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OVERVIEW

We are an antimicrobial peptide (“AMP”) therapeutics company. We focus on two core therapeutic areas, namely anti-infectives and metabolic diseases and are dedicated to addressing significant unmet global health needs through our proprietary breakthrough technologies and drug candidates.

Our Core Product, PL-5 (Pecelaganan, 培來加南), received NDA approval in June 2026 for secondary infection of burn wounds, making it is the FIC Ganan-class drug globally that has received NDA approval, according to Frost & Sullivan. Leveraging the “Membrane Discrimination Mechanism,” a theory our founder first co-proposed in 2006, PL-5 represents a novel mechanism of action, with peptide secondary structure folding to disrupt the integrity of microbial membranes, to address the challenges associated with antibiotic-resistance. With its key advantages of anti-resistance, broad-spectrum and high efficacy, PL-5 offers a breakthrough solution for treating multidrug-resistant infections, and we plan to pursue additional indications for secondary infections in other types of wounds through further clinical trials in China, such as the treatment of DFI, as well as the treatment and prevention of infections in wounds caused by physical trauma. It has been consecutively selected as the National Major Scientific and Technological Special Project for “Significant New Drugs Development” during the Twelfth and the Thirteenth Five-Year Plan Period (國家十二五、十三五“重大新藥創製”科技重大專項).

Our key product, PL-3301, is a thermosensitive peptide gel for the treatment of oropharyngeal candidiasis. Our another key product, PL-18, is an AMP drug for the treatment of vulvovaginal candidiasis (“VVC”), and may also have applications in treating a range of gynecological infections, including bacterial vaginitis, fungal vaginitis and mixed vaginitis. Both key products are also based on the “Membrane Discrimination Mechanism,” aiming to fill clinical gaps in their respective treatment fields.

In addition to the aforementioned anti-infective drugs, we are actively expanding our pipeline into therapeutic areas including metabolic diseases, oncology, and autoimmune disorders, with multiple assets currently at the preclinical stage.

Our preclinical asset PL-MD-333 is an oral FGF19/FGF21 inducer and lipid metabolism modulator, according to Frost & Sullivan. Preclinical studies indicate that PL-MD-333 may reduce adiposity, increase the percentage of lean muscle mass, and demonstrate synergistic effects when used in combination with glucagon-like peptide-1 (“GLP-1”) receptor agonists such as semaglutide, positioning it as a promising candidate with the potential to transform the treatment paradigm for metabolic diseases.

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Area	Item	MoA/Target	Indication	Region	Dosage Form	Regulatory Authorities	Preclinical/IND Enabling	Phase I	Phase II	Phase III or Pivotal	NDA	Sponsor	Source	Current Status/Next Milestone ^(a)	Commercial Rights
Anti-infection	PL-5  <small>Pre-equivalent^(b)</small>	Membrane Discrimination Mechanism	Secondary infection of burn wounds	China	Spray	NMPA						The Group	Self-developed	NDA Approved in June 2026	 正大天晴 Chinese Mainland (Chia Tai Tianqing) ex-Chinese Mainland (the Group)
			IWGDF Grade II diabetic foot infection	US	Spray	FDA ^(c)						The Group	Self-developed	Phase II initiated in January 2024; To complete Phase II by September 2028	
	PL-3301 	Membrane Discrimination Mechanism	Oropharyngeal candidiasis infection	China	Thermo-sensitive gel	NMPA						The Group	Self-developed	To initiate Phase II by September 2026	
			Pulmonary infection	US	Inhalant	FDA						The Group	Self-developed	IND Approval in June 2024 ^(d)	
Metabolism	PL-18 	Membrane Discrimination Mechanism	Vulvovaginal candidiasis	China/US	Suppository	NMPA/FDA						The Group	Self-developed	To submit IND by December 2027	To be developed independently
				China	Suppository + Gel ^(e)	NMPA						The Group	Self-developed	Phase II initiated in October 2024; To complete Phase II by January 2025; To submit IND by January 2025 for review of our supplementary submission	
	PL-MD-333P ^(f)	FGF19/FGF21 (small molecule; peptidomimetic)	Obesity	US	Suppository	FDA						The Group	Self-developed	Phase II Approval in October 2024 ^(g)	
				China/US	Capsule	NMPA/FDA						The Group	Self-developed	To submit IND by March 2027	

