccine for Pediatric Rotavirus Diarrhea in China

Drug	Company	Drug Type	Route of Administration	Approval Time	Full Schedule Doses	Estimated Full Vaccination Cost per Child* (RMB)
Hexavalent rotavirus live attenuated vaccine	Wuhan Institute of Biological Products Co. Ltd	Prophylactic Vaccines	Oral	2025/08/19	3	~960
Trivalent Reassortant Rotavirus Live Attenuated Vaccine	Lanzhou Institute of Biological Products Co. Ltd	Prophylactic Vaccines	Oral	2023/04/17	3	~750
Pentavalent rotavirus live attenuated vaccine	MSD	Prophylactic Vaccines	Oral	2018/04/12	3	900~980
Rotavirus Live attenuated vaccine	Lanzhou Institute of Biological Products Co. Ltd	Prophylactic Vaccines	Oral	2001/01/01	3	510~650

Note: This table was last updated on June 13, 2026

**Prophylactic Vaccine for Pediatric Rotavirus Diarrhea in China are non-NIP vaccines. Actual retail prices may vary by province and municipality due to differences in procurement prices and administration fees. The estimates above are based on publicly available local procurement and listed prices, including administration fees.*

Source: NMPA, Frost & Sullivan Analysis

As of the Latest Practicable Date, there are eleven drug candidates for pediatric rotavirus diarrhea in the global clinical-stage pipeline, among which nine are in China. With the exception of HY1002 and SK08, all other candidates are vaccines. SK08 is the only LBP currently under development. The following tables provide an overview of the competitive landscape of non-vaccine clinical pipelines in pediatric rotavirus diarrhea treatment:

Global and China Non-Vaccine Clinical Pipelines in Pediatric Rotavirus Diarrhea Treatment

Drug Code	Company	Type of Drug	Route of Administration	Highest Phase of Trial	First Posted Date	Regulatory Authority
SK08	Guangzhou Zhiyi Biotechnology Co., Ltd.	LBP	Oral	Phase II clinical trial approved*	2024/09/18	NMPA
Recombinant Human Lactoferrin Lysozyme (HY1002)	Wuhan Healthgen Biotechnology Corp.	Enzyme	Oral	Phase III	2021/09/30	NMPA

Note: This table was last updated on June 13, 2026

**SK08 received an IND approval from the NMPA for the initiation of a Phase II clinical trial.*

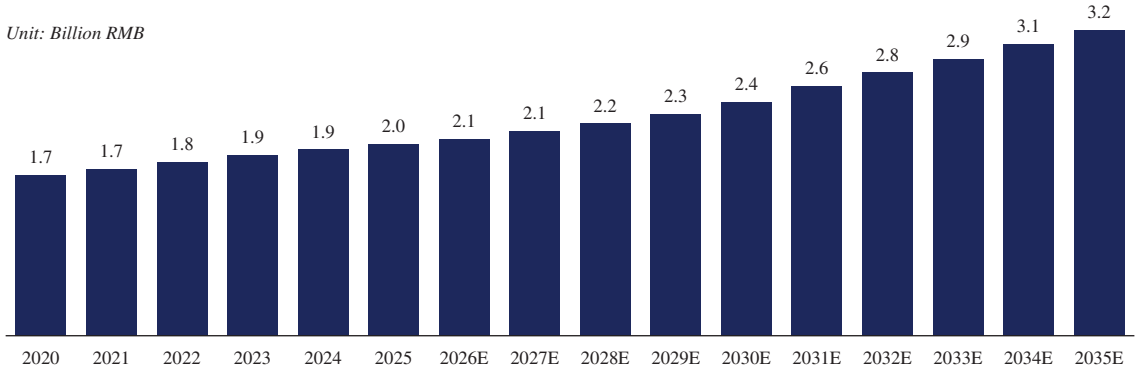
Source: Clinical Trials, NMPA, Frost & Sullivan analysis

Market Size of Pediatric Rotavirus Diarrhea Drug in China, 2020-2035E

From 2020 to 2025, the market of pediatric rotavirus diarrhea in China has grown from RMB1.7 billion to RMB2.0 billion, with a CAGR of 3.6%. It is estimated to achieve RMB3.2 billion in 2035, with a CAGR of 5.5% from 2030 to 2035.

Pediatric Rotavirus Diarrhea Drug Market Size in China, 2020-2035E

Period	CAGR
2020-2025	3.6%
2025-2030E	4.0%
2030E-2035E	5.5%



Source: Frost & Sullivan analysis

ULCERATIVE COLITIS DRUG MARKET

Overview of UC

UC is a chronic, non-specific IBD of which the exact etiology remains partially understood, primarily involves the mucosal and submucosal layers of the rectum and colon. Clinical manifestations include recurrent episodes of diarrhea, abdominal pain, and the passage of mucus and blood in the stool. UC is characterized by its protracted course, high relapse rates and difficulty in curing. Persistent chronic inflammatory stimulation not only leads to intestinal mucosal ulceration and fibrosis but also significantly elevates the long-term risk of colorectal cancer ("**CRC**"). Research of JAMA indicates that for UC patients with a disease duration exceeding 20 years, the risk for CRC is approximately 1.7 times higher than that of the general population. Consequently, UC is classified by the World Health Organization as a modern refractory disease and is regarded as a highly challenging chronic condition within the field of gastroenterology. While UC is more common in Western countries, the incidence and prevalence of UC have been steadily rising in China.

