

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from the report prepared by Frost & Sullivan, which was commissioned by us, 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 Sole Sponsor, Sole [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy.

OVERVIEW

Introduction to Peptide Drugs

Peptide drugs are compounds composed of a series of well-ordered amino acids linked by peptide bonds. They possess characteristics that lie between traditional small-molecule drugs and large-molecule protein therapeutics, and may be derived from naturally occurring bioactive peptides or produced through chemical synthesis or genetic engineering technologies. In terms of mechanisms, peptide drugs typically bind to specific receptors or act as enzyme inhibitors/agonists to regulate physiological processes and achieve therapeutic effects.

Advantages of Peptide Drugs

Although head-to-head clinical trials are currently lacking, several literature reviews have highlighted the advantages of peptide drugs based on their mechanisms, pharmacology, and platform characteristics. A primary advantage is their exceptional specificity. Studies indicate that peptides bind to receptors or enzymes with high affinity and selectivity. Furthermore, their molecular size and backbone flexibility make them better suited than small molecules for covering expansive protein surfaces, particularly protein-protein interaction interfaces. This makes peptides highly effective for addressing biological targets that are traditionally considered undruggable for small molecules.

In addition to their targeting capabilities, peptides offer distinct advantages in immunogenicity and safety. Research demonstrates that they generally exhibit lower immunogenicity and antigenicity compared to larger biological therapies, such as proteins and antibodies. Their safety profile is bolstered by highly predictable metabolic pathways; because peptides typically break down into amino acids or smaller fragments, cytochrome P450 (CYP)-mediated metabolic interactions are relatively rare. Analyses of peptide drugs approved between 2008 and 2024 further confirm that the overall risk of clinically relevant drug-drug interactions (DDIs) remains exceptionally low, even for larger peptides.

Finally, peptide drugs demonstrate remarkable efficacy in clinical applications. They deliver high affinity and potency, which allows them to exert robust therapeutic effects at remarkably low concentrations.

This high efficiency, combined with their precise targeting, gives peptides a unique and highly valuable role in treating conditions involving complex target types

Global and China Peptide Drug Market, 2020–2030E

Global peptide drug market size continues to grow, rising from USD62.8 billion in 2020 to USD137.7 billion in 2025. The global peptide drug market size is expected to grow at a CAGR of 10.3% between 2025 and 2030, increasing to USD224.3 billion in 2030. In 2025, by therapeutic field, diabetes accounted for the largest share of the global peptide drug market at 59.6% with USD82.1 billion, followed by weight management at 24.8% with USD34.1 billion, oncology at 8.2% with USD11.3 billion, other therapeutic fields at 5.9% with USD8.1 billion, while peptide-based anti-infective drugs accounted for 1.5% with USD2.0 billion.

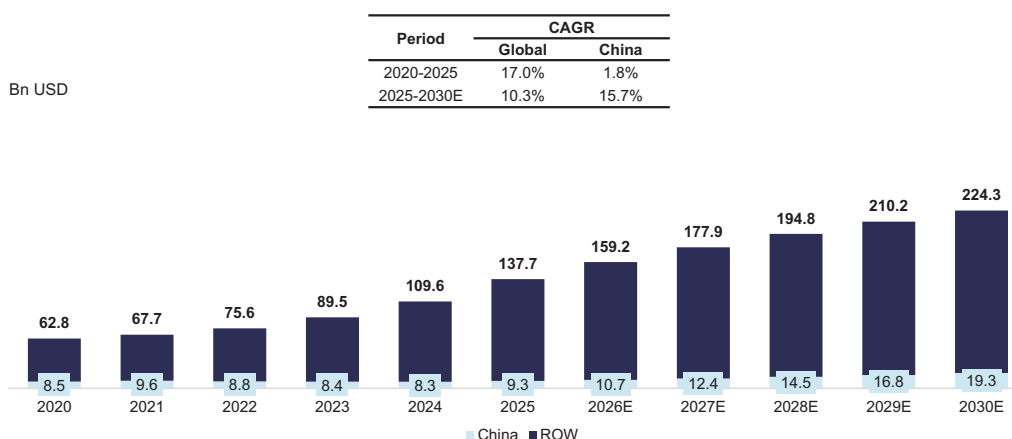
China peptide drug market size grew from USD8.5 billion in 2020 to USD9.3 billion in 2025, and it is expected to grow at a CAGR of 15.7% between 2025 and 2030, reaching USD19.3 billion in 2030. In 2025, by therapeutic field, diabetes accounted for the largest share of the China peptide drug market at 47.4% with USD4.4 billion, followed by growth and development at 15.9% with USD1.5 billion, immune modulation at 10.4% with USD1.0 billion, weight management at 8.3% with USD0.8 billion, cardiovascular disease at 6.3% with USD0.6 billion, other therapeutic fields at 4.8% with USD0.4 billion, and nervous system at 4.3% with USD0.4 billion, while peptide-based anti-infective drugs

INDUSTRY OVERVIEW

accounted for 2.7% with USD0.2 billion. The slight decline in the China peptide drug market from 2020 to 2024 was mainly attributable to significant pricing pressure following the implementation of the national volume-based procurement programme for insulin (initiated in 2021 and implemented from 2022), as well as temporary disruptions caused by the COVID-19 pandemic. In contrast, the forecast growth is mainly supported by the rapid expansion of GLP-1 receptor agonists, driven by increasing adoption in diabetes management as well as significant growth in new indications such as obesity. Compared to traditional peptide drugs, GLP-1 therapies are characterised by higher pricing levels, broader patient populations and expanding clinical applications, which are expected to drive substantial market value growth.

- Global peptide drug market size continues to grow, rising from USD62.8 billion in 2020 to USD137.7 billion in 2025. The global peptide drug market size is expected to grow at a CAGR of 10.3% between 2025 and 2030, increasing to USD224.3 billion in 2030.
- China peptide drug market size grew from USD8.5 billion in 2020 to USD9.3 billion in 2025, and it is expected to grow at a CAGR of 15.7% between 2025 and 2030, reaching USD19.3 billion in 2030.

Global and China Peptide Drug Market Size, 2020-2030E



Source: Annual reports, expert interviews, Frost & Sullivan Analysis

Growth Drivers and Future Trends of the Peptide Drug Market

Advancing Precision-Targeted Anti-Infective Therapies to Address Resistance and Complex Infections. The growth of peptide therapeutics in the anti-infective field is driven by their alignment with precision-targeted therapy. Antimicrobial peptides can selectively act on pathogen-specific targets, enabling effective treatment of bacterial and fungal infections while potentially reducing host toxicity. This approach directly responds to rising antimicrobial resistance, increasing complex infections, and the expanding immunocompromised population, offering a promising pathway for developing novel, low-resistance anti-infective therapies.

Breakthrough Delivery Technologies Enhance Long-Term Treatment Adherence. R&D is increasingly focused on developing non-invasive, targeted, or long-acting delivery platforms, such as suppositories, sprays, and semi-solid or formulations, which may reduce dosing frequency to once daily or even once monthly, thereby substantially improving adherence in chronic disease management. In parallel, oral peptide technologies capable of protecting peptides from enzymatic degradation in the gastrointestinal tract are also making meaningful progress.

Expansion into Frontier Therapeutic Areas to Address Diverse Medical Needs. The application scope of peptide therapeutics is rapidly expanding beyond traditional metabolic indications. Market development is increasingly concentrated on three major directions: infectious diseases, with antimicrobial peptides addressing the growing challenge of antibiotic resistance; inflammatory and autoimmune disorders, through immunomodulatory peptides that selectively regulate dysregulated immune responses; and oncology, leveraging peptide-drug conjugates to enable targeted delivery of cytotoxic agents to tumor cells and open new avenues in cancer therapy.

INDUSTRY OVERVIEW

Challenges, Threats, and Entry Barriers of the Peptide Drug Market

Market Challenges: Developing innovative peptide therapies globally faces severe biochemical limitations, particularly poor oral bioavailability and rapid enzymatic degradation in the human body. Simultaneously, the Chinese market struggles with highly complex large-scale synthesis requirements, which significantly elevate daily manufacturing costs and deeply complicate the stringent quality control processes necessary for long-term commercial viability and clinical success.

Market Threats: Massive research and development expenses render innovative peptide treatments exceptionally vulnerable to fierce competition from cheaper, widespread small-molecule generics globally. Furthermore, China’s aggressive volume-based procurement policies severely threaten corporate profit margins by forcing companies to implement drastic price reductions just to secure essential access to the dominant public hospital distribution networks.

Market Entry Barriers: Market entry strictly demands proprietary solid-phase peptide synthesis technologies and advanced purification infrastructure to manage complex molecular structures. Furthermore, securing exclusive patents for specialized permeation enhancers or lipid nanoparticle delivery platforms is absolutely mandatory to overcome inherent peptide instability, creating a remarkably high technological barrier for new developers in both Chinese and global pharmaceutical markets.

ANTI-INFECTIVE DRUG MARKET

Overview of Anti-Infective Drugs

Anti-infective drugs are a broad class of therapeutics used to kill or inhibit pathogenic microorganisms, such as bacteria and fungi, and are widely used in the treatment of infectious diseases and infection-related complications.

Antifungal drugs. Antifungal agents are primarily used to treat infections caused by pathogenic fungi and are commonly classified according to their mechanisms of action. Major categories include agents that target sterol synthesis (such as imidazole and triazole compounds), those that inhibit fungal cell wall synthesis (such as echinocandins), and agents that interfere with nucleic acid synthesis (such as 5-fluorocytosine). These drugs are widely applied in both mucosal and systemic fungal infections, particularly in immunocompromised populations.

Antibacterial drugs. Antibacterial agents act by either killing bacteria (bactericidal) or inhibiting bacterial growth (bacteriostatic). They are commonly classified based on their mechanisms of action, including agents that target bacterial cell wall synthesis (e.g., penicillins and cephalosporins), disrupt bacterial cell membranes (e.g., polymyxins), or interfere with essential bacterial enzymes and metabolic processes (e.g., rifamycins). A limited number of antibacterial agents also demonstrate activity against protozoal pathogens. Antibacterial agents constitute the most important and widely used subgroup within anti-infective therapies.

Antiviral drugs. Antiviral drugs act by inhibiting viral replication or interfering with key stages of the viral life cycle, rather than directly destroying virus particles. Most are virus-specific, with a limited number showing broader activity, and they play an important role in the management of chronic viral infections and in epidemic or pandemic response.

Other anti-infective drugs. Other categories of anti-infective drugs include agents targeting chlamydia, mycoplasma, rickettsia, parasites, and helminths, which are clinically relevant causes of infectious diseases. These pathogens can cause systemic or localized infections and often require specialized therapeutic approaches.

Global and China Anti-Infective Drug Market, 2020–2030E

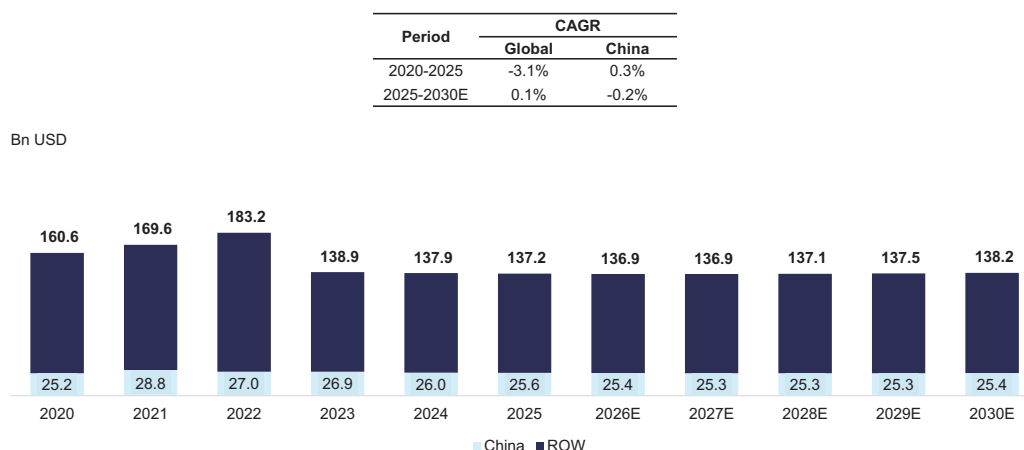
The global anti-infective drug market stood at USD137.2 billion in 2025, projected to dip to USD138.2 billion by 2030. The recent decline stems from plummeting demand for anti-COVID-19 drugs/vaccines post-pandemic, plus patent expirations of HIV drugs spurring generic competition. The global anti-infective drug market demonstrates a similar phased dynamic but is primarily influenced by pandemic-related demand fluctuations and long-term structural characteristics of the market. The negative CAGR observed during 2020 to 2025 was mainly attributable to a high base effect driven by elevated use of anti-infective drugs during the COVID-19 pandemic, followed by a normalisation of demand as the pandemic subsided. During the period from 2025 to 2030, the market is expected to

INDUSTRY OVERVIEW

remain relatively stable, as it continues to be dominated by generic antibiotics subject to ongoing pricing pressure, while innovative anti-infective therapies have not yet reached large-scale commercialisation.