Note:  Core Product  Key Product  Directly to Phase II clinical trial

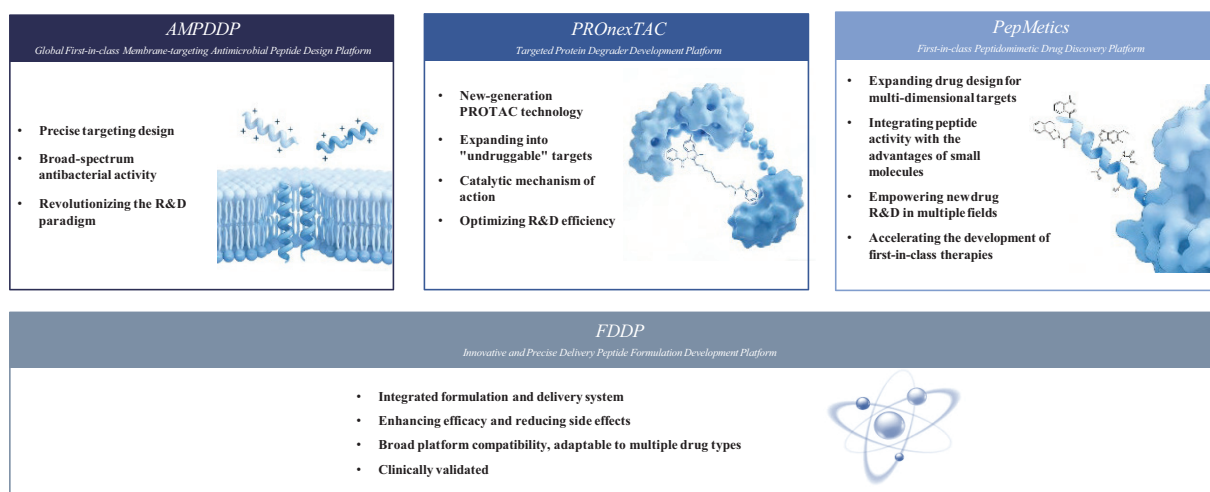
IWGDF refers to the International Working Group on the Diabetic Foot; MASH refers to metabolic dysfunction-associated steatohepatitis; NMPA refers to the National Medical Products Administration of the PRC; FDA refers to the U.S. Food and Drug Administration; FGF19/FGF21 refers to fibroblast growth factor 19 and fibroblast growth factor 21; PARP-1 refers to poly(ADP-ribose) polymerase 1.

- (1) All of our candidate products were independently developed by us, and with respect to the Core Product, PL-5, the University of Colorado licensed to us only the patent rights relating to the underlying compound formula, rather than transferring a complete drug asset. Our founder, Dr. Chen, is one of the principal inventors of the underlying antimicrobial peptide molecule of PL-5, which was developed based on the results of his postdoctoral research project. The transformation from a compound formula into a candidate drug asset primarily depended on our independently completed drugability development, process optimization, preclinical studies, and subsequent clinical development. The University of Colorado and the other co-inventors were not involved in this process. Accordingly, it would not be appropriate to regard PL-5 as a drug asset acquired through a typical in-licensing or acquisition arrangement. For further details, see “Business — Our Collaborations and Licensing Arrangements — Licensing Arrangements with the University of Colorado.”
- (2) In December 2022, we entered into an exclusive commercial cooperation agreement with Chia Tai Tianqing regarding the rights and interests of PL-5 in Chinese Mainland. For further details, please see “Business — Our Collaborations and Licensing Arrangements — Exclusive Commercial Cooperation Agreement with Chia Tai Tianqing.”
- (3) In March 2022, after reviewing the data generated from our Phase I and Phase II clinical trials conducted in China, together with other relevant submission materials, the FDA raised no objection to PL-5 proceeding directly to a Phase II clinical trial. The FDA’s no-objection position was based on its review of the relevant clinical data and other submission materials, and was not subject to any preconditions that we were required to satisfy before commencing the Phase II clinical trial.
- (4) In June 2024, we received an approval from the FDA authorizing us to initiate a Phase I clinical trial for PL-3301.
- (5) Based on the results of the Phase Ib/II clinical trial, a twice-daily dosing regimen is planned for the subsequent clinical development of PL-18. However, the excipient levels in the suppository formulation are not suitable for twice-daily administration. Animal efficacy studies demonstrated that twice-daily administration of PL-18 gel showed antifungal efficacy comparable to that of the positive control. Accordingly, the formulation is proposed to be changed from a suppository to a gel to support twice-daily administration. For further details regarding the clinical trial results and our communications with the CDE, please see “Summary of Clinical Trial Results” and “Material Communications with Competent Authorities,” respectively, under “Business — Our Products and Pipeline — PL-18 (α-Helical Antimicrobial Peptide), Our Key Product.”
- (6) In October 2024, after reviewing the data generated from our Phase I clinical trials conducted in China and Australia, together with other relevant submission materials, the FDA raised no objection to PL-18 proceeding directly to a Phase II clinical trial. The FDA’s no-objection position was based on its review of the relevant clinical data and other submission materials, and was not subject to any preconditions that we were required to satisfy before commencing the Phase II clinical trial.
- (7) All product candidates shown in this pipeline chart are currently under development as monotherapies, except for PL-MD-333, which has also shown the potential for combination treatment with semaglutide.
- (8) “Clinical trial completion” generally refers to the date on which the last subject completes the final protocol-specified visit or procedure in the relevant clinical trial, commonly understood as last patient out, last subject last visit or last participant last visit, with reference to ClinicalTrials.gov, the ICH E3 guideline and ChtCTR clinical trial registration practice.