Prevalence of UC Globally and in China

The global number of patients with UC increased from 4,096.6 thousand in 2020 to 5,251.5 thousand in 2025, with a CAGR of 5.1%. The number is expected to grow to 6,163.3 thousand in 2030 and 6,875.8 thousand in 2035, with a CAGR of 3.3% between 2025 and 2030 and 2.2% between 2030 and 2035.

The number of patients with UC in China increased from 432.8 thousand in 2020 to 628.1 thousand in 2025, with a CAGR of 7.7%. The number is expected to grow to 892.7 thousand in 2030, with a CAGR of 7.3% between 2025 and 2030.

Current Treatment

Current treatment for UC is generally guided by disease severity and treatment phase. The therapeutic objectives are to induce clinical remission during the active phase, normalize serum or fecal inflammatory markers and achieve endoscopic mucosal healing where possible. During remission, long-term maintenance therapy is typically required to sustain steroid-free remission, maintain inflammatory marker control and mucosal healing, and reduce the risk of relapse and complications.

For patients with mild to moderate active UC, mesalazine remains the mainstay therapy for both induction and maintenance. Oral mesalazine is commonly used as first-line therapy for mildly active UC, while rectal mesalazine may be used for proctitis-type UC. If patients with mild-to-moderate or moderate active UC do not respond adequately to mesalazine, treatment may be escalated to systemic oral corticosteroids or biologic therapy for induction of remission.

For severe active UC, oral or intravenous corticosteroids are recommended for induction of remission, but corticosteroids are not recommended for maintenance therapy. In patients with moderate-to-severe UC who are corticosteroid-dependent or have inadequate response or intolerance to conventional therapies, thiopurine immunosuppressants, biologics such as infliximab (IFX) or vedolizumab (VDZ), and small-molecule drugs including JAK inhibitors may be considered. For moderate-to-severe active UC and acute severe ulcerative colitis ("**ASUC**"), continued maintenance therapy with biologics or small-molecule drugs is generally recommended. The following table shows the safety and efficacy analysis of UC treatment:

Safety and Efficacy Analysis of UC Treatment

Treatment	Efficacy	Safety
5-Aminosalicylic acid (5-ASA): Mesalamine	• 6-8 weeks: clinical response 60-70%, remission 40-70%, mucosal healing 30-80% • Maintenance: relapse rate 42.4% (642 patients) (vs placebo 65% (454 patients)) • 4.8g/day vs 2.4g/day: faster symptom resolution (19 vs. 29 days), higher mucosal healing at week 6 (80% vs. 68%) • Ceiling effect: 58.7% fail induction remission	• Inadequate for moderate-to-severe active UC • Long-term monitoring of renal and liver function required
Glucocorticoids: Budesonide MMX	• 9mg × 8 weeks: combined clinical + endoscopic remission 17.7% vs 6.2% (P=0.0002); symptom relief 26.3% vs 14.3% (P2, P=0.0015); histological healing 9.9% vs 6.7% (P=0.2625); mucosal healing 27.6% vs 17.1% (P=0.0092); • 6mg: remission rate 10.9%, no statistical significance	• Adverse events: 6.3% (9mg), 9.5% (6mg), 12.4% (placebo) • serious AE and glucocorticoid-related AE similar across groups, facial hirsutism, constipation and tenesmus, hypertensive crisis, iatrogenic Cushing's syndrome, headache, acne and insomnia
Biologicals: Vedolizumab	• 12-month (321 UC patients): clinical remission 51%, endoscopic remission 41%; Corresponding rates for corticosteroid-free remission 37%; deep remission only 30% • conservative NRI: >80% failed deep remission at 12 months	• 5.6% (6/106) anti-drug antibodies (ADA) • Mild-to-moderate AEs: nasopharyngitis, upper respiratory infections, headaches, mild injection site reactions
Biologicals: Infliximab	• ACT1 (364 patients) Week 8: clinical remission: 69.4% (5mg/kg)/61.5% (10mg/kg) vs. 37.3% (Placebo), clinical response: 38.8% (5mg/kg)/32% (10mg/kg) vs. 14.9% (Placebo), Mucosal Healing: 62% (5mg/kg)/59% (10mg/kg) vs. 33.9% (Placebo) • ACT2 (364 patients) Week 8: clinical remission: 64.5% (5mg/kg)/69.2% (10mg/kg) vs. 29.3% (Placebo), clinical response: 27.5% (5mg/kg)/33.9% (10mg/kg) vs. 5.7% (Placebo), Mucosal Healing: 60.3% (5mg/kg)/61.7% (10mg/kg) vs. 30.9% (Placebo)	• Common respiratory and urinary tract infections; serious infections included pneumonia and sepsis, 7 opportunistic infections (2 fatal fungal cases), 14 tuberculosis cases (4 fatal), a higher rate at 10 mg/kg in RA patients • In the pediatric UC trial (60 children), ALT elevation occurred in 17% (10/60) within 3 times the upper limit of normal, 7% (4/60) at ≥3 times, and 2% (1/60) at ≥5 times the upper limit of normal.
Biologicals: Adalimumab (anti-TNF)	• Week 8: (518 UC patients) clinical remission 17% vs 9% (P=.019), clinical response 50% vs 35% (P<.001), mucosal healing 41% vs 32% (P=.032) • Week 52: (518 UC patients) clinical remission 17% vs 9% (P=.004), clinical response 30% vs 18% (P=.002), mucosal healing 25% vs 15% (P=.009)	• Serious AE 12% (both groups); injection site reactions 12% vs 4% (P<0.001); hematologic adverse event (2% vs 0%; P=.003) • No deaths, demyelinating diseases, or lymphomas reported
JAK inhibitors: Upadacitinib and Tofacitinib (Xeljanz)	• A meta-analysis including six studies and 903 patients demonstrated that upadacitinib was associated with significantly higher clinical remission rates at 8–14 weeks compared with tofacitinib (OR 1.77; 95% CI: 1.18–2.66; I^2 = 32%). • The pooled OR of SFCR at weeks 8–14 was 1.98 (95% CI: 1.32–3.97; I^2 = 30%) when comparing upadacitinib to tofacitinib • A meta-analysis including eight studies and 823 patients showed that patients taking upadacitinib had significantly lower odds of drug discontinuation compared with those taking tofacitinib (OR 0.51; 95% CI: 0.34–0.77; I^2 = 22%).	• Higher incidence of serious cardiac events and cancers (5mg twice daily dosage and 10mg twice daily dosage) • serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with the arthritis and ulcerative colitis