In China, the market reached USD25.6 billion in 2025, forecast to hit USD25.4 billion by 2030. Its contraction has been driven by pandemic-related drops in medical visits, successive rounds of volume-based procurement reducing drug prices, and stricter antibiotic control policies. In China, the historical growth pattern of the anti-infective drug market was shaped by a combination of policy-driven controls and pandemic-related demand fluctuations. Over the past years, strengthened national efforts to combat AMR, including the implementation of antibiotic stewardship policies, have led to more rational and restricted use of antimicrobial drugs. In addition, the inclusion of key antibacterial drugs such as ceftazidime and vancomycin in volume-based procurement programmes resulted in significant price reductions, exerting downward pressure on market value. Furthermore, during the COVID-19 pandemic, the use of anti-infective drugs remained at elevated levels, and the subsequent normalisation of demand after the pandemic led to a decline from this high base.

Global and China Anti-infective Drug Market, 2020-2030E



Source: Annual reports, expert interviews, Frost & Sullivan Analysis

Growth Drivers and Future Trends of the Anti-Infective Drug Market

High Unmet Need: Infectious Disease Burden and Antimicrobial Resistance Crisis. On one hand, complex and refractory wound infections, such as diabetic foot infections and surgery-associated infections, are increasingly prevalent, compounded by the growing population of elderly and immunocompromised patients, driving sustained demand for effective treatments. On the other hand, traditional antibiotics face significant limitations in addressing these infections due to resistance issues — particularly against “superbugs” like MRSA — and adverse effects. This creates a clear clinical entry point for platform technologies based on novel mechanisms, such as antimicrobial peptides. By focusing on the development of next-generation antimicrobial drugs with multi-target activity and low resistance potential, these approaches aim to precisely address infections caused by drug-resistant pathogens and complex cases, thereby potentially fulfilling the most urgent unmet market needs. Policy support is also a positive factor. In 2022, the National Health Commission issued the Notice on Printing and Distributing the National Action Plan to Contain Antimicrobial Resistance (2022–2025), aiming to reduce drug-resistant infections, raise public awareness of and promote the rational use of antibiotics, and ensure 100% traceable sales of retail antibacterial drugs.

Innovation Driving Treatment Paradigms and Product Evolution. The anti-infective drug market is experiencing growth, driven by a shift towards precision formulations that meet the evolving needs of modern healthcare. A notable development in this area is the advancement of AMPs, which have enabled the creation of topical drug delivery systems such as sprays, suppositories, and oral gels. These systems facilitate the direct application of therapeutic agents to localized infection sites, enhancing the effectiveness of treatment. By focusing the drug’s action on the infection site, these delivery methods minimize systemic exposure, reduce the risk of side effects, and ultimately improve patient outcomes and treatment adherence.

INDUSTRY OVERVIEW

Challenges, Threats, and Entry Barriers of the Anti-infective Drug

Market Market Challenges: The rapidly escalating global crisis of antimicrobial resistance drastically diminishes the clinical efficacy of established treatments over time. Consequently, medical researchers consistently face overwhelming scientific difficulties in discovering entirely novel mechanisms of action required to effectively combat and outpace continuously evolving superbugs across both international healthcare systems and Chinese domestic hospital networks today.

Market Threats: The continuous development of resistance by dangerous pathogens severely shortens the profitable commercial lifespan of new anti-infective drugs. Furthermore, strict hospital budget caps and aggressive antibiotic stewardship programs implemented both globally and specifically in China heavily restrict the prescription frequency and overall sales volume of newly launched, high-priced, and innovative broad-spectrum antibiotics right from the start.

Market Entry Barriers: Commercial success specifically requires navigating specialized regulatory incentives, like the Qualified Infectious Disease Product designation globally or priority review in China. Furthermore, demonstrating strong clinical results demands access to highly specialized global clinical trial networks. These networks must be capable of rapidly recruiting severely infected patients across multiple intensive care units before standard routine antibiotics hide the specific therapeutic benefits of the new drug candidate.

PEPTIDE-BASED ANTI-INFECTIVE DRUG MARKET

Overview of Peptide-Based Anti-Infective Drugs

Peptide-based anti-infective drugs are short amino acid sequences that kill or inhibit pathogenic microorganisms primarily through direct membrane disruption and/or immune modulation mechanisms. Among this class, antimicrobial peptides (AMPs) represent the most extensively studied and clinically relevant category, serving as key effectors of innate immunity and forming the scientific foundation of peptide-based anti-infective therapeutics. AMPs demonstrate broad-spectrum activity against Gram-positive bacteria, Gram-negative bacteria and fungi, and exhibit comparable bactericidal and fungicidal effects against both drug-susceptible and drug-resistant strains, including clinically significant multidrug-resistant organisms such as MRSA, VRE, Copper-green bacterium (*Pseudomonas aeruginosa*), *Acinetobacter baumannii*, as well as pathogenic fungi such as *Candida* spp. and *Aspergillus* spp. These characteristics position peptide-based anti-infective drugs as a promising therapeutic class in addressing both antimicrobial and antifungal resistance.

Traditional antibiotics and antifungal agents face major limitations driving the shift toward novel therapies. Widespread antimicrobial use has fueled the rapid emergence and global spread of resistance, reducing the effectiveness of treatments and complicating the management of infections. Conventional agents are also associated with adverse effects, including microbiota disruption, gastrointestinal toxicity, allergic reactions and nephrotoxicity, limiting long-term tolerability. The World Health Organization has highlighted several high-priority “superbugs” posing urgent public health threats, including carbapenem-resistant Enterobacteriaceae (CRE), ESBL-producing *E. coli* and *K. pneumoniae*, Copper-green bacterium (*Pseudomonas aeruginosa*), MRSA, VRE and multidrug-resistant *Acinetobacter baumannii*, while drug-resistant fungal pathogens such as azole-resistant *Candida* and *Aspergillus* species are increasingly implicated in invasive and healthcare-associated infections with limited treatment options.

In contrast, AMPs offer multiple advantages: a lower possibility for resistance development due to different mechanisms, rapid disruption of microbial membranes, potential immunomodulatory effects that enhance host defenses, and activity against both bacteria and fungi. This widening gap between the declining effectiveness of traditional antimicrobials and the mechanistic promise of peptides underscores the strong strategic rationale for advancing peptide-based anti-infective agents in the fight against multidrug-resistant bacterial and fungal infections.

Overseas and China-Marketed Peptide-Based Anti-Infective Drugs

As of the Latest Practicable Date, only a limited number of peptide-based anti-infective drugs have been approved by the FDA, and most of such approvals were granted in earlier years, with one product approved as early as the 1970s and only five approvals in nearly 25 years. In China, peptide-based anti-infective drugs approved by the NMPA are also limited, with only seven such products approved, and the approved product landscape in this field remains highly concentrated and sparsely populated.

INDUSTRY OVERVIEW

Table 3 Peptide-based Anti-infective Drugs Approved by FDA

Genetic Name	Brand Name	Target/MOA	Company	Indication	Category	Administration	Approval Date
Rezafungin . . .	REZZAYO	Glucan synthase	Mundi Pharma	IC	Antifungal	Injection	2023/3/22
Oritavancin . . .	ORBACTIV	Peptidoglycan	Melinta Therapeutics	ABSSSI	Antibacterial	Injection	2014/8/6
Dalbavancin . . .	DALVANCE	Peptidoglycan	Abbvie	Skin infection, ABSSSI	Antibacterial	Injection	2014/5/23
Telavancin. . . .	VIBATIV	Peptidoglycan	Cumberland Pharmaceuticals	HAP, VAP, ABSSSI	Antibacterial	Injection	2009/9/11
Anidulafungin . .	ERAXIS	Glucan synthase	Vicuron Pharmaceuticals	IC	Antifungal	Injection	2006/2/17
Colistimethate Sodium	COLY-MYCIN M	Bacterial cell membranes	PH Health	Gram-negative bacterial infection	Antibacterial	Injection	1970/6/4

Notes: only includes originator drugs, excluding generics; only antibacterial and antifungal agents were included; IC = invasive candidiasis.

Source: FDA, Frost & Sullivan analysis

Table 4 Peptide-based Anti-infective Drugs Approved by NMPA

Genetic Name	Brand Name	Target/MOA	Company	Indication	Category	Administration	Approval Date
Peceleganan	普亦克	Membrane disruption	Protelight	Secondary infections of first-degree or superficial second-degree burn and scald wounds caused by <i>Staphylococcus epidermidis</i> , <i>Staphylococcus haemolyticus</i> , or <i>Acinetobacter baumannii</i>	Antibacterial	Spray	2026/6/17
Telavancin	NA	Peptidoglycan	Cumberland Pharmaceuticals	HAP, VAP, <i>Staphylococcus aureus</i> infection	Antibacterial	Injection	2025/2/11
Daptomycin	Cubicin	Bacterial membrane	Cubist Pharmaceuticals	cSSSI, Adult <i>Staphylococcus aureus</i> (including methicillin-susceptible and methicillin-resistant) bloodstream infection (bacteremia), including associated right-sided infective endocarditis, Pediatric <i>Staphylococcus aureus</i> bloodstream infection	Antibacterial	Injection	2009/9/2
Micafungin	Mycamine	Glucan synthase	Astellas Pharma	Fungemia, respiratory fungal infection, gastrointestinal fungal infection	Antifungal	Injection	2006/9/1
Caspofungin. . . .	Cancidas	Glucan synthase	MSD	Suspected fungal infection, candidemia and other <i>Candida</i> infections, esophageal candidiasis, invasive aspergillosis refractory to other treatments	Antifungal	Injection	2002/10/29
Teicoplanin	Targocid	Peptidoglycan	Gruppo Lepetit	Serious Gram-positive bacterial infections and serious staphylococcal infections	Antibacterial	Injection	2000/12/15
Vancomycin	Vancocin	Peptidoglycan	Eli Lilly	Infections caused by MRSA and other bacteria	Antibacterial	Injection	2000/5/27

Notes: only includes originator, excluding generic drugs; only antibacterial and antifungal agents were included.

Source: NMPA, Frost & Sullivan analysis

INDUSTRY OVERVIEW

Overseas and China Competitive Landscape of Peptide-Based Anti-Infective Drugs

As of the Latest Practicable Date, there were six clinical-stage peptide-based anti-infective drug candidates under development, whereas seven peptide-based anti-infective drug candidates were being developed in China.

Table 5 Overseas Competitive Landscape of Peptide-based Anti-infective Drugs

Pipeline	Phase	Target/MOA	Company	Indication	Category	Administration	First posted date
PLG0206	Phase II/III	Bacterial cell membranes	Peptilogics	PJI	Antibacterial/ Antifungal	Injection	2025/10/9
LTX-109	Phase II	Bacterial cell membranes	Lytix Biopharma	Nasal decolonization of <i>staphylococcus aureus</i>	Antibacterial/ Antifungal	Topical	2023/6/25
OMN6	Phase II	Bacterial cell membranes	Omnix Medical	Gram-negative bacterial infection	Antibacterial/ Antifungal	Injection	2023/10/11
PL-5	Phase II	Bacterial and fungal cell membranes	ProteLight	Diabetic foot infection	Antibacterial/ Antifungal	Spray	2024/1/3
Rezafungin . . .	Phase II	Glucan synthase	Mundi Pharma	Chronic pulmonary aspergillosis	Antifungal	Injection	2025/1/27
PL-18.	Phase I	Bacterial and fungal cell membranes	ProteLight	Colpomycosis, bacterial vaginitis, mixed vaginitis	Antibacterial/ Antifungal	Suppository	2022/4/22

Notes: only includes originator, excluding generic drugs; only including antibacterial and antifungal agent pipelines first posted over the past four years; PJI = Periprosthetic joint infection.