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Currently, our product pipeline is progressing steadily. PL-5 has received NDA approval as a Class 1 innovative drug from the NMPA in June 2026, and we are in the process of conducting a Phase II clinical trial for PL-5 in the U.S., PL-3301 and PL-18 are now in clinical development, while multiple preclinical assets are advancing under their respective development plans. Moving forward, we will remain committed to focusing on core technology upgrades and clinical translation of our pipeline. We will continue to deepen our presence in the global peptide therapeutics field through differentiated strategy, aiming to provide more clinically meaningful treatment solutions for patients worldwide.

To facilitate our drug discovery, we have established four technology platforms that significantly support our research and development (“R&D”): the membrane-targeting mechanism-based antimicrobial peptide *de novo* design platform (“AMPDDP”), the PROTAC-based targeted protein degrader discovery platform (“PRONexTAC”), the novel mechanism-based peptidomimetic discovery and development platform (“PepMetrics”), and the innovative peptide formulation diversified development and precision delivery platform (“FDDP”). These platforms underpin our differentiated product pipeline, characterized by high technological barriers and outstanding clinical value. It enables the development of multiple potential first-in-class products designed to overcome limitations of traditional therapies.



OUR COMPETITIVE STRENGTHS

Multiple peptide-based therapeutics in the field of anti-infective therapy

Our core product PL-5 is a FIC Ganan-class anti-infective drug

Our core product PL-5 is a novel-mechanism anti-infective AMP drug, with the molecular name “Pecelaganan.” According to Frost & Sullivan, PL-5 is the FIC Ganan-class drug globally that has received NDA approval, according to Frost & Sullivan, and it represents a novel mechanism of action to address the challenges associated with antibiotic-resistance. The novelty of our Core Product primarily lies in its peptide molecular design, which gives rise to its distinctive molecular property of being inducible into an α -helical structure.

We have completed Phase III clinical trials for PL-5 targeting secondary wound infection in China, and applied for NDA approval from the NMPA as a Class 1 new drug in December 2024. We received the NDA approval in June 2026, making it a FIC Ganan-class anti-infective drug. In the meantime, we are conducting a Phase II clinical trial in the U.S. for the treatment of diabetic foot infections classified as International Working Group on the Diabetic Foot Grade II (“IWGDF Grade II”), which is expected to be finalized by the third quarter of 2028.

Compared with conventional antibiotics, AMPs offer three core advantages: (i) activity against antibiotic-resistant bacteria with a low risk of inducible resistance, as PL-5 showed *in vitro* antibacterial activity against multiple antibiotic-resistant pathogens listed in the World Health Organization’s Bacterial Priority Pathogens List (2024 update), including *Acinetobacter baumannii*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*, and, based on its cell membrane-targeting mechanism and our resistance induction studies, PL-5’s MIC remained generally stable upon repeated exposure; (ii)

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broad-spectrum antibacterial activity, as PL-5 adopts a “Membrane Discrimination Mechanism” and has shown inhibitory and bactericidal activity against a broad range of clinically isolated strains across multiple Gram-positive and Gram-negative bacterial species in both preclinical *in vitro* studies and our Phase III clinical trials; and (iii) high effectiveness, as the published literature reports that AMPs can achieve rapid bacterial killing, and PL-5’s activity against antibiotic-resistant bacteria and broad spectrum may reduce reliance on bacterial culture and antimicrobial susceptibility testing before initiating therapy.