Source: Literature Review, Frost & Sullivan Analysis

Clinical Needs

Diagnostic and Assessment Gaps. Despite recent advancements in therapeutics, clinical needs remain in the management of UC, ranging from diagnostic precision to long-term disease control. Currently, UC lacks a definitive "gold standard" diagnostic tool, relying on exclusionary diagnosis that struggles to differentiate atypical cases from Crohn's disease or infectious enteritis. Furthermore, existing scoring tools (Mayo, UCEIS) remain subjective, and there is a critical shortage of non-invasive markers for accurate prognosis and early risk stratification.

Therapeutic Plateaus and Safety Risks. In terms of drug treatment, the efficacy of conventional therapies has reached a plateau. For mild-to-moderate UC, 5-ASA efficacy has peaked, with a lack of alternative adjuncts. For moderate-to-severe cases, biologics and small molecule drugs face primary non-response, secondary loss of response, and anti-drug antibodies. Crucially, current therapies over-suppress the immune system, risking serious infections and lymphoma while ignoring gut dysbiosis, leading to poor mucosal healing. For ASUC, options remain limited by corticosteroid resistance or dependence, with no ideal rapid tapering regimens available.

Long-Term Management and The LBP Solution. Long-term care is hindered by poor compliance, missed flat-type dysplasia in CRC screening, unmanaged extraintestinal or psychological complications, and "one-size-fits-all" dosing. High costs further limit innovative drug access at grassroots levels. To break this impasse, LBPs offer a profound market opportunity: they achieve disease remission by reconstructing microbiota diversity and promoting intestinal barrier repair, completely avoiding the risks of systemic immunosuppression.

Competitive Landscape of UC Treatment Globally and in China

As of the Latest Practicable Date, among LBPs for UC treatment in the clinical stage globally, SK08 is the only pipeline in China currently under clinical development. Meanwhile, it is also the only one among the seven global LBP pipelines for this indication that is led by a Chinese company. The following tables provide an overview of the competitive landscape of under development products for UC, encompassing both global and China:

Global Clinical Pipelines of LBPs in UC Treatment

Drug Code	Company	Type of LBP	Route of Administration	Highest Phase of Trial	First Posted Date	Regulatory Authority
ADS024	Adiso Therapeutics	Single-strain	Oral	Phase II	2022/03/10	FDA
MH002	MRM Health	Multi-strain	Oral	Phase II	2025/12/22	FDA
MGT-006	Metagen Therapeutics	FMT	Oral	Phase I/II	2026/05/26	PMDA[2]
SK08	Guangzhou Zhiyi Biotechnology Co., Ltd.	Single-strain	Oral	Phase II clinical trial approved[1]	2025/01/18	FDA
					2020/03/24	NMPA
LIV001	Liveome	Multi-strain	Oral	Phase I	2024/11/18	EMA[2]
MB310	Microbiotica	Multi-strain	Oral	Phase I	2024/08/13	EMA[2], MHRA[2]
R-3750	Rise Therapeutics	Engineered	Oral	Phase I	2022/12/28	FDA

Note: This table was last updated on June 13, 2026

1. SK08 received the approvals from the NMPA & FDA for the initiation of a Phase II clinical trial.

2. PMDA refers to Pharmaceuticals and Medical Devices Agency of Japan; EMA refers to European Medicines Agency of the European Union; MHRA refers to Medicines and Healthcare products Regulatory Agency of the United Kingdom.