Source: ClinicalTrials, Frost & Sullivan analysis

Table 6 Competitive Landscape of Peptide-based Anti-infective Drugs in China

Pipeline	Phase	Target/MOA	Company	Indication	Category	Administration	First posted date
PL-3301	Phase II	Bacterial and fungal cell membranes	ProteLight	OPC	Antibacterial/ Antifungal	Oral gel	2026-08-19
HRS9432	Phase II	Glucan synthase	Fujian Shengdi Pharmaceutical	Candidemia, invasive candidiasis	Antifungal	Injection	2023-12-27
YB211	Phase II	30S ribosomal subunit	Mudanjiang Youbo Pharmaceutical	ABSSSI	Antibacterial	Injection	2025-03-07
ASK0912	Phase II	NA	Jiangsu Aosaikang Pharmaceutical	HAP	Antibacterial	Injection	2026-01-12
PL-18.	Phase I/II	Bacterial and fungal cell membranes	ProteLight	VVC	Antibacterial/ Antifungal	Suppository	2023-08-14
TQD3524	Phase I	Bacterial cell membranes	Chia Tai Tianqing Pharmaceutical	Anti infection	Antibacterial	Injection	2024-07-09
SM-V-61	Phase I	Peptidoglycan precursor	Shanghai Tangji	ABSSSI	Antibacterial	Injection	2024-11-05

Notes: only includes originator, excluding generic drugs; only including antibacterial and antifungal agent pipelines first posted over the past three years;

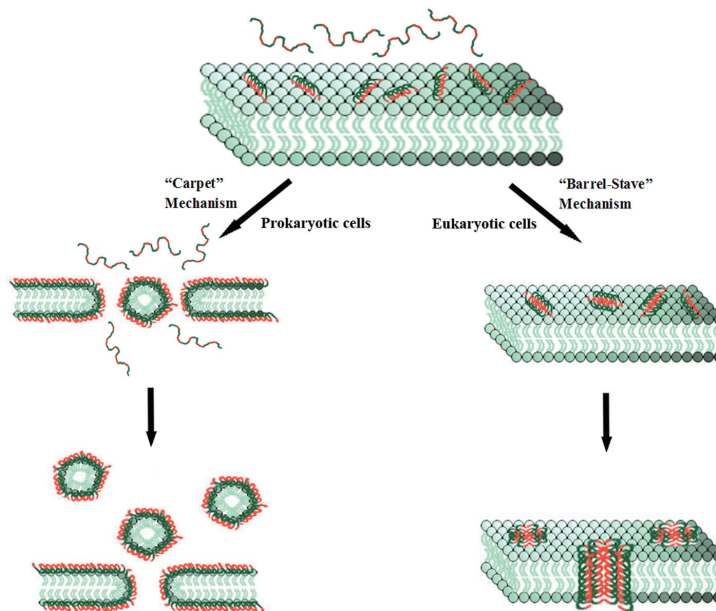
Source: CDE, Literature research, Frost & Sullivan analysis

INDUSTRY OVERVIEW

Introduction to the “Membrane Discrimination Mechanism” and Its Mechanistic & Clinical Advantages

Peptide-based anti-infective drugs primarily exert their antimicrobial activity through a “Membrane Discrimination Mechanism.” Driven by electrostatic attraction, positively charged peptides diffuse toward bacterial surfaces and are able to pass through the cell walls of both Gram-positive and Gram-negative bacteria. Under the combined effects of electrostatic forces and the negative transmembrane potential of bacterial cytoplasmic membranes, peptides are attracted to and accumulate on the membrane surface, where the hydrophobic membrane environment induces the formation of an amphipathic α -helical structure with distinct hydrophobic and hydrophilic faces. Following membrane association, the hydrophobic face of the peptide interacts with the fatty acid components of membrane phospholipids, causing peptide molecules to insert and flip into the hydrophobic core of the lipid bilayer. As increasing numbers of peptide molecules undergo this insertion and flipping process, the surface tension and structural integrity of the membrane are progressively disrupted. When a critical concentration of peptides is reached, the bacterial cytoplasmic membrane becomes permeable, destabilized, or collapsed, resulting in leakage of intracellular contents and rapid bacterial death. This physical, membrane-targeting mechanism does not rely on a single enzymatic target or metabolic pathway and is therefore fundamentally different from conventional small-molecule antibiotics. As a result, peptide-based anti-infective drugs typically demonstrate broad-spectrum antimicrobial activity, rapid bactericidal effects, and a lower propensity for resistance development, including activity against drug-resistant strains. These mechanistic characteristics translate into important clinical advantages, particularly in the treatment of refractory and multidrug-resistant infections, and support the development of peptide-based therapies as next-generation anti-infective solutions.

Membrane Discrimination Mechanism



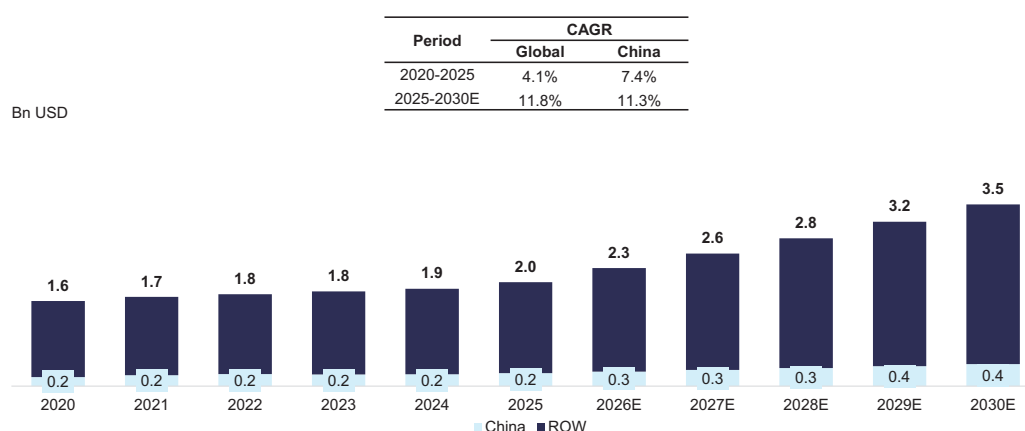
INDUSTRY OVERVIEW

Global and China Peptide-Based Anti-Infective Drug Market, 2020–2030E

In 2025, the global market for peptide-based anti-infective drugs reached USD2.0 billion. Driven by the escalating global challenge of antimicrobial resistance (AMR) and the critical need for a “last line of defense” against multi-drug resistant pathogens, the market is projected to expand to USD3.5 billion by 2030, representing a CAGR of 11.8%. This robust growth is further underpinned by continuous breakthroughs in peptide synthesis and stabilization technologies, which have significantly enhanced the therapeutic window and patient compliance of these high-potency drugs, allowing them to capture a larger share of the global anti-infective sector.

Concurrently, the Chinese market for peptide-based anti-infective drugs stood at USD0.2 billion in 2025. As China shifts its focus toward high-quality domestic innovation and clinical-value-oriented healthcare, this market is projected to grow to USD0.4 billion by 2030, reflecting a CAGR of 11.3%. This upward trajectory is fueled by the deepening penetration of innovative therapeutics under the National Reimbursement Drug List (NRDL) and a strategic emphasis on “import substitution.” As domestic players overcome the technical barriers of large-scale peptide manufacturing, the Chinese market is poised to transition from a reliance on conventional antibiotics to an era of high-barrier, peptide-based precision anti-infectives.

Global and China Peptide-based Anti-infective Drugs Market Size, 2020-2030E



Source: Annual reports, expert interviews, Frost & Sullivan Analysis

Growth Drivers and Future Trends of Peptide-Based Anti-Infective Drugs

Clinical Demand & Resistance Pressure. The growth of peptide-based anti-infective drugs is driven by the global antimicrobial resistance crisis, where multidrug-resistant organisms such as Carbapenem-resistant *Acinetobacter baumannii* (CRAB), Carbapenem-resistant Enterobacterales (CRE) and third generation cephalosporin-resistant Enterobacterales (3GCRE), Carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) reduce the effectiveness of traditional antibiotics, leading to prolonged treatment, higher costs, and increased mortality. Rising clinical demand from complex infections in diabetic foot infection, burn, surgical, and immunocompromised patients, as well as emerging infectious diseases, further fuels the need for new broad-spectrum, fast-acting therapies.

Enhanced Drug Delivery Systems. Effective drug delivery systems are critical for the success of peptide-based therapeutics. Peptides often face challenges related to bioavailability and tissue penetration, which can hinder their clinical efficacy. Their large molecular size and susceptibility to enzymatic breakdown can limit their absorption and ability to effectively reach the targeted infection sites. Advances in delivery technologies, such as thermosensitive gels, spray formulations, and other precision-targeted delivery systems, are helping to overcome these obstacles. These innovations enable controlled release of the drug over time, enhancing bioavailability and improving targeted delivery to infection sites, thereby increasing the overall therapeutic effectiveness of peptide-based treatments.

Challenges, Threats, and Entry Barriers of the Peptide-Based Anti-Infective Drug Market

Market Challenges: Companies may face immense difficulties balancing extremely potent antimicrobial efficacy with minimal human toxicity during initial drug formulation. Additionally, ensuring the sustained biochemical stability of these highly sensitive antimicrobial peptides within complex, enzyme-rich infection microenvironments remains a massive research and development hurdle for pharmaceutical companies actively operating in global and Chinese clinical settings.

INDUSTRY OVERVIEW

Market Threats: The rapid acceleration of bacterial pathogen mutation rates consistently threatens to render newly approved peptide anti-infectives clinically ineffective shortly after launch. Simultaneously, highly affordable and deeply entrenched traditional generic antibiotics continuously dominate current global and Chinese markets, severely undermining the commercial viability and targeted pricing power of these highly sensitive, premium-priced therapeutic interventions.

Market Entry Barriers: Entering the peptide-based anti-infective drug market generally requires strong integrated capabilities, including peptide design and optimization, established manufacturing processes and quality control systems, as well as the ability to conduct clinical studies in complex infection settings. In addition, advancing clinical development and regulatory approvals under global and China regulatory frameworks also requires substantial development infrastructure and compliance capabilities, which collectively create certain barriers to entry for new market participants.

SECONDARY WOUND INFECTION DRUG MARKET

Overview of Secondary Wound Infection

Secondary wound infection refers to an infection that occurs in an existing wound following initial injury, surgery or chronic tissue damage, typically resulting from the invasion and colonization of pathogenic microorganisms during the wound healing process. It can develop across a wide range of wound types, including surgical wounds, traumatic wounds, diabetic wounds, pressure ulcers and iatrogenic wounds. Disruption of the skin barrier in acute or chronic wounds facilitates microbial accumulation and invasion, making secondary infection one of the most frequent and challenging wound-related complications in clinical practice.

Global and China Incidence of Secondary Wound Infection, 2020–2035E

Global incidence number of secondary wound infection increased from 74.4 million in 2020 to 79.4 million in 2025. The number is expected to increase to 85.1 million in 2030 at a CAGR of 1.4% from 2025 to 2030. The number is expected to grow to 91.4 million in 2035, at a CAGR of 1.4%.

Incidence number of secondary wound infection in China increased from 16.8 million in 2020 to 18.9 million in 2025. The number is expected to increase to 20.3 million in 2030 at a CAGR of 1.5% from 2025 to 2030. The number is expected to grow to 21.3 million in 2035, at a CAGR of 0.9%.

Treatment Paradigm for Secondary Wound Infection

The treatment paradigm for secondary wound infection emphasizes comprehensive wound management combined with rational antimicrobial use. Core principles include wound cleansing, debridement of necrotic tissue, maintenance of a moist healing environment, and the use of systemic or topical antimicrobial agents only when infection is clinically confirmed. The strategies vary by wound type. For example, diabetic wounds and pressure ulcers often require long-term wound care and careful antimicrobial stewardship, while surgical and traumatic wounds emphasize infection prevention and early intervention. In China, guidelines stress culture-based pathogen identification, appropriate antibiotic selection, and avoidance of unnecessary prophylactic antimicrobial use to reduce resistance risk.