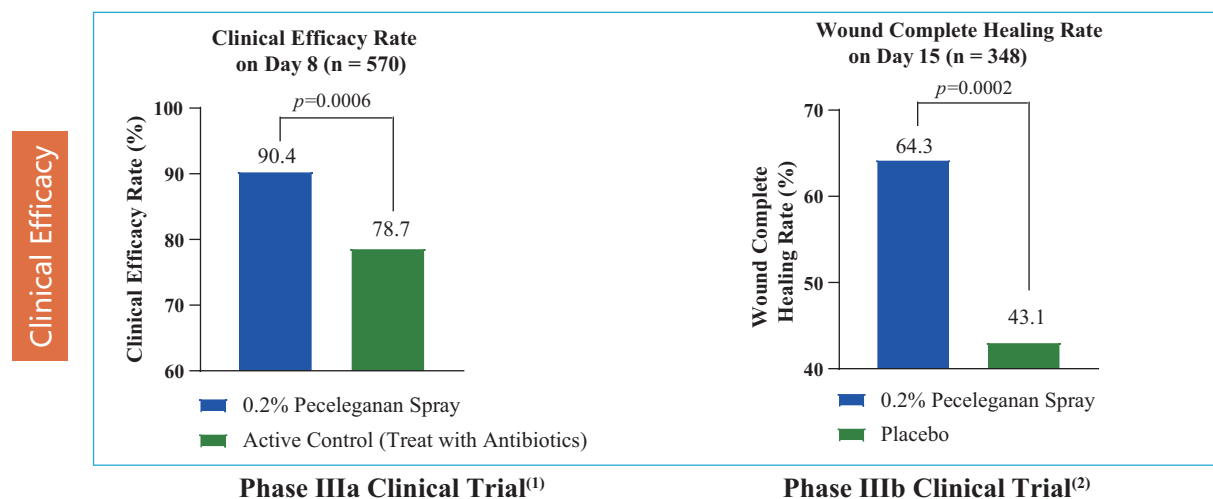
Secondary Wound Infections

According to Frost & Sullivan, the incidence number of secondary wound infections worldwide and in China was 79.4 million and 18.9 million in 2025, respectively. According to the same source, the market size for the secondary wound infection drug market in 2025 is USD12.2 billion worldwide and USD0.9 billion in China. The worldwide market size for the secondary wound infection drug is expected to grow to USD14.1 billion in 2030 at a CAGR of 3.0% from 2025 to 2030, and the China market size for the secondary wound infection drug is expected to grow to USD1.1 billion in 2030 at a CAGR of 4.1% from 2025 to 2030, according to Frost & Sullivan.

Despite the significant disease burden, current market lacks effective treatment options. Specifically, with the widespread use of antimicrobials, the issue of pathogen resistance is becoming increasingly severe, with many causative bacteria having developed multidrug resistance to traditional antibiotics. WHO considers antimicrobial resistance to be one of the top global public health threats in the 21st century. Furthermore, according to Frost & Sullivan, clinical treatment typically necessitates prior bacterial identification, which may lead to delays in intervention. In the meantime, non-pharmacological wound care therapies such as dressings, nitric oxide gas therapy, and negative pressure wound therapy have demonstrated limited efficacy in certain patient populations. Consequently, a significant number of patients have to undergo surgical debridement, and in severe cases, they may face an increased risk of limb amputation.

In our clinical trials in China, PL-5 has demonstrated an encouraging efficacy and safety profile for the treatment of secondary wound infections, showing activity against a broad range of multidrug-resistant pathogens. Clinical data indicate that PL-5 can achieve complete eradication of drug-resistant bacteria in certain cases, including *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, Methicillin-resistant *Staphylococcus aureus* (“MRSA”) and multidrug-resistant *Acinetobacter baumannii* carrying the NDM-1 gene, all of which are among the most clinically challenging drug-resistant pathogens worldwide according to WHO.