Source: Clinical Trials, NMPA, Frost & Sullivan analysis

China Clinical Pipelines of LBPs in UC Treatment

Drug Code	Company	Type of LBP	Route of Administration	Highest Phase of Trial	First Posted Date
SK08	Guangzhou Zhiyi Biotechnology Co., Ltd.	Single-strain	Oral	Phase II clinical trial approved*	2020/03/24

Note: This table was last updated on June 13, 2026

**SK08 received an IND approval from the NMPA for the initiation of a Phase II clinical trial.*

Source: Clinical Trials, NMPA, Frost & Sullivan Analysis

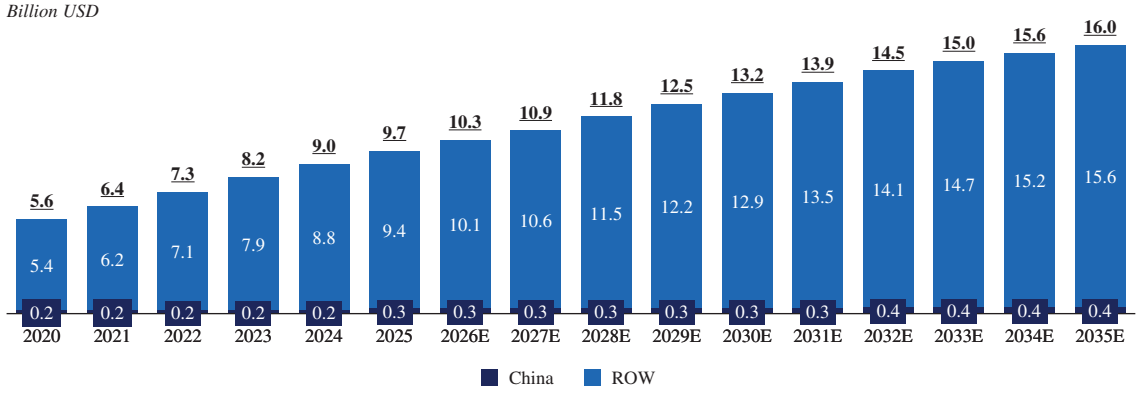
Market Size of UC Globally and in China, 2020-2035E

From 2020 to 2025, the Global UC market has grown from USD5.6 billion to USD9.7 billion, representing a CAGR of 11.7%, primarily driven by the rapid launch and increasing adoption of biologic therapies, supported by the continued launch of biologic therapies, including guselkumab, risankizumab, and mirikizumab. It is estimated to achieve USD16.0 billion in 2035, with a CAGR of 3.9% from 2030 to 2035.

From 2020 to 2025, with the introduction of innovative therapies, particularly biologics, the China UC market has grown from USD0.2 billion to USD0.3 billion, representing a CAGR of 10.6%. It is estimated to achieve USD0.4 billion in 2035, with a CAGR of 3.6% from 2030 to 2035.

Market Size of UC Globally and in China, 2020-2035E

Period	CAGR		
	China	ROW	Global
2020-2025	10.6%	11.7%	11.7%
2025-2030E	5.2%	6.4%	6.4%
2030E-2035E	3.6%	3.9%	3.9%



Source: Frost & Sullivan analysis

ADVANCED SOLID TUMORS (IN COMBINATION WITH ANTI-PD-1/L1 MONOCLONAL ANTIBODIES) DRUG MARKET

Overview of Advanced Solid Tumor

Advanced solid tumors generally refer to solid tumors that have already invaded surrounding tissues or metastasized to distant sites, including but not limited to lung cancer, CRC, breast cancer, gastric cancer, and liver cancer. At this stage, the treatment goals for patients have shifted from curative intent to tumor burden control, improvement in quality of life, and prolongation of survival.

The clinical management of advanced solid tumors currently relies on chemotherapy, radiotherapy, targeted therapy, and the revolutionary development of immunotherapy (represented by PD-1/PD-L1 inhibitors). Although ICIs have significantly prolonged survival for some patients, their clinical application still faces formidable challenges including patient response rates are limited, drug resistance is a concern, and there is significant individual variability in treatment efficacy. The clinical benefit of PD-1/PD-L1 inhibitors is limited to a specific patient population, and there is heterogeneity in treatment efficacy. Current studies indicate that the objective response rate in the overall population of advanced cancer patients is only about 20.0%. Specifically, the objective response rate for anti-PD-1 therapy in relapsed/refractory classical Hodgkin lymphoma is approximately 60.0%-70.0%, whereas the response rate for monotherapy in head and neck cancer, advanced non-small cell lung cancer, and urothelial carcinoma is typically only about 13.0%-21.0%. Furthermore, responses may vary across different lesions in the same patient, and treatment is often accompanied by primary and secondary resistance. Therefore, combination therapy with PD-1/PD-L1 inhibitors has become one of the key strategies for optimizing clinical efficacy. Recent pioneering research has established that the gut microbiota acts as a critical

"switch" in modulating host anti-tumor immune responses. Consequently, LBPs demonstrate immense potential in remodeling the tumor immune microenvironment (TIME). The combination of LBPs and ICIs is expected to convert "cold tumors" into "hot tumors," thereby significantly enhancing the response rates of immunotherapy and overcoming resistance. This synergistic therapy not only provides a novel intervention pathway for patients with advanced solid tumors but also unlocks vast opportunities for the LBP industry within the multi-billion dollar oncology drug market.