INDUSTRY OVERVIEW

Treatment Paradigm of Secondary Wound Infection in China

Secondary Wound Infection				
ABSSSI	Diabetic Wounds	Pressure Wounds	Burn Wounds	Iatrogenic wounds
<p>Oral options:</p> <ul style="list-style-type: none">MinocyclineTrimethoprim and sulfamethoxazoleDoxycyclineClindamycinLinezolidTedizolid <p>Intravenous options:</p> <ul style="list-style-type: none">ClindamycinTrimethoprim and sulfamethoxazoleVancomycinTigecyclineLinezolidDaptomycinCeftarolineDalbavancinTedizolidTelavancin...	<p>No/mild superficial infection:</p> <ul style="list-style-type: none">Usually no antibacterials needed. If required, target Gram-positive cocci (GPC). <p>Moderate/severe/deep infection:</p> <ul style="list-style-type: none">Acute/untreated wounds: Use narrow-spectrum agents targeting GPC.Chronic/treated wounds: Use IV broad-spectrum agents covering GNB (including drug-resistant <i>Pseudomonas aeruginosa</i>) and anaerobes; add antifungals if needed. <p>China-specific regimens:</p> <ul style="list-style-type: none">GPB: Linezolid, Vancomycin, TeicoplaninGNB: Piperacillin/Tazobactam, Amikacin, Meropenem, Imipenem	<p>Wound Care & Treatment:</p> <ul style="list-style-type: none">Debride non-viable tissue; maintain moist wound healing.Use appropriate support surfaces; tailor dressings to wound stage.Systemic antibiotics only for confirmed infection.	<ul style="list-style-type: none">Topical antifungals: Clotrimazole, Ketoconazole, Nystatin, TerbinafineAntifungal disinfectants: Sodium Bicarbonate Solution, Tincture of IodineSilver-containing preparations: Silver Sulfadiazine, Silver NitrateSpecial cases: For invasive fungal infections (<i>Mucor</i>/<i>Aspergillus</i>/<i>Fusarium</i>) unresponsive to systemic therapy plus debridement, add topical wet dressing with Amphotericin B	<p>Wound Care & Local Management:</p> <ul style="list-style-type: none">Cleanse, debride necrotic tissue, maintain moist environment.Use dressings suited to wound stage and exudate. <p>Antimicrobial Stewardship:</p> <ul style="list-style-type: none">Reserve systemic/topical antimicrobials for confirmed infection.Obtain cultures, use correct agent/dose, reassess frequently.

Source: WSES/GAIS/WSIS/SIS-E/AAST global clinical pathways for patients with skin and soft tissue infections, 《中國糖尿病足診治臨床路徑(2023版)》, 《2019版壓力性潰瘍/損傷預防和治療臨床實踐指南》,《燒傷侵襲性真菌感染診斷與防治實踐指南(2024版)》, Frost & Sullivan Analysis

China-Marketed Secondary Wound Infection Drug

As of the Latest Practicable Date, three drugs have been approved for the treatment of secondary wound infections, including one drug specifically approved for secondary infections of first-degree or superficial second-degree burn and scald wounds caused by *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, or *Acinetobacter baumannii*, and two drugs approved for ABSSSI and DFI, respectively, which represent certain subtypes within the broader category of secondary wound infections.

China Competitive Landscape of Pipelines for Treatment of Secondary Wound Infection

As of the latest practicable date, within the scope of pipeline programs active over the past three years, in China, only two single pipeline candidates — MRX-4 and YB211 — have been identified.

Secondary Wound Infections Drugs Approved by NMPA

Generic Name	Brand Name	Target/MOA	Company	Indication	Category	Administration	Approval Date	NRDL Inclusion Year	Price RMB /Unit	Dosage Form	Frequency	Cost per Patient (RMB)
Peceleganan	普亦克	Membrane disruption	ProteLight	Secondary Infection of Burn Wounds	Antibacterial	Spray	2026/6/17	N/A	N/A	0.2%	Once daily for 7 consecutive days	N/A
Omadacycline	組再乐	30S rProteins	ZAI Lab	ABSSSI, etc.	Antibacterial	Injection, oral	2021/12/14	2022	480	0.1g	Once daily	~2,500
Linezolid	Zyvox	30S rProteins, 50S rProteins	Pfizer	Diabetic foot infection, etc.	Antibacterial	Injection, oral	2006/9/12	2009	23.4	0.6g	8-12 hour (once)	~650

1. Only includes originator, excluding generic drugs and products no longer marketed
2. Only antibacterial and antifungal agents were included.
3. ABSSSI=Acute bacterial skin and skin structure infection; Secondary Infection of Burn and Scald Wounds=Secondary infections of first-degree or superficial second-degree burn and scald wounds caused by *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, or *Acinetobacter baumannii*
4. Some products have more than one standard administration dosage, information provided in the table is a just an example

Source: NMPA, Frost & Sullivan analysis

INDUSTRY OVERVIEW

China Competitive Landscape of Secondary Wound Infections Pipeline

Pipeline	Phase	Target/MOA	Company	Indication	Category	Administration	First posted date
MRX-4	NDA	Inhibition of bacterial protein	Micurx	ABSSSI; HAP; VABP; HCAP; BSI	Antibacterial	Injection	2025/5/20
YB211	Phase II	30S ribosomal subunit	Mudanjiang Youbo Pharmaceutical	ABSSSI	Antibacterial	Injection	2025/3/7

1. Only includes originator, excluding generic drugs
2. Only including antibacterial and antifungal agent pipelines first posted over the past three years
3. ABSSSI=Acute bacterial skin and skin structure infection; HAP=Hospital-Acquired Bacterial Pneumonia; VABP=Ventilator-Associated Bacterial Pneumonia; HCAP=Healthcare-Associated Pneumonia; BSI=Bloodstream Infection

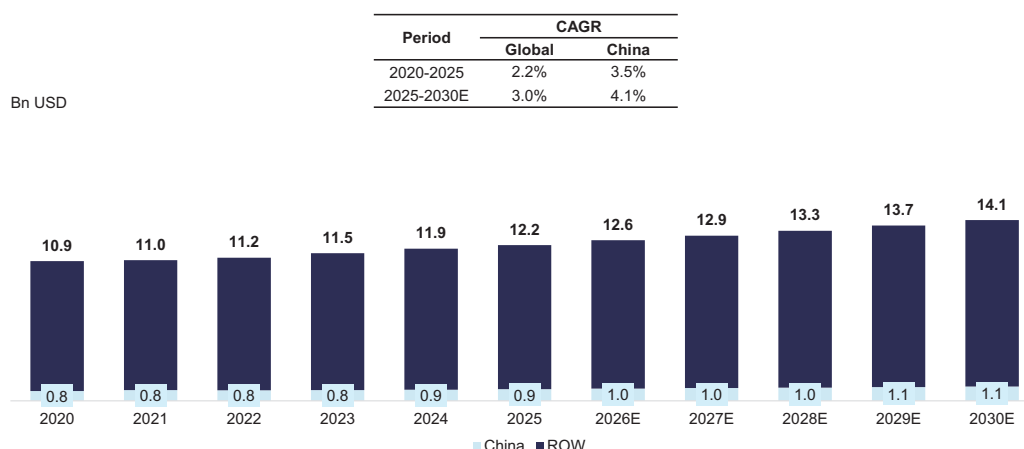
Source: CDE, Frost & Sullivan analysis

Global and China Secondary Wound Infection Drug Market, 2020–2030E

The global market for secondary wound infection drugs reached USD12.2 billion in 2025 and is projected to expand to USD14.1 billion by 2030, at a CARG of 3.0%. This growth is primarily underpinned by the increasing global prevalence of metabolic disorders, particularly diabetes, which frequently results in chronic complications such as diabetic foot ulcers that are highly susceptible to persistent secondary infections. Additionally, the rising volume of complex surgical interventions and a heightened clinical focus on infection control protocols in post-operative care are driving the sustained demand for advanced anti-infective therapies designed to accelerate wound closure and prevent systemic complications.

In China, the secondary wound infection drug market reached USD0.9 billion in 2025 and is expected to increase to USD1.1 billion by 2030, at a CAGR of 4.1%. This upward trajectory is largely shaped by the country’s demographic shift towards an aging population, which presents a higher clinical burden of non-healing wounds and compromised immune responses. The market expansion is further catalyzed by the structural optimization of clinical treatment guidelines and the increased accessibility of innovative anti-infective agents through the National Reimbursement Drug List (NRDL). As healthcare infrastructure continues to modernize, there is a clear transition toward specialized wound management solutions that offer superior clinical outcomes over traditional therapies.

Global and China Secondary Wound Infection Drug Market Size, 2020-2030E



Source: Annual reports, expert interviews, Frost & Sullivan Analysis

Overview of Secondary infection of burn wounds

Secondary infection of burn wounds refers to an infection that develops in a burn or scald wound following the initial thermal injury, typically resulting from the invasion and colonization of pathogenic microorganisms during the wound healing process. Disruption of the skin barrier and the resulting moist wound environment make burn and scald wounds particularly susceptible to microbial colonization, and infection is one of the most common and clinically significant complications of burn injury, contributing to a substantial proportion of burn-related mortality. Common causative pathogens include *Staphylococcus aureus* and *Pseudomonas aeruginosa*, as well as coagulase-negative staphylococci such

INDUSTRY OVERVIEW

as *Staphylococcus epidermidis* and *Staphylococcus haemolyticus*, and *Acinetobacter baumannii*, the latter of which is associated with high rates of multidrug resistance. Left untreated, secondary infection can delay wound healing and increase the risk of progression to deeper or systemic infection, underscoring the clinical need for effective antimicrobial treatment of first-degree and superficial second-degree burn and scald wounds.

Global and China Incidence of Secondary Infection of Burn Wounds, 2020–2035E

Global incidence number of secondary infection of burn wounds increased from 28.2 million in 2020 to 28.6 million in 2025. The number is expected to increase to 29.0 million in 2030 at a CAGR of 0.3% from 2025 to 2030. The number is expected to grow to 29.5 million in 2035, at a CAGR of 0.3%.

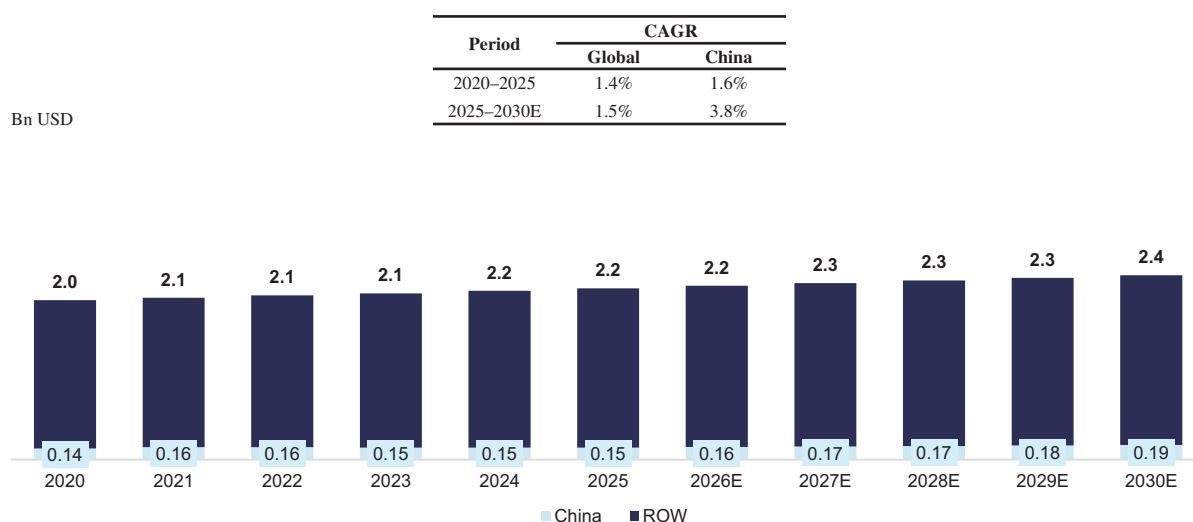
Incidence number of secondary infection of burn wounds in China increased from 2.66 million in 2020 to 2.87 million in 2025. The number is expected to increase to 2.92 million in 2030 at a CAGR of 0.3% from 2025 to 2030. The number is expected to grow to 2.96 million in 2035, at a CAGR of 0.3%.

Global and China Secondary Infection of Burn Wounds Drug Market, 2020–2030E

The global market for secondary infection of burn wounds drugs reached USD2.2 billion in 2025 and is projected to expand to USD2.4 billion by 2030, at a CAGR of 1.5%, reflecting a relatively stable burn injury incidence and mature infection-control standards in developed markets.

In China, the market reached USD0.15 billion in 2025 and is expected to reach USD0.19 billion by 2030, at a CAGR of 3.8%. This above-global growth is largely driven by rising antimicrobial resistance among key burn-wound pathogens in China, including MRSA and increasingly resistant *Klebsiella pneumoniae*, which is driving greater reliance on newer anti-infective agents, together with expanding NRDL reimbursement coverage improving access to innovative therapies.

Global and China Secondary Infection of Burn Wounds Drug Market Size, 2020–2030E



Source: Annual reports, expert interviews, Frost & Sullivan Analysis

Challenges, Threats, and Entry Barriers of Secondary Wound Infection Drug Market

Market Challenges: As no drug has been specifically approved for secondary wound infection and the category spans diverse wound subtypes and pathogens, there is no single standardized treatment pathway and developers must pursue narrower sub-indications rather than a unified approval. Accordingly, there can be no assurance that the Core Product will capture market share in the Chinese Mainland or the United States, which remains a key market challenge.