The following diagram shows the clinical efficacy of PL-5:



Notes:

- (1) Clinical efficacy rate on Day 8, the primary endpoint of the Phase IIIa clinical trial, 0.2% Pecemegagan spray in the treatment group as compared with the active control drug silver sulfadiazine (“SSD”) cream, an antibiotic.
- (2) Wound complete healing rate on Day 15, the primary endpoint of the Phase IIIb clinical trial, 0.2% Pecemegagan spray in the treatment group as compared with the placebo control.

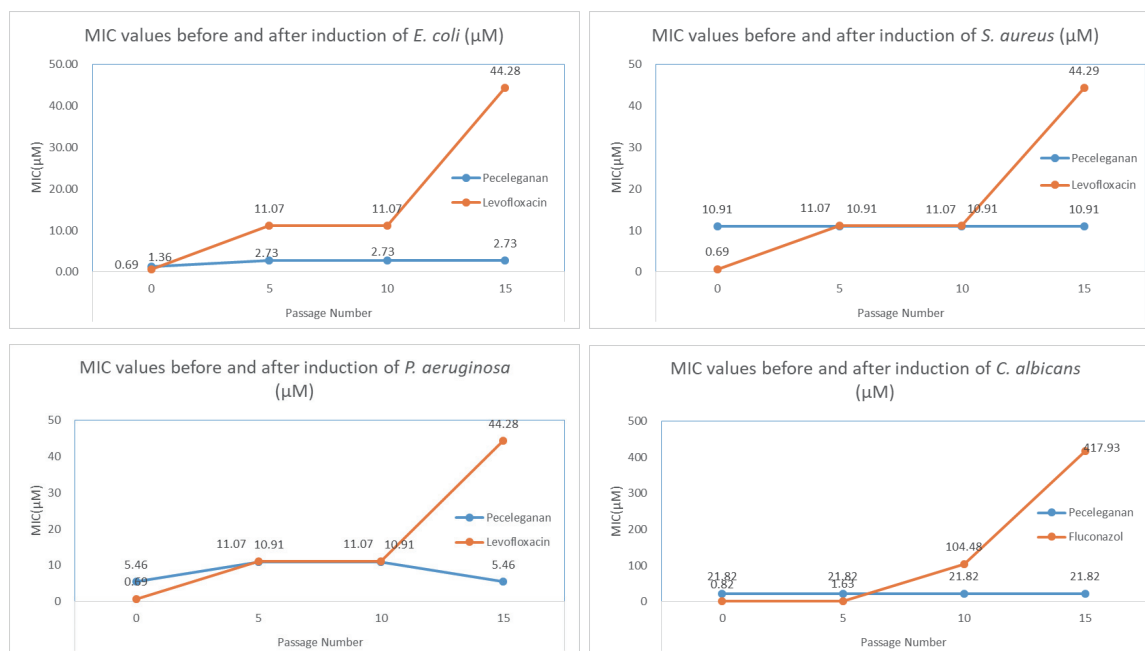
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Superiority over active control (Phase IIIa). The 0.2% Peceleganan Spray achieved a clinical efficacy rate of 90.4% on Day 8, demonstrating a statistically significant advantage over the 78.7% of the active control group ($p = 0.0006$).

Accelerated healing versus placebo (Phase IIIb). On Day 15, the wound complete healing rate for the treatment group reached 64.3%, significantly higher than the 43.1% observed in the placebo group ($p = 0.0002$), confirming the product’s ability to effectively promote wound closure.

Favorable Safety Profile. PL-5 has also demonstrated a favorable safety profile. The safety data for the PL-5 were comparable to that of the placebo, with a low incidence of adverse events. Furthermore, given that PL-5 exhibits broad-spectrum and rapid antimicrobial activity, it may reduce the need for bacterial identification testing prior to use.