Incidence of Solid Tumor in China

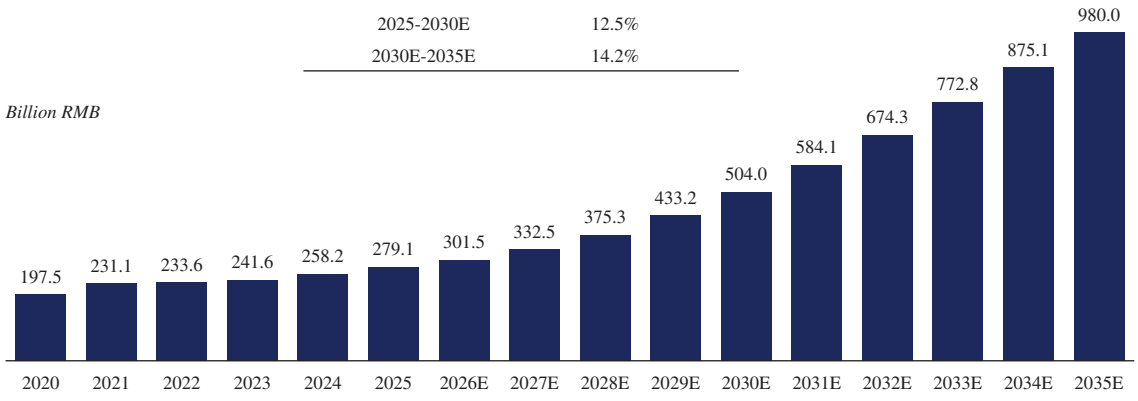
The incidence of solid tumor in China increased from 4,429.0 thousand cases in 2020 to 4,916.0 thousand cases in 2025, with a CAGR of 2.2%. The number is expected to grow to 5,487.0 thousand in 2030, reflecting a CAGR of 2.1% between 2025 and 2030.

China Anti-tumor Drug Market Size and Forecast, 2020-2035E

From 2020 to 2025, the Chinese anti-tumor drug market has grown from RMB197.5 billion to RMB279.1 billion, with a CAGR of 7.2%. It is estimated to achieve RMB504.0 billion in 2030, with a CAGR of 12.5% from 2025 to 2030.

China Anti-tumor Drug Market Size and Forecast, 2020-2035E

Period	CAGR
2020-2025	7.2%
2025-2030E	12.5%
2030E-2035E	14.2%



Source: Frost & Sullivan Analysis

CHEMOTHERAPY-INDUCED DIARRHEA DRUG MARKET

Overview of CID

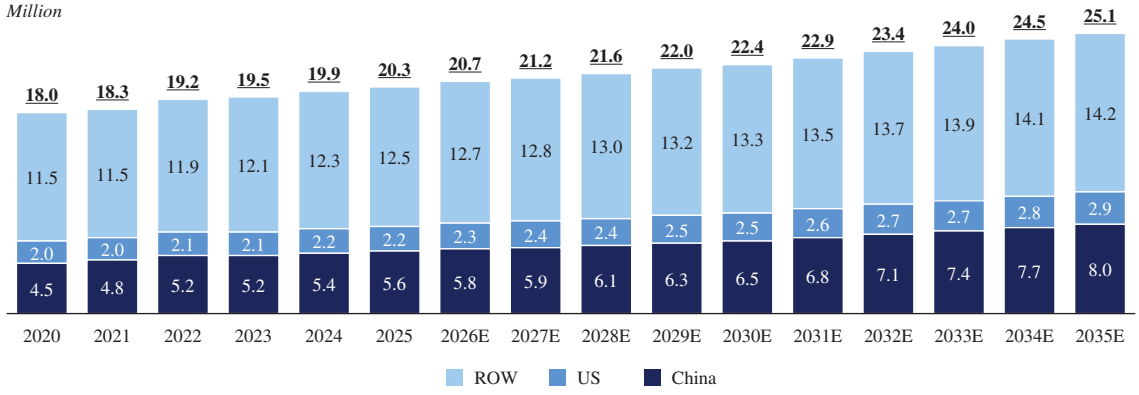
Chemotherapy, as a vital tool in cancer treatment, plays a critical role in the field of oncology. However, CID is a troublesome adverse reaction that can lead to reduced chemotherapy doses, treatment delays or discontinuation, and changes to treatment regimens, in severe cases, it can be life-threatening. As the global incidence of cancer continues to rise and chemotherapy becomes increasingly widespread in cancer treatment, the number of patients experiencing CID is also on the rise.

Incidence of CID in China, 2020-2035E

The incidence of CID in China increased from 4.5 million cases in 2020 to 5.6 million cases in 2025, with a CAGR of 4.5%. The number is expected to grow to 6.5 million in 2030, reflecting a CAGR of 3.2% between 2025 and 2030. The incidence of CID globally increased from 18.0 million cases in 2020 to 20.3 million cases in 2025, with a CAGR of 2.5%. The number is expected to grow to 22.4 million in 2030, reflecting a CAGR of 2.0% between 2025 and 2030.