Market Threats: Treatment is dominated by inexpensive, widely available generic antibiotics used across wound subtypes, setting a high pharmacoeconomic bar for novel therapies. In addition, antimicrobial-stewardship guidelines that restrict antimicrobial use to clinically confirmed infections, coupled with conservative prescribing behavior, may further constrain the uptake of new, higher-priced products.

INDUSTRY OVERVIEW

Market Entry Barriers: Because approval is granted by specific sub-indication rather than for secondary wound infection as a whole, new entrants must conduct separate, indication-specific clinical trials satisfying the distinct requirements of the NMPA and the FDA for each. This fragmented and capital-intensive development path, compounded by entrenched low-cost generics, raises the barriers to entry.

Growth Drivers and Future Trends of Secondary Wound Infection Drug Market

Clinical Need Driven Secondary Wound Infection Drug Market. The secondary wound infection drug market is driven by severe clinical needs, underpinned by rising antimicrobial resistance, biofilm-related treatment challenges, and a growing population of high-risk patients with underlying conditions such as diabetes and immunosuppression. These factors have collectively reduced the effectiveness of conventional therapies, creating an urgent demand for more effective anti-infective solutions. Although new therapies may carry higher unit costs, they are expected to lower overall healthcare expenditures by shortening healing time, reducing amputation rates, and decreasing hospital stays, while addressing significant unmet medical needs and extending value from infection control to comprehensive chronic wound management.

Rising Incidence of Infected Wounds Driving Market Expansion. The rising incidence of secondary wound infections in China and worldwide is driving demand for anti-infective therapies, thereby expanding the secondary wound infection drug market. Globally, the incidence of secondary wound infection increased from 74.4 million cases in 2020 to 79.4 million cases in 2025 and is expected to reach 85.1 million cases by 2030, representing a CAGR of 1.4% from 2025 to 2030. In China, incidence increased from 16.8 million cases in 2020 to 18.9 million cases in 2025 and is projected to reach 20.3 million cases by 2030, with a CAGR of 1.5% from 2025 to 2030. As secondary wound infections can delay wound healing and prolong hospitalization, the growing number of infected wounds continues to support demand for anti-infective therapies.

Future Market Focus on Peptide-Based Anti-Infective Drugs. Looking ahead, the secondary wound infection drug market is expected to increasingly focus on antimicrobial peptide-based and peptide-based anti-infective therapies, which offer sustained antimicrobial activity, reduced dosing frequency, and the ability to disrupt biofilms while supporting tissue repair and microbiome balance. At the same time, formulation technologies are evolving toward long-acting retention sprays, gels, temperature- or pH-sensitive hydrogels, and film-forming dressings, designed to improve drug residence time, reduce dressing change frequency, and enable non-contact, uniform delivery, thereby enhancing treatment convenience and overall therapeutic outcomes.

DIABETIC FOOT INFECTION DRUG MARKET

Overview of Diabetic Foot Infection

Diabetic foot infection (“DFI”) is one of the most common and severe complications of diabetes mellitus. It typically occurs in patients with peripheral neuropathy, peripheral arterial disease, and/or poor glycaemic control, often developing from minor skin injuries or chronic foot ulcers that become colonized and infected by pathogenic microorganisms. Accordingly, as DFI develops within a pre-existing wound, typically a diabetic foot ulcer, that subsequently becomes colonized and infected, rather than the infection itself being the originating cause of the wound, it constitutes a form of secondary wound infection and is not considered a primary wound infection. A primary wound infection refers to an infection in which microbial invasion is the initial cause of the wound, as distinct from an infection that arises as a complication of a wound already present. Infection may progress to deep soft tissue involvement, abscess formation, osteomyelitis, and systemic infection, significantly impairing wound healing. According to the World Health Organization (WHO), diabetic foot complications remain a major global health burden, with a lower-limb amputation occurring approximately every 20 seconds worldwide. A substantial number of patients suffer from chronic, non-healing foot ulcers associated with high risks of infection, amputation, and mortality. Current therapies are mainly systemic antibiotics, which have gaps in coverage against drug-resistant pathogens and may fail to reach effective concentrations in ischemic or poorly perfused wounds, leaving significant unmet medical needs for more effective and targeted treatments. In recent years, the number of innovative drugs approved for diabetic foot infections (DFI) has been relatively limited. This scarcity does not indicate a lack of clinical demand. Instead, it primarily stems from the overarching challenges of anti-infective research and development alongside the inherent complexities of designing DFI clinical trials.

INDUSTRY OVERVIEW

In real-world clinical practice, the DFI patient population continues to expand rapidly. Existing treatment paradigms face significant limitations due to complex underlying systemic diseases, the unique microenvironment of diabetic wounds, and the escalating global crisis of antimicrobial resistance. Current treatments heavily rely on traditional systemic antibiotics. These standard options often yield limited efficacy and carry a high risk of infection recurrence. Furthermore, they frequently fail to halt disease progression toward lower extremity amputation. There remains a profound unmet clinical need for therapies that offer stable efficacy, robust resistance control, and effective localized infection management. From a pharmacoeconomic perspective, the severe financial burden associated with prolonged hospitalizations and amputations creates a strong market willingness to pay for innovative therapies that can effectively resolve infections and accelerate wound healing.

Against this backdrop, new anti-infective therapies featuring differentiated mechanisms of action demonstrate immense clinical and commercial value. This is especially true for drugs designed to overcome multi-drug resistance and optimized for topical or localized application. By delivering high therapeutic concentrations directly to the infection site while minimizing systemic toxicity, our core product directly addresses the shortcomings of traditional antibiotics. Therefore, the limited number of historical drug approvals in this space actually highlights an uncrowded competitive landscape. The combination of urgent unmet medical needs and a continuously growing patient base robustly confirms the commercial viability of our core product. Its differentiated clinical profile perfectly positions it to capture significant market share and capitalize on substantial commercialization opportunities.

Global and China Incidence of Diabetic Foot Infection, 2020–2035E

Global incidence number of diabetic foot infection increased slightly from 29.7 million in 2020 to 32.5 million in 2025. The number is expected to increase to 36.0 million in 2030 at a CAGR of 2.1% from 2025 to 2030. The number is expected to grow to 40.3 million in 2035, at a CAGR of 2.3%.

Incidence number of diabetic foot infection in China increased from 10.4 million in 2020 to 10.7 million in 2025. The number is expected to increase to 11.5 million in 2030 at a CAGR of 1.5% from 2025 to 2030. The number is expected to grow to 12.4 million in 2035, at a CAGR of 1.4%.

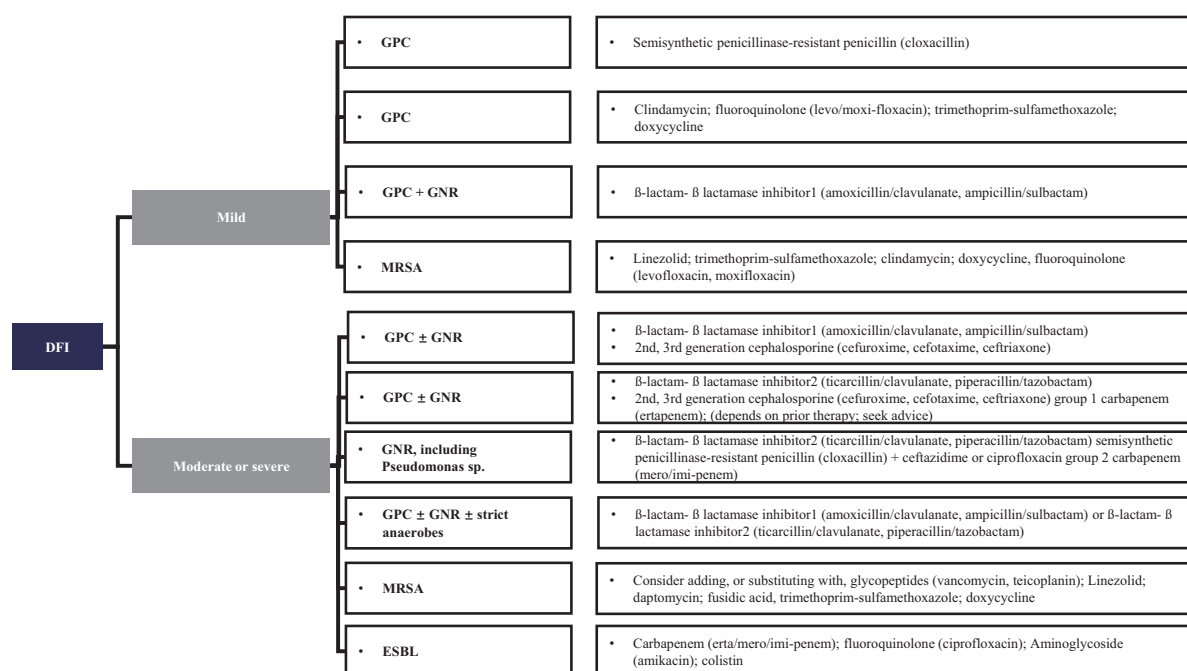
Incidence number of diabetic foot infection in the US increased from 0.8 million in 2020 to 1.0 million in 2025. The number is expected to increase to 1.2 million in 2030 at a CAGR of 4.1% from 2025 to 2030. The number is expected to grow to 1.5 million in 2035, at a CAGR of 3.5%.

Treatment Paradigm for Diabetic Foot Infection

The treatment paradigm for DFI is guided by infection severity, pathogen spectrum, and the presence of ischemia or osteomyelitis. Mild infections typically involve superficial skin and soft tissue, whereas moderate to severe infections may involve deeper structures and systemic manifestations. The current treatment strategies emphasize culture-guided antimicrobial therapy, surgical debridement of necrotic tissue, optimisation of local wound care, and correction of underlying metabolic and vascular abnormalities. DFI is often characterised by mixed infections, involving Gram-positive bacteria, Gram-negative bacteria, and, in some cases, fungi, with multidrug-resistant pathogens accounting for approximately 20% of cases. This complexity necessitates careful antimicrobial stewardship and often prolonged treatment courses, increasing clinical and economic burden.

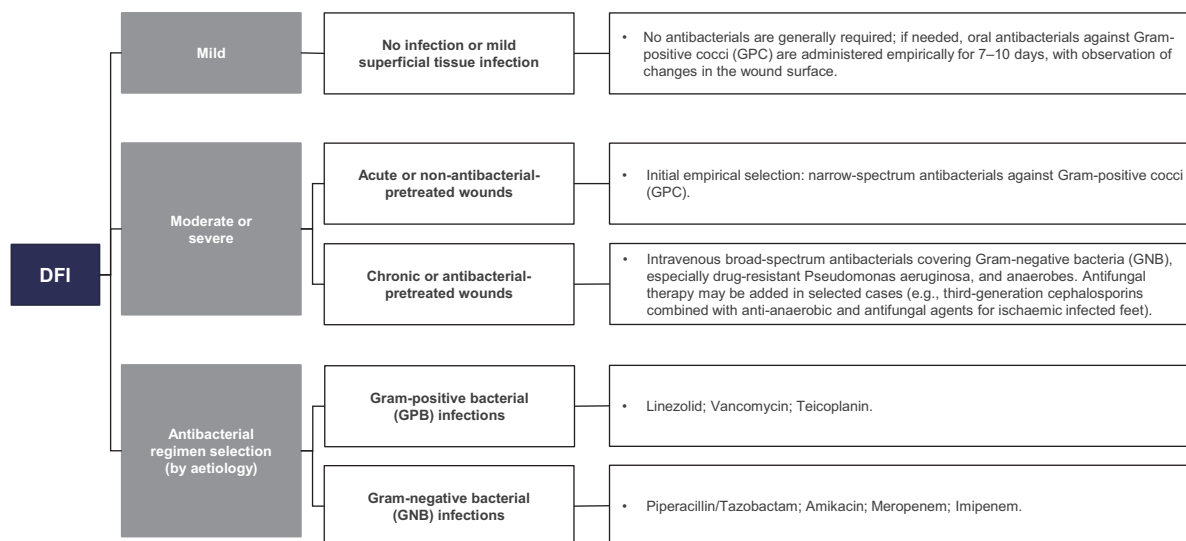
INDUSTRY OVERVIEW

Treatment Paradigm for Diabetic Foot Infection in U.S.



Source: IWGDF/IDSA 2023, Frost & Sullivan Analysis

Treatment Paradigm of Diabetic Foot in China



Source: 《中國糖尿病足診治臨床路徑 (2023版)》, Literature Review, Frost & Sullivan Analysis

Global Marketed Diabetic Foot Infection Drug

As of the Latest Practicable Date, the FDA has approved only two drugs, although these products were not specifically developed for diabetic foot infections.