Based on the “Membrane Discrimination Mechanism” co-proposed by our founder, Dr. Chen Yuxin in 2006, PL-5 exhibits activity against a broad range of bacteria. It primarily interacts with bacterial cell membranes, leading to rapid disruption of membrane integrity. In addition, the development of resistance to membrane-active peptides, such as PL-5, whose sole target is the cytoplasmic membrane, is not expected, because this would require substantial changes in the lipid composition of cell membranes of microorganisms. In our preclinical studies, under serial passage induction conditions (i.e., repeated exposure designed to induce resistance), the minimum inhibition concentration (“MIC”) of PL-5 remained generally stable against bacteria (*E. coli*, *S. aureus* and *P. aeruginosa*; and fungi (*C. albicans*). In contrast, the MIC of the antibiotics increased to approximately 44.28~44.29 μM for levofloxacin (bacteria) and 417.93 μM for fluconazole (fungi), suggesting a low risk of resistance induction for PL-5 in this *in vitro* model. In antibiotic resistance induction experiments, bacteria developed a 64-fold increase in resistance against levofloxacin and the fungus developed an approximately 502-fold increase in resistance against fluconazole. However, bacteria and fungus exhibit almost no resistance against PL-5. The following figure shows the resistance induction tests:



In light of the favorable clinical trial results demonstrated by PL-5 as compared to antibiotics, we believe PL-5 is well positioned to address the clinical needs and capture market opportunities.

Diabetic Foot Infections

Among chronic wound infections, diabetic foot infections pose particularly serious clinical risks. According to Frost & Sullivan, diabetes-related complications result in a lower-limb amputation approximately every 20 seconds worldwide. At this moment, millions of patients with diabetes suffer from foot ulcers that are difficult to heal. According to Frost & Sullivan, the number of patients

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suffering from diabetic foot infections in 2025 was as high as 32.5 million globally. The market size for the diabetic foot infection drug market in 2025 is USD3.1 billion globally and is expected to grow to USD3.4 billion by 2030, according to Frost & Sullivan.

We are advancing a Phase II clinical trial for PL-5 for the treatment of diabetic foot infections in the U.S., further expanding its indication scope. As a critical scenario for severe wound infections, diabetic foot presents high amputation risks and limited existing treatment options. This clinical trial is designed to specifically address the clinical challenges of diabetic foot infections, broaden the clinical application scenarios for PL-5, cover a wider range of unmet treatment needs, and enhance the product’s market value and clinical impact. In 2022, the U.S. Food and Drug Administration (“FDA”) approved our Phase II clinical trial of PL-5 in the U.S., following its review of the existing clinical data from China, without requiring a prior Phase I study. As of the Latest Practicable Date, the Phase II trial was ongoing with planned enrollment of 90 subjects and expected completion in the third quarter of 2028.

In addition, in the Phase IIIa clinical trial for the treatment of secondary wound infections conducted in China, there were 19 patients with diabetic foot infections enrolled. In the analysis for clinical efficacy of these 19 patients, the treatment group demonstrated superior clinical efficacy compared to the positive control group treated with SSD. Based on the full analysis set (“FAS”), the clinical response rate on Day 8 was 94.1% (16/17) for the treatment group, in contrast to 0.0% (0/2) for the positive control group. This difference was statistically significant ($p = 0.0175$).

PL-5 utilizes a spray formulation that can directly reach deep wound sites, overcoming the limitation of traditional ointments in covering wound crevices. This spray formulation, when combined with medicated saturated gauze dressings, allows rapid penetration into deep wound areas where bacterial proliferation occurs, thus improving bactericidal efficiency. Simultaneously, it avoids the scraping procedure required during traditional ointment dressing changes, reducing secondary injury and patient pain, significantly enhancing patient compliance, and aligning with practical clinical treatment needs.

We have entered into exclusive commercial cooperation agreement for the commercialization of PL-5 with Chia Tai Tianqing in December 2022. During the collaboration, we have granted Chia Tai Tianqing exclusive rights to promote PL-5 and conduct other commercialization activities in the Chinese mainland for all indications approved by the relevant authorities. The collaboration with Chia Tai Tianqing aims to leverage its mature commercialization infrastructure in the Chinese mainland to accelerate the early-stage commercialization of our Core Product, PL-5, while also providing financial support for our ongoing global R&D and daily operations related to the product. We will continue to be responsible for PL-5’s R&D, global clinical trials, and regulatory strategy. We also retain the commercialization rights outside the Chinese mainland during the collaboration.

Our key product, PL-3301, is a potential first-in-class thermosensitive gel formulation developed for the treatment of oropharyngeal candidiasis

Our key product, PL-3301, is an innovative antifungal drug candidate with a novel mechanism of action. It is an α -helical antimicrobial peptide-based therapeutic and a potential first-in-class thermosensitive gel formulation specifically designed for treating oropharyngeal candidiasis. We developed PL-3301 in-house and hold independent global intellectual property rights relating to it. We are currently advancing clinical trials for PL-3301 targeting the oropharyngeal candidiasis (“OPC”) indication. Currently, we have completed a Phase Ia clinical trial and a Phase Ib clinical trial for PL-3301 in China, and we have been granted an approval from the FDA for a Phase I clinical trial in the U.S. in 2024. All these clinical trials in China and the U.S. are for the treatment of OPC.