Incidence of CID Globally and in China, 2020-2035E

Period	CAGR			
	Global	China	U.S.	ROW
2020-2025	2.5%	4.5%	2.3%	1.7%
2025-2030E	2.0%	3.2%	2.5%	2.5%
2030E-2035E	2.3%	4.0%	2.4%	1.9%



Source: Frost & Sullivan Analysis

Current Treatment

Current treatment for CID is primarily based on a structured assessment of patient history, presenting symptoms and risk factors, followed by severity stratification under the CTCAE grading system. In clinical practice, CID is generally categorized into uncomplicated and complicated diarrhea to guide treatment decisions, with severity ranging from mild changes in stool consistency or frequency to life-threatening consequences requiring urgent intervention.

For uncomplicated CID, particularly Grade 1/2 diarrhea, treatment is mainly symptomatic and supportive. Common management measures include dietary modifications, such as easily digestible and low-irritation foods, oral rehydration and antidiarrheal therapy. Loperamide is commonly used as a first-line pharmacological option, while oral rehydration salts may be particularly considered for elderly patients or patients with Grade 2 diarrhea.

For complicated or severe CID, including Grade 3/4 diarrhea or cases associated with dehydration, fever, hypotension, tachycardia or suspected infection, more intensive management is required. Such patients may need laboratory and stool investigations, intravenous fluid and electrolyte replacement, close clinical monitoring and hospitalization. Octreotide, a synthetic somatostatin analogue injection that reduces gastrointestinal secretion and helps promote water and electrolyte absorption, may also be used where clinically appropriate. Overall, the current treatment paradigm for CID remains focused on symptom control, rehydration, supportive care and prevention of serious complications.

Clinical Needs

Chemotherapy remains a cornerstone of cancer treatment. In 2025, approximately 6.9 million and 3.4 million cancer patients in China and the U.S., respectively, received chemotherapy. Diarrhea is one of the most common chemotherapy-related complications, with reported incidence rates reaching up to 80% among patients undergoing chemotherapy.

The clinical needs regarding CID can be summarized in the following three dimensions: (i) Effective control of CID to ensure continuity and dose intensity of chemotherapy. CID is a major dose-limiting toxicity in clinical oncology. Since the efficacy of chemotherapy is closely linked to maintaining the planned dose intensity and schedule, the occurrence of CID often leads to dose reductions, treatment delays, or even discontinuation, thereby compromising treatment outcomes and affecting patients' long-term prognosis. With the widespread use of high-intensity combination chemotherapy regimens, the incidence and severity of CID have been rising, becoming a major bottleneck in optimizing cancer treatment, (ii) Currently, the clinical management of CID remains fragmented, lacking standardized, tiered management and intervention pathways, and relies heavily on individual clinicians' experience rather than unified, evidence-based protocols. The pathophysiology of CID is highly heterogeneous including secretory, osmotic, and immune-mediated mechanisms, and often overlaps with gastrointestinal toxicity from targeted or immunotherapy, complicating accurate diagnosis and clinical decision-making. Therefore, there is an urgent need to establish a structured, stepwise, comprehensive management model, and (iii) Current CID treatment regimens are primarily symptomatic and supportive, lacking effective drugs that target the underlying pathogenesis. Long-term or high-dose use of loperamide carries safety risks, including intestinal obstruction and arrhythmias. Octreotide faces challenges such as high costs, limited health insurance coverage, and inconvenient administration, especially for outpatients. There is an urgent clinical need for innovative intervention strategies that are safer, more accessible, and target underlying pathophysiological mechanisms (such as repairing intestinal mucosal damage or modulating the microbiota).

Competitive Landscape of CID Globally and in China

As of the Latest Practicable Date, there are currently two LBP pipelines in clinical development for CID, with one pipeline each in the U.S. and China. The U.S. clinical pipeline corresponds to SK10 reflecting that Chinese companies have begun to demonstrate a certain level of global competitiveness in the field of oncology supportive care. In addition, there are currently no approved products globally or in China for CID. The following tables provide an overview of the competitive landscape of under development products for CID, encompassing both in global and China:

Global Clinical Pipelines of LBPs for CID

Drug Code	Company	Type of LBP	Route of Administration	Highest Phase of Trial	First Posted Date	Regulatory Authority
SK10	Guangzhou Zhiyi Biotechnology Co., Ltd.	Single-strain	Oral	Phase I	2023/09/07	FDA
KAL-002	Sichuan Anaerobic Biotech	Multi-strain	Oral	Phase I	2025/08/18	NMPA

Note: This table was last updated on June 13, 2026

Source: Clinical Trials, NMPA, Frost & Sullivan analysis

China Clinical Pipelines of LBPs for CID

Drug Code	Company	Type of LBP	Route of Administration	Highest Phase of Trial	First Posted Date
KAL-002	Sichuan Anaerobic Biotech	Multi-strain	Oral	Phase I	2025/08/18