Global Competitive Landscape for Diabetic Foot Infection Pipelines

As of the Latest Practicable Date, the global clinical pipeline for diabetic foot infection remains limited, with only two clinical-stage candidates identified worldwide, both in Phase II development.

INDUSTRY OVERVIEW

Diabetic Foot Infection Drugs Approved by FDA

Genetic Name	Brand Name	Target /MOA	Company	Indication	Category	Administration	Approval Date	Medical Insurance Inclusion Status	Price USD /Unit	Dosage Form	Frequency	Cost per Patient (USD)
Ertapenem	INVANZ	PBPs	MSD	Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis	Antibacterial	Injection	2001/11/21	Medicare Part B	136.4	1g	Once daily	~1,240
Linezolid	ZYVOX	30S rProteins, 50S rProteins	Pfizer	Complicated skin and skin structure infections, including diabetic foot infections without osteomyelitis	Antibacterial	Oral	2000/4/18	Medicare Part D	265.1	0.6g	Twice daily	~7,400

1. Only includes originator, excluding generic drugs and products no longer marketed
2. PBPs=Penicillin-Binding Proteins
- Source: FDA, Frost & Sullivan analysis

Global Competitive Landscape of Pipelines for Treatment of Diabetic Foot Infection

Pipeline	Phase	Target/MOA	Company	Indication	Category	Administration	First posted date
TP-102	Phase II	Bacteriophage lysis	TechnoPhage	Diabetic foot infection	Phage	Topical	2023/7/17
PL-5	Phase II	Membrane discrimination mechanism	ProteLight	Diabetic foot infection	Antibacterial/Antifungal	Spray	2024/1/3

1. Only includes originator, excluding generic drugs
2. Only including antibacterial and antifungal agent pipelines first posted over the past three years
- Source: ClinicalTrials, FDA, Frost & Sullivan analysis

Diabetic Foot Infection Drugs Approved by NMPA

Genetic Name	Brand Name	Target/MOA	Company	Indication	Category	Administration	Approval Date	NRDL Inclusion Year	Price RMB /Unit	Dosage Form	Frequency	Cost per Patient (RMB)
Piperacillin+Tazobactam	Tazocin 特治星	β -lactamase inhibitor, PBP inhibitor	Pfizer	Diabetic foot infection, etc.	Antibacterial	Injection	1996/7/12	2009	200/vial	4.5g	6-12 hour (once)	~5,300
Linezolid	Zyvox 斯沃	30S rProteins, 50S rProteins	Pfizer	Diabetic foot infection, etc.	Antibacterial	Oral	2006/9/12	2009	120-180/tablet	0.6g	8-12 hour (once)	~2,400

- Note: Only includes originator, excluding generic drugs
- Source: NMPA, Frost & Sullivan Analysis

China Competitive Landscape of Pipelines for Treatment of Diabetic Foot Infection

Pipeline	Phase	Target/MOA	Company	Indication	Category	Administration	First posted date
MRX-4	Phase III	50S ribosomal subunit	MicuRx	Diabetic foot infection (moderate to severe)	Antibacterial	Injection/Oral	2022/7/25
MK0826	Phase III	PBP inhibitor	Merck	Diabetic foot infection	Antibacterial	Injection	2014/4/2

1. Only includes originator, excluding generic drugs
2. Only including antibacterial and antifungal agent pipelines first posted over the past three years
- Source: CDE, Frost & Sullivan analysis

Global and China Diabetic Foot Infection Drug Market, 2020–2030E

The global market for diabetic foot infection (DFI) drugs reached USD3.1 billion in 2025 and is projected to grow to USD3.4 billion by 2030. The diabetic foot infection drug market in U.S. in 2025 is USD1.2 billion. It is estimated that the diabetic foot infection drug market will grow to USD1.4 billion in 2030. This steady yet moderate expansion reflects a mature therapeutic landscape that is increasingly focused on high-value interventions to mitigate the severe risk of lower-limb amputations. As diabetes becomes a chronic lifelong condition for a growing patient base, the market is shifting toward advanced anti-infectives that can penetrate complex biofilms and address the rising prevalence of multi-drug resistant (MDR) pathogens in chronic ulcers.

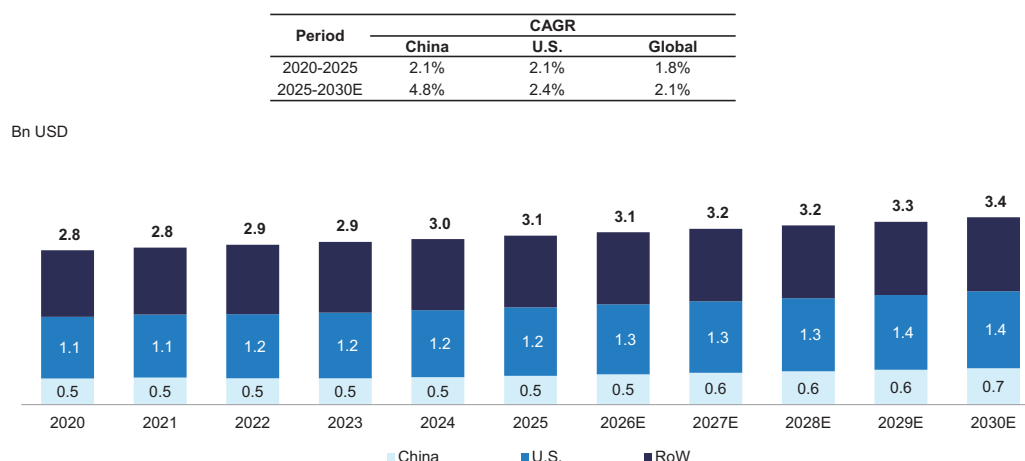
INDUSTRY OVERVIEW

In 2025, the DFI drug market in China was valued at USD0.5 billion and is estimated to reach USD0.7 billion by 2030. This growth outpaces the global average, driven by China’s significant diabetic population and the intensifying clinical burden of late-stage complications. The market trajectory is characterized by a rapid transition toward specialized anti-infective regimens, catalyzed by improved diagnostic rates and the integration of innovative therapies into the National Reimbursement Drug List.

US Diabetic Foot Infection Drug Market by Severity of Diabetic Foot Infection, 2020–2030E

The DFI anti-infective drug market can be segmented by severity, in line with the IWGDF/IDSA classification, into mild infection (Grade 2) and moderate-to-severe infection (Grade 3 to 4). In the U.S., the mild infection segment increased from USD0.3 billion in 2020 to USD0.3 billion in 2025. The market is expected to increase to USD0.4 billion in 2030 at a CAGR of 3.4% from 2025 to 2030, outpacing the moderate-to-severe infection segment, which is expected to grow at a CAGR of 1.9% over the same period. In 2025, the addressable market for the PL-5 was approximately USD0.3 billion in the U.S..

Global, China, and U.S. Diabetic Foot Infection Drug Market Size, 2020-2030E



Source: Annual reports, expert interviews, Frost & Sullivan Analysis

Growth Drivers and Future Trends of Diabetic Foot Infection Drug Market

Rising Incidence Among a Growing Diabetic Population: In both China and the United States, the DFI drug market is driven primarily by the rising incidence of DFI, a complication that expands in step with the diabetic population as diabetic foot ulcers become infected. In China, DFI incidence rose from 10.4 million cases in 2020 to 10.7 million cases in 2025 and is projected to reach 11.5 million cases by 2030 (CAGR of 1.5% from 2025 to 2030). In the United States, DFI incidence rose from 1.0 million cases in 2025 and is projected to reach 1.2 million cases by 2030 (CAGR of 4.1% from 2025 to 2030). As DFI is typically polymicrobial, highly recurrent and, in severe cases, progresses to osteomyelitis and amputation, each case generates repeated and prolonged anti-infective treatment, making the enlarging patient base a key driver of the market in both geographies.

Resistant and Complex Infection Drive Market: The diabetic foot infection (DFI) market is driven by urgent clinical needs, a growing patient base, and high economic value. DFI often involves multidrug-resistant pathogens and biofilms, making conventional antibiotics less effective and creating demand for therapies like antimicrobial peptides that disrupt bacterial membranes and biofilm-resident bacteria. Mixed aerobic and anaerobic infections further support the need for broad-spectrum coverage. Severe cases with deep tissue involvement or osteomyelitis represent high-value segments, while more effective therapies can reduce amputations, hospital stays, and repeated interventions.

Peptide Therapeutics and Delivery Innovation. The market is increasingly focused on peptide-based anti-infective drugs optimized for stability, selectivity, and local safety. Topical spray formulations enable direct application to infected wounds, allowing high local drug concentrations at the site of infection while minimizing systemic exposure. For diabetic foot infections, this local

INDUSTRY OVERVIEW

delivery approach is particularly advantageous in ischemic or poorly perfused tissues where systemic antibiotics often fail to achieve effective concentrations, thereby improving antimicrobial efficacy, biofilm penetration, and overall treatment convenience.

Challenges, Threats, and Entry Barriers of Diabetic Foot Infection Drug Market

Market Challenges: Diabetic foot infections typically involve compromised blood flow, significantly reducing the effectiveness of conventional systemic treatments. This underlying pathology heavily complicates clinical trial recruitment and therapeutic validation across global and Chinese healthcare systems. Overcoming these physiological barriers necessitates advanced therapies engineered for targeted local delivery directly at the wound site.

Market Threats: The high risk of rapid amputation frequently forces cautious physicians to bypass experimental drugs and immediately rely on established surgical interventions alongside heavy antibiotic protocols. This deeply entrenched, risk averse clinical behavior severely limits the ability of novel pharmacological therapies to gain wide adoption among medical specialists. Notwithstanding the above, innovative therapies with clear differentiated clinical value, particularly in settings where existing treatments have limited efficacy or where antimicrobial resistance is a concern, may still achieve relatively rapid adoption in clinical practice.

Market Entry Barriers: Developing targeted DFI drugs requires coordinating complex multidisciplinary clinical trial sites involving podiatrists, endocrinologists, and infectious disease specialists. Furthermore, both the FDA and China’s NMPA mandate highly specific tissue culture validations and strict DFI specific non inferiority margins. These requirements create massive regulatory and logistical barriers that heavily block standard pharmaceutical companies lacking dedicated diabetic complication research divisions.

OROPHARYNGEAL CANDIDIASIS DRUG MARKET

Overview of Oropharyngeal Candidiasis

Oropharyngeal candidiasis (“**OPC**”) is a fungal infection of the oral cavity and the oropharynx, primarily caused by *Candida* species, most commonly *Candida albicans*. It typically presents with white plaques or patches on the tongue, inner cheeks, palate, and/or the oropharyngeal mucosa, and may be accompanied by erythema, soreness, burning sensation, and, in more severe cases, dysphagia. Common risk factors include immunosuppression, diabetes, antibiotic or corticosteroid use, denture wearing, and poor oral hygiene. While OPC is generally treatable with topical or systemic antifungal agents, recurrent, persistent, or severe cases may require prolonged treatment and ongoing monitoring, particularly in high-risk patient populations.

Global and China Prevalence of Oropharyngeal Candidiasis, 2020–2035E

The global prevalence of OPC increased from 534.2 million cases in 2020 to 580.9 million cases in 2025, representing a CAGR of 1.8% over the period from 2020 to 2025. The number of cases is projected to increase to 622.5 million by 2030, at a CAGR of 1.4% from 2025 to 2030, and further to 659.3 million by 2035, at a CAGR of 1.2% from 2030 to 2035.

In China, the prevalence of OPC increased from 78.0 million cases in 2020 to 81.7 million cases in 2025, corresponding to a CAGR of 0.9% over the same period. The number of cases is expected to rise to 85.3 million by 2030, at a CAGR of 0.9% from 2025 to 2030, and further to 88.5 million by 2035, at a CAGR of 0.7% from 2030 to 2035.

In the US, the prevalence of OPC increased from 20.9 million cases in 2020 to 21.7 million cases in 2025, corresponding to a CAGR of 0.8% over the same period. The number of cases is expected to rise to 22.2 million by 2030, at a CAGR of 0.5% from 2025 to 2030, and further to 22.7 million by 2035, at a CAGR of 0.4% from 2030 to 2035.

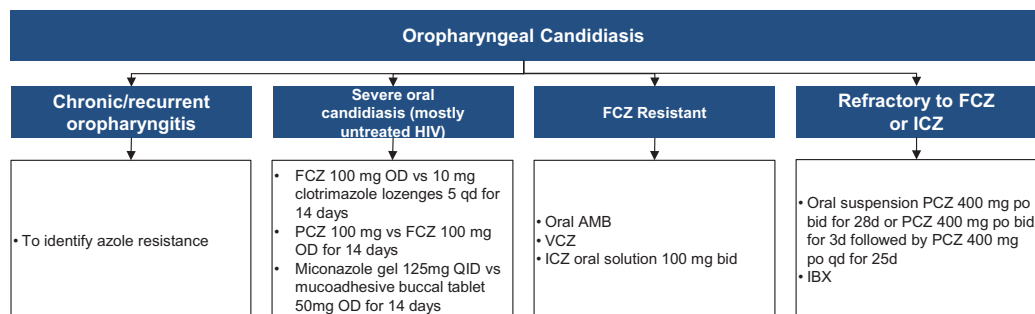
Treatment Paradigm for Oropharyngeal Candidiasis

The treatment paradigm for OPC is primarily based on antifungal drug therapy, with treatment selection guided by disease severity, antifungal resistance profile, prior treatment response, and underlying patient conditions. Clinical management generally follows a stepwise approach, escalating from topical to systemic therapy as disease severity increases or resistance emerges. In China, treatment strategies for OPC are broadly divided into topical antifungal therapy and systemic antifungal therapy. Despite regional differences in treatment pathways, current standard-of-care therapies remain centred on

INDUSTRY OVERVIEW

azole-based antifungal agents, with escalation to other antifungal classes primarily occurring in resistant or refractory cases. Limitations of existing therapies include emerging antifungal resistance, variable clinical efficacy, systemic exposure associated with oral therapies and challenges related to patient adherence, highlighting the need for more effective and convenient treatment options.

Treatment Paradigm for Oropharyngeal Candidiasis



Notes: bid=twice a day; FCZ=fluconazole; IBX=ibrexafungerp; ICZ=itraconazole; LD=loading dose; N=number of subjects investigated; po=orally; PCZ=posaconazole; QoE=quality of evidence; SoR=strength of recommendation; VCZ=voriconazole.

Source: Global guideline for the diagnosis and management of candidiasis: an initiative of the ECMM in cooperation with ISHAM and ASM, Literature Review, Frost & Sullivan Analysis

Global and China-Marketed Oropharyngeal Candidiasis Drugs

As of the Latest Practicable Date, three antifungal originator drugs have been approved for the treatment of OPC in both the United States and China.

Table 10 Oropharyngeal Candidiasis Drugs Approved by FDA

Genetic Name	Brand Name	Target/MO A	Company	Indication	Category	Administration	Approval Date	Medical Insurance Inclusion Status	Cost per Patient (USD)
Miconazole	Oravig	CYP51	Galt Pharmaceuticals	OPC	Antifungal	Oral (buccal)	2010/4/16	NA	~1,500
Posaconazole	Noxafil	CYP51	Merk Sharp & Dohme B.V.	OPC	Antifungal	Oral	2006/9/15	Medicare Part D	~1,100
Fluconazole	Diflucan	CYP51	Pfizer	OPC, etc	Antifungal	Oral	1990/1/29	Medicare Part D	~50

1. Only includes originator, excluding generic drugs

Source: FDA, Frost & Sullivan analysis

Table 11 Oropharyngeal Candidiasis Drugs Approved by NMPA

Genetic Name	Brand Name	Target/MO A	Company	Indication	Category	Administration	Approval Date	NRDL Inclusion Year	Price RMB /Unit	Dosage Form	Frequency	Cost per Patient (RMB)
Posaconazole	Noxafil	CYP51	Merk Sharp & Dohme B.V.	OPC, etc	Antifungal	Oral	2013/6/3	2017	1,540.0	105ml (40mg/ml)	One to three times a day	~1,540
Itraconazole	Sporanox	CYP51	Janssen	OPC, etc	Antifungal	Oral	2003/12/31	2009	587.5	150ml:1.5g	Twice a day/once daily	~590
Fluconazole	Diflucan	CYP51	Pfizer	OPC, etc	Antifungal	Oral, injection	1990/11/22	2009	131.3	50mg	Once daily	~3,900

1. Only includes originator, excluding generic drugs

Source: NMPA, Frost & Sullivan analysis

Overseas and China Competitive Landscape for Oropharyngeal Candidiasis Pipelines

As of the Latest Practicable Date, no clinical-stage pipeline candidates have been identified overseas with OPC, and only one active pipeline candidate (PL-3301) has been identified in China.

Table 12 China Competitive Landscape for Oropharyngeal Candidiasis Pipelines

Pipeline	Phase	Target/MO A	Company	Indication	Category	Administration	First posted date
PL-3301	Phase II	Bacterial and fungal cell membranes	ProteLight	OPC	Antibacterial/ Antifungal	Oral (Thermosensitive gel)	2026/8/19

Notes: only includes originator, excluding generic drugs; only including pipelines first posted over the past three years;

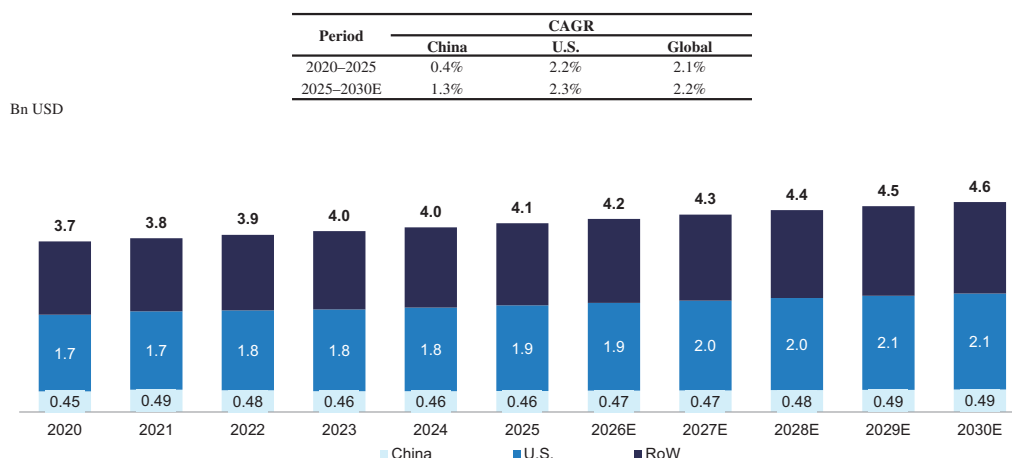
Source: CDE, Frost & Sullivan analysis

INDUSTRY OVERVIEW

Global and China Oropharyngeal Candidiasis Drug Market, 2020–2030E

The global OPC drug market reached USD4.1 billion in 2025. Driven by a growing at-risk population and sustained demand for antifungal therapies, the global market is expected to expand to USD4.6 billion by 2030. Over the historical period from 2020 to 2025, the market grew at a CAGR of 2.1%, and is projected to grow at 2.2% from 2025 to 2030. In 2025, oropharyngeal candidiasis drug market in U.S. is USD1.9 billion. It is estimated that the oropharyngeal candidiasis drug market in U.S. will grow to USD2.1 billion in 2030. In China, the OPC drug market reached USD0.46 billion in 2025. The market is expected to grow to USD0.49 billion by 2030. The China market recorded a CAGR of 0.4% from 2020 to 2025, and is projected to grow at 1.3% from 2025 to 2030. The continuous growth is underpinned by the essential nature of antifungal therapies in managing opportunistic infections and improving the quality of life for chronic disease patients. While the growth rate remains moderate, the market is seeing a qualitative shift toward next-generation antifungal agents that offer improved mucosal adhesion and reduced systemic side effects, ensuring a resilient and defensive value proposition within the broader anti-infective landscape.

Global, China, and U.S. Oropharyngeal Candidiasis Drug Market Size, 2020–2030E



Source: Annual reports, expert interviews, Frost & Sullivan Analysis

Growth Drivers and Future Trends of Oropharyngeal Candidiasis Drug Market

Disease Burden Driving Next-Generation Antifungal Therapies The OPC drug market is driven by a high and rising disease burden, particularly among immunocompromised populations, the elderly and patients with diabetes, as well as by recurrent infections and suboptimal responses to conventional azole therapies. Symptom severity, including oral pain and dysphagia, sustains treatment demand. In addition, widespread use of broad-spectrum antibiotics, poor oral hygiene and improved clinical awareness continue to expand diagnosis and treatment rates. Looking ahead, the market is expected to evolve toward next-generation non-azole and peptide-based therapies supported by advanced local delivery platforms, such as thermosensitive and mucoadhesive formulations, to enhance local retention and efficacy. Long-acting, targeted topical therapies are anticipated to gain wider adoption, particularly in recurrent disease and high-risk populations, and are expected to serve as an important pathway for the early commercialisation of innovative antifungal technologies.

Challenges, Threats, and Entry Barriers of Oropharyngeal Candidiasis Drug Market

Market Challenges: Maintaining consistently effective drug concentrations within the dynamic oral cavity despite constant salivary washout presents a massive pharmacological challenge. Additionally, ensuring rapid fungicidal action without introducing severe local irritation or bitter tastes is essential for significantly improving historically poor patient compliance rates across both global and Chinese healthcare markets.

Market Threats: The rapid evolutionary emergence of highly azole-resistant fungal strains aggressively threatens to permanently neutralize existing clinical pipelines. Overcoming this severe threat and suppressing cheap over-the-counter generics requires introducing entirely novel fungicidal mechanisms that physically rupture fungal cell walls, actively preventing the pathogen’s ability to mutate or develop long-term resistance.

INDUSTRY OVERVIEW

Market Entry Barriers: Successful market entry absolutely requires proprietary mucoadhesive formulation technologies capable of surviving continuous dilution while rapidly delivering powerful fungicidal payloads. Disrupting heavily saturated markets demands exclusive patents for advanced, non-azole mechanisms specifically engineered for instantaneous localized action, erecting massive biochemical barriers exclusively isolating this highly specialized oral drug delivery sector.

GYNECOLOGICAL FUNGAL INFECTION DRUG MARKET

Overview of Gynecological Fungal Infection and Vulvovaginal Candidiasis

Gynecological fungal infections are primarily caused by *Candida* species and most commonly affect the vulva and vagina, leading to conditions such as vulvovaginal candidiasis. These infections typically present with symptoms including vaginal itching, abnormal discharge, burning sensation, and local discomfort. Common predisposing factors include hormonal changes, pregnancy, diabetes, antibiotic use, and immunosuppression, which may disrupt the normal vaginal microecological balance and facilitate fungal overgrowth. While the majority of gynecological fungal infections are mild and responsive to antifungal treatment, recurrent or complicated infections may occur and can have a material impact on quality of life. Effective management generally requires accurate diagnosis, appropriate topical or systemic antifungal therapy, and management of underlying risk factors to reduce recurrence and disease burden.

Vulvovaginal candidiasis (“VVC”) is the most common form of gynecological fungal infection, predominantly caused by *Candida albicans*. It is characterised by pruritus, irritation, abnormal vaginal discharge and discomfort, and represents a frequent reason for gynecological consultation among women of reproductive age. Risk factors include antibiotic use, hormonal fluctuations (such as pregnancy or contraceptive use), diabetes, immunosuppression and elevated estrogen levels. Although most cases of acute VVC are treatable with topical or oral antifungal agents, recurrent VVC, commonly defined in clinical practice as four or more episodes per year, generally requires longer treatment duration or maintenance therapy. Recurrent VVC is often associated with reduced quality of life, and in some cases involves *non-albicans Candida* species with reduced susceptibility to conventional azole antifungals.

Global and China Prevalence of Vulvovaginal Candidiasis, 2020–2035E

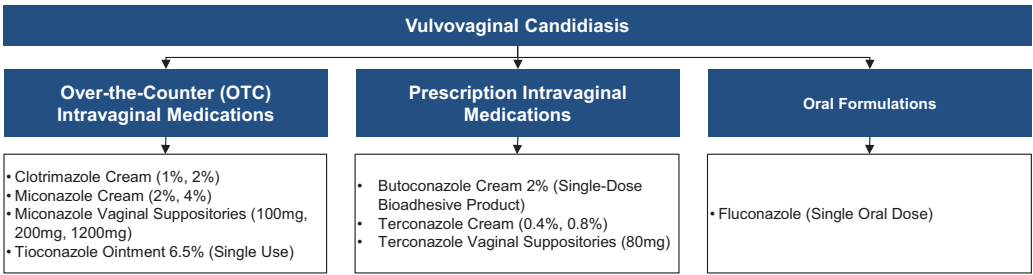
The global prevalence of VVC increased from 445.0 million cases in 2020 to 470.2 million cases in 2025. Driven by demographic factors and persistent predisposing conditions, the number of VVC cases is projected to increase to 494.2 million by 2030, representing a CAGR of 1.0% from 2025 to 2030, and further to 516.7 million by 2035, at a CAGR of 0.9% from 2030 to 2035. In China, the prevalence of VVC increased from 78.8 million cases in 2020 to 80.0 million cases in 2025. The number of cases is expected to grow to 80.8 million by 2030, corresponding to a CAGR of 0.2% from 2025 to 2030, and further to 81.5 million by 2035, at a CAGR of 0.2% from 2030 to 2035. In the US, the prevalence of VVC increased from 9.4 million cases in 2020 to 9.9 million cases in 2025. The number of cases is expected to grow to 10.3 million by 2030, corresponding to a CAGR of 0.8% from 2025 to 2030, and further to 10.7 million by 2035, at a CAGR of 0.7% from 2030 to 2035.