Note: This table was last updated on June 13, 2026

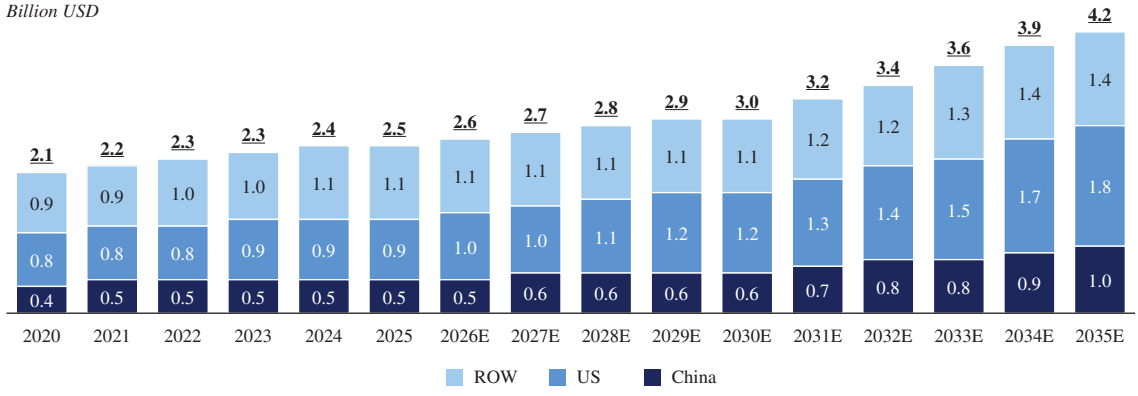
Source: Clinical Trials, NMPA, Frost & Sullivan Analysis

Global and China CID Drug Market Size and Forecast, 2020-2035E

The Global CID Drug Market Size mainly comprises China, the U.S., and the Rest of the World. From 2020 to 2025, the market increased from USD2.1 billion to USD2.5 billion, representing a CAGR of 3.0%. The market is expected to continue expanding, growing from USD3.0 billion in 2030 to USD4.2 billion by 2035.

Global and China CID Drug Market and Forecast*, 2020-2035E

CAGR	Global	China	U.S.	ROW
2020-2025	3.0%	3.4%	3.9%	2.2%
2025-2030E	3.9%	5.3%	5.6%	4.0%
2030E-2035E	6.9%	8.1%	8.5%	2.6%



** Note: Global CID Drug Market Size includes both prophylactic and therapeutic drugs*

Source: Frost & Sullivan Analysis

PROBIOTIC RAW MATERIALS MARKET

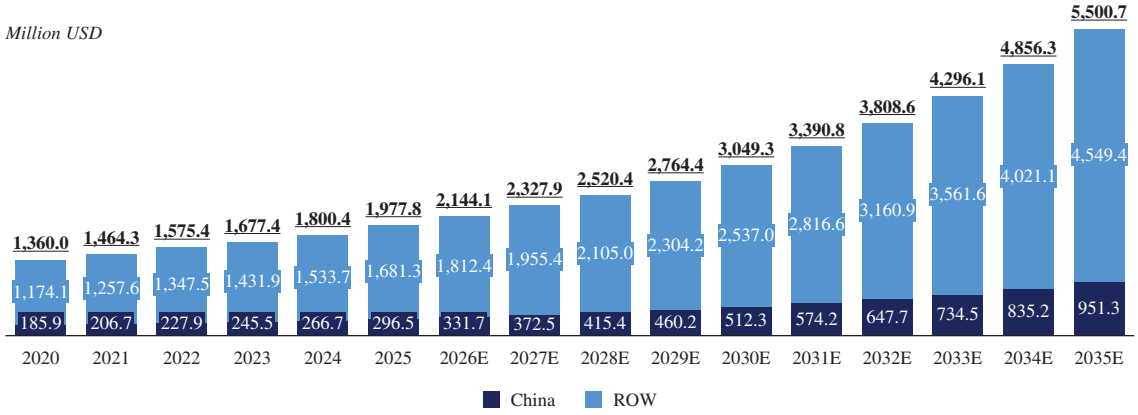
Market Size of Probiotic Raw Materials Used in Human Health Products Globally and in China, 2020-2035E

The global probiotic raw materials market for human health has demonstrated steady growth, with market size increased from USD1,360.0 million in 2020 to USD1,977.8 million in 2025, representing a CAGR of 7.8%. Driven by continuously expanding demand and the diversification of application scenarios, the market is expected to further grow to USD3,049.3 million by 2030 and is projected to reach USD5500.7 million at a CAGR of 12.5% from 2030 to 2035, indicating strong growth potential.

The probiotic raw materials market for human health in China increased from USD185.9 million in 2020 to USD296.5 million in 2025, representing a CAGR of 9.8% over the period. In the medium to long term, as the application of probiotics in the healthcare sector continues to deepen and the penetration of high value-added strain products increases, the market is poised to enter an accelerated growth phase, and is projected to reach USD951.3 Million with a CAGR of 13.2% from 2030 to 2035.