Treatment Paradigm for Vulvovaginal Candidiasis

The treatment paradigm for VVC is primarily based on antifungal therapy, with treatment selection varying by disease severity, recurrence status, causative *Candida* species, and patient characteristics, as reflected in clinical practice in both the United States and China. In the United States, treatment primarily comprises over-the-counter and prescription intravaginal azole formulations, supplemented by single-dose oral fluconazole, forming a relatively standardised regimen for uncomplicated cases, while in China, treatment strategies are more stratified by clinical scenarios, with different regimens adopted for uncomplicated and complicated cases, non-albicans infections, pregnancy, host abnormalities and drug-resistant *Candida*. According to Frost & Sullivan, more than 50% of patients experience recurrence after completion of consolidation therapy, and the recurrence rate increases to 80.9% after discontinuation of weekly maintenance treatment. In addition, existing therapies show reduced efficacy against non-albicans species and face patient adherence challenges associated with repeated or prolonged treatment regimens, indicating structural limitations of current treatment options and an ongoing need for more effective, durable and patient-friendly therapies.

INDUSTRY OVERVIEW

Treatment Paradigm for Vulvovaginal Candidiasis



Source Sexually Transmitted Infections Treatment Guidelines 2021, Frost & Sullivan Analysis

Overseas and China-Marketed Vulvovaginal Candidiasis Drugs

As of the Latest Practicable Date, only four drugs approved for the treatment of VVC both in the United States and China.

Vulvovaginal Candidiasis Drugs Approved by FDA

Genetic Name	Brand Name	Target/MOA	Company	Indication	Category	Administration	Approval Date	Medical Insurance Inclusion Status	Cost per Patient (USD)
Oteseconazole	VIVJOA	CYP51	Mycovia Pharmaceuticals	RRVVC	Antifungal	Oral	2022/4/26	Medicare Part D	~3,000
Ibrexafungerp	BREXAFEMME	Glucan synthase	GSK	VVC	Antifungal	Oral	2021/6/1	Medicare Part D	~540
Fluconazole	DIFLUCAN	CYP51	Pfizer	VVC, etc.	Antifungal	Oral	1990/1/29	Medicare Part D	~6
Miconazole	MONISTAT 7	CYP51	Medtech Products	VVC	Antifungal	Topical	1974/1/30	—	~20

1. Only includes originator, excluding generic drugs

Source: FDA, Frost & Sullivan analysis

Vulvovaginal Candidiasis Drugs Approved by NMPA

Genetic Name	Brand Name	Target/MOA	Company	Indication	Category	Administration	Approval Date	NRDL Inclusion Year	Price RMB /Unit	Dosage Form	Frequency	Cost per Patient (RMB)
Ibrexafungerp	恒美達	Glucan synthase	Scynexis/Hansen	VVC	Antifungal	Oral	2025/4/1	—	NA	0.15g	Twice a day/once daily	NA
Oteseconazole	瑞必康	CYP51	Mycovia Pharmaceuticals	VVC	Antifungal	Oral	2023/6/27	2024	1,680.0	0.15g	Once daily	~1,680
Itraconazole	Sporanox	CYP51	Janssen	VVC, etc.	Antifungal	Oral	2000/2/9	2009	587.5	150ml:1.5g	Twice a day/once daily	~90
Clotrimazole	Canesten	CYP51	Bayer	VVC	Antifungal	Topical	1999/7/28	2009	37.2	0.5g	One-five times daily	~37

1. Only includes originator, excluding generic drugs

Source: NMPA, Frost & Sullivan analysis

Overseas and China Competitive Landscape for Vulvovaginal Candidiasis Pipelines

As of the Latest Practicable Date, only two active Overseas pipeline candidates, which is currently in Phase I/II clinical development for VVC and bacterial vaginitis. In China, only two active competitive landscape of VVC drug pipelines.

Overseas Competitive Landscape for Vulvovaginal Candidiasis Pipelines

Pipeline	Phase	Target/MOA	Company	Indication	Category	Administration	First posted date
BGY-1601	Phase I/II	Microbiome modulation	Nexbiome Therapeutics	VVC, BV	Microbiome-based therapy	Topical	2024/6/10
PL-18	Phase I	Membrane discrimination mechanism	ProteLight	Colpomycosis, bacterial vaginosis, mixed vaginitis	Antibacterial/Antifungal	Topical(Suppository)	2022/4/22

INDUSTRY OVERVIEW

1. Only includes originator, excluding generic drugs
2. Only including pipelines first posted over the past four years

Source: FDA, Frost & Sullivan analysis

Table 16 China Competitive Landscape for Vulvovaginal Candidiasis Pipelines

Pipeline	Phase	Target/MOA	Company	Indication	Category	Administration	First posted date
WXSH0102 . . .	Phase II	NA	Cisen pharmaceutical	VVC	Antifungal	Oral	2024/12/25
PL-18.	Phase I/II	Bacterial and fungal cell membranes	ProteLight	VVC	Antibacterial/ Antifungal	Topical (Suppository)	2023/8/14
GLS-W1100 . . .	Phase I	NA	Hangzhou Grand Biologic	VVC	Biologics	Topical	2025/4/11

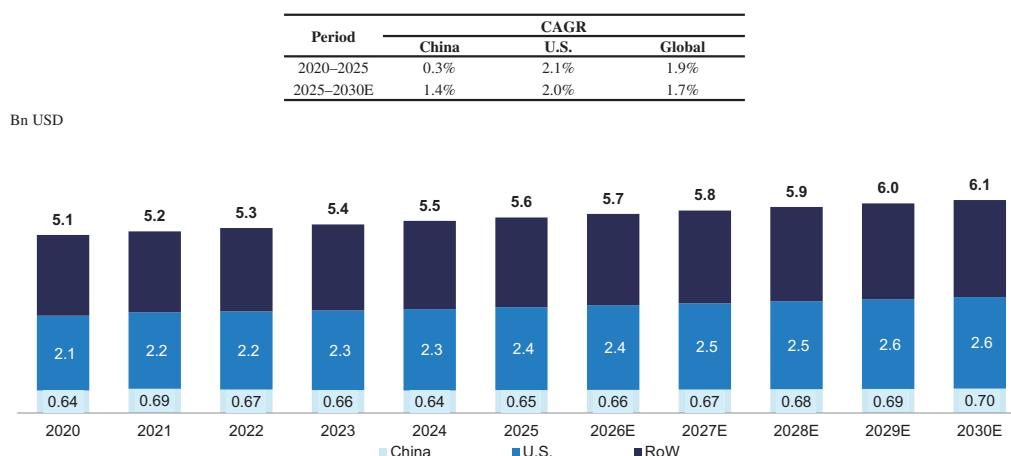
Notes: only includes originator, excluding generic drugs; only including pipelines first posted over the past three years.

Source: CDE, Literature research, Frost & Sullivan analysis

Global and China Vulvovaginal Candidiasis Drug Market, 2020–2030E

The global VVC drug market reached USD5.6 billion in 2025, and is expected to grow to USD6.1 billion by 2030. Over the period from 2020 to 2025, the market grew at a CAGR of 1.9%, and is projected to grow at a CAGR of 1.7% from 2025 to 2030. In 2025, the vulvovaginal candidiasis drug market in U.S. is USD2.4 billion. It is estimated that the vulvovaginal candidiasis drug market in U.S. will grow to USD2.6 billion in 2030 at a CAGR of 2.1%. In China, the VVC drug market amounted to USD0.65 billion in 2025. The market is estimated to increase to USD0.70 billion by 2030. From 2020 to 2025, the China VVC drug market expanded at a CAGR of 0.3%, and is projected to grow at a CAGR of 1.4% from 2025 to 2030. This steady trajectory is underpinned by the essential nature of VVC treatments and an increasing clinical focus on Recurrent VVC (RVVC), which necessitates long-term management and more sophisticated therapeutic regimens. While the overall growth remains moderate, the market is undergoing a qualitative transformation as patient demand shifts to localized therapies with superior safety profiles. This transition to next-generation treatments is expected to bolster market value, providing a highly resilient and defensive revenue base for industry participants.

Global, China, and U.S. Vulvovaginal Candidiasis Drug Market Size, 2020–2030E



Source: Annual reports, expert interviews, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Growth Drivers and Future Trends of Vulvovaginal Candidiasis Drug Market

Limitations of Traditional Therapies and Unmet Needs: The growth of the VVC drug market is primarily driven by the limitations of existing azole-based therapies and evolving patient and regulatory dynamics. A substantial proportion of recurrent VVC patients exhibit poor response or resistance to conventional treatments, creating demand for therapies with novel mechanisms of action. Mixed infections further complicate diagnosis and treatment, supporting the need for broader-spectrum solutions.

Innovative and Differentiated Therapies: The future VVC drug market is expected to evolve toward more innovative and differentiated therapeutic approaches. Antimicrobial peptides and other membrane-targeting agents are being developed to address drug resistance and recurrent disease, while advances in formulation technologies are enabling longer-acting and more convenient vaginal delivery systems.

Challenges, Threats, and Entry Barriers of Vulvovaginal Candidiasis Drug Market

Market Challenges: Treating vulvovaginal candidiasis globally and in China faces significant clinical obstacles, particularly frequent disease recurrence and widespread patient independent medication practices. Unsupervised drug misuse frequently causes inaccurate diagnoses and inappropriate early treatments. Furthermore, balancing potent fungal eradication with the essential preservation of healthy natural vaginal microbiomes remains a highly complex pharmacological challenge for medical researchers.

Market Threats: The rapid emergence of severe antifungal resistance, specifically against widely used azole treatments like fluconazole, aggressively threatens the clinical efficacy of existing global pipelines. Additionally, the massive market availability of extremely cheap generic alternatives constantly exerts heavy downward pressure on prices, drastically reducing the overall commercial profitability of newly introduced premium prescription antifungal medications.

Market Entry Barriers: Manufacturers must successfully master highly localized vaginal drug delivery platforms, such as thermosensitive bioadhesive gels, ensuring prolonged targeted exposure. Furthermore, establishing incredibly rigid intellectual property surrounding uniquely selective, microbiome-sparing molecular mechanisms creates an unimaginably steep scientific barrier, completely blocking standard pharmaceutical companies relying on indiscriminate, outdated conventional antifungal active ingredients.

MARKET ANALYSIS OF OTHER INDICATIONS FOR PEPTIDE DRUG

Obesity

Overview of Obesity

Obesity is a chronic metabolic disease characterised by excessive body fat accumulation and is a major risk factor for multiple comorbidities, including cardiovascular diseases, type 2 diabetes, MASH, and obstructive sleep apnea. The global burden of overweight and obesity is substantial and continues to increase, with approximately 38% of the global population being overweight or obese in 2020 and the related economic impact reaching USD1.96 trillion, while in China the medical costs attributable to overweight and obesity are expected to increase to RMB418 billion by 2030. The obesity management typically requires long-term, multi-modal intervention, including lifestyle modification, pharmacotherapy, and, in severe cases, bariatric surgery. Clinical challenges include poor long-term adherence, weight regain after treatment discontinuation, and limited durability of non-pharmacological interventions, driving increasing reliance on effective pharmacological therapies.

China & Global Market Size of Obesity Therapeutics

The global obesity therapeutics market has expanded rapidly in recent years, driven by rising prevalence and improved pharmacological efficacy. In 2025, the global market for overweight/obesity drugs reached USD29.5 billion. It is projected to expand to USD66.0 billion by 2030, representing a robust CAGR of 17.4% from 2025 to 2030.

From 2020 to 2025, the market size of overweight/obesity drugs in China grew from RMB1.9 billion to RMB9.6 billion, representing a CAGR of 38.2%. Looking ahead, the market is expected to expand rapidly, reaching RMB36.8 billion in 2030 with a CAGR of 30.8% from 2025 to 2030.

INDUSTRY OVERVIEW

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the major markets for which our drug candidates are positioned. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. We have agreed to pay Frost & Sullivan a total fee of RMB0.7 million for the preparation of the Frost & Sullivan Report, and we believe that such fees are consistent with the market rate. The payment of such amount was not contingent upon our successful [REDACTED] or on the results 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 have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the pharmaceutical market 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.