Global and China Probiotic Raw Materials for Human Health Market Size and Forecast, 2020-2035E

CAGR	Global	China	ROW
2020-2025	7.8%	9.8%	7.4%
2025-2030E	9.0%	11.6%	8.6%
2030E-2035E	12.5%	13.2%	12.4%



Source: Frost & Sullivan Analysis

Growth Drivers and Future Trends of Probiotic Raw Materials Market

Growth Drivers

Demographic Shifts Driving Demand Growth. The accelerating trend of population aging is driving sustained demand for functional products that support gut health and immune regulation. As older adults become increasingly receptive to and reliant on probiotic products, the market is expanding steadily. At the same time, this trend is prompting companies to develop differentiated products tailored to specific demographics, thereby driving upgrades in product portfolios.

Rising Health Awareness and Upgraded Consumption. As consumers become increasingly health-conscious, the role of probiotics in improving digestive function and boosting immunity has been progressively validated by both scientific research and market recognition. Furthermore, amid the trend toward consumption upgrading, consumers are placing higher demands on product functionality, personalization, and quality. This is driving the probiotics market to expand into niche demographics (such as infants, children, women, and the elderly) and specialized functional areas (such as gut health and metabolic regulation), thereby opening up new growth opportunities for the industry.

Policy Support and Improved Regulation to Standardize Industry Development. The gradual improvement of the regulatory framework (such as the management of the list of microbial strains and quality standards) has raised the barriers to entry in the industry, helping to regulate market order, improve product quality, and foster the growth of high-quality enterprises. Guided by policy, the industry is gradually evolving toward greater standardization and regulation, thereby promoting long-term healthy development.

Future Trends

Industrial Structure Shifts toward Higher Value-added Sectors. The traditional probiotic market is mature and highly homogenized. Growth is now driven by next-generation probiotics with differentiated functions and clear MoA. Backed by microbiome science, these next-generation strains command higher entry barriers and premium value. While western firms currently dominate this high-end segment, Chinese enterprises are accelerating domestic import substitution through advanced R&D (e.g., AKK strain initiatives).

Industrial Upgrading and Targeted Development. With advancements in metagenomics, synthetic biology, and high-throughput screening technologies, the probiotics industry is transitioning from a traditional, experience-driven model to one that is "science-driven and precision-oriented". In the future, the industry will achieve a comprehensive technological upgrade across the entire value chain, from strain screening and functional validation to large-scale production, thereby driving the development and efficient production of strains with well-defined functions and clear MoA.

Evolving Diversity of Product Applications. The application of probiotic raw materials is shifting from a traditional, single-function focus on gut health to diverse functional areas such as immune regulation, metabolic health, oral health, and women's health. In the field of oral health, relevant studies indicate that specific strains can play a positive role in reducing the risks associated with dental caries and halitosis by inhibiting the colonization of pathogenic bacteria and regulating the oral microbiome. In the field of women's health, probiotics have demonstrated potential applications in regulating the vaginal microbiome balance and supporting gynecological health management. Driven by these diverse application needs, the market potential for probiotic raw materials is expected to expand further.

Industry Standards and Convergence. Regulatory oversight of probiotics continues to tighten worldwide, and the ongoing refinement of relevant standards and guidelines helps raise industry entry barriers and improve product quality. At the same time, the synergistic advancement of regulation and scientific research will further promote interdisciplinary integration between probiotics and fields such as medicine, nutrition, and food, driving the industry toward higher value-added development.

Analysis of Barriers to Entry in the Probiotic Raw Materials Industry

Barriers to Strain Resource Acquisition and Functional Validation. The core competitive advantage of the industry lies in possessing proprietary microbial strain resources with clearly defined functions that can be repeatedly validated. High-quality strains typically result from long-term screening and accumulation, they must have well-defined functional mechanisms and application scenarios such as gut regulation and immune modulation, and their safety and efficacy must be validated through *in vitro* and *in vivo* experiments as well as clinical studies. A strain library backed by proprietary intellectual property rights forms the key foundation for a company's competitive differentiation.

Barriers in Quality Control and Production Systems. Probiotics impose stringent requirements on strain viability, stability, and quality control during the manufacturing process. Companies must establish comprehensive production and quality control systems to ensure that products maintain high quality and functional stability throughout their shelf life, which places high demands on production processes and quality management capabilities.

Regulations and Market Access Barriers. Globally, regulations governing probiotics continue to tighten. In China, probiotic raw materials and their use in food and health supplements must comply with relevant laws and standards, including but not limited to: "the List of Strains Permitted for Use in Food," "the List of Strains Permitted for Use in Infant and Toddler Food," and "the Specifications for the Classification of Live Bacterial Counts in Probiotic Foods (industry standard)". The aforementioned regulatory framework sets forth explicit requirements regarding strain origin, safety assessment, and production quality control, thereby raising the overall industry entry barriers.

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [**REDACTED**], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the worldwide and China drug markets of LBPs, IBS, RVGE, UC, advanced solid tumor, CID and probiotic raw materials. Frost & Sullivan is an independent global market research and consulting company founded in 1961 and is based in the U.S. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries.

We have included certain information from the Frost & Sullivan Report in this Document because we believe such information facilitates an understanding of the drug markets as mentioned above for potential [**REDACTED**]. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

We have agreed to pay Frost & Sullivan a fee of RMB0.68 million for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the content of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [**REDACTED**]. We confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by Frost & Sullivan which may qualify, contradict or have an impact on the information set forth in this section in any material respect.