OPC is a highly prevalent infectious disease among immunocompromised populations. According to Frost & Sullivan, in China, the number of cases of OPC reached approximately 81.7 million in 2025 and are most commonly observed in high-risk groups such as cancer patients undergoing radiotherapy or chemotherapy, HIV/AIDS patients, and the frail elderly population. Specifically, patients with severe OPC may experience extensive oral mucosal erosion, ulceration, and severe pain, rendering them unable to eat or swallow normally and, in extreme cases, requiring nasogastric feeding for nutritional support. Current clinical treatments face significant bottlenecks: Existing antifungal drugs are increasingly affected by drug resistance, leading to diminishing clinical efficacy; oral administration is prone to

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saliva wash-out, resulting in short drug retention time on mucosal lesions and necessitating frequent dosing to maintain effective concentrations; and some drugs are associated with side effects, making them unsuitable for use in severely immunocompromised patients.

PL-3301’s mechanism of action targets the fungal cell membrane, offering potent fungicidal activity with a low propensity for inducing resistance. Preclinical data demonstrate that PL-3301 exhibits highly effective antifungal activity against *Candida albicans*, achieving fungal killing rates of over 90% in relevant animal models. Unlike conventional antifungal agents that rely on interference with fungal metabolic enzymes, PL-3301 acts by disrupting the integrity of the fungal cell membrane. This mechanism of action fundamentally reduces the likelihood of resistance development, effectively addressing the key clinical limitation of resistance associated with traditional antifungal therapies.

PL-3301 is a potential first-in-class peptide-based thermosensitive gel formulation, optimally designed for oral mucosal administration. The formulation is liquid at room temperature but rapidly transforms into gel upon contact with the oral mucosa at physiological temperatures of 30–35°C. Following administration, it adheres firmly to the infected site, enabling sustained drug release for up to 24 hours. This formulation is designed to solve the industry-wide challenge of rapid drug wash-out in traditional oral topical therapies. By enabling prolonged mucosal retention and sustained exposure, PL-3301 is intended to reduce the need for frequent dosing. Moreover, the gel formulation is gentle in texture and non-irritating to damaged mucosa, significantly improving patient compliance and aligning perfectly with the practical clinical needs for treating oral infections in immunocompromised populations.

PL-3301 has the potential to be further developed across additional mucosal candidiasis indications, enriching its prospective clinical application scenarios. In addition to its current focus on OPC, we may explore the development of PL-3301 for other candidiasis indications, such as esophageal candidiasis and cutaneous candidiasis, as well as other mucosal candidiasis. This strategy aims to address the unmet needs across different infection sites and patient populations, continuously enhancing PL-3301’s clinical value and market reach.

In particular, we are advancing the preclinical development of PL-3301 for a pulmonary infection indication, and plan to submit an IND application for this indication by December 2027.

Our key product, PL-18, is a potential first-in-class therapeutic designed to treat mixed gynecological bacterial and fungal infections

Our key product, PL-18, is an innovative anti-infective drug candidate with a novel mechanism of action. It is an α -helical AMP-based therapeutic, for which we hold global intellectual property rights. Preclinical data indicates that PL-18 shows broad activity across multiple gynecological infection models, including bacterial vaginitis, VVC, and mixed vaginitis. Currently, we are advancing clinical trials for PL-18 for the treatment of VVC. As of the Latest Practicable Date, we have completed a Phase I clinical trial in Australia and a Phase I and a Phase Ib/II clinical trial in China to evaluate PL-18 administered as a vaginal suppository. We have obtained approval from the FDA to conduct a Phase II clinical trial in the U.S..

Gynecological infections are a common disease among women. In China, the prevalence of VVC reached approximately 80.0 million in 2025 with a persistently high recurrence rate, according to Frost & Sullivan. Existing clinical treatment options are subject to significant limitations. Gynecological infections are often polymicrobial in nature, involving both bacterial and fungal pathogens. However, existing antibacterial therapies are effective only against bacterial pathogens, while antifungal agents only target fungal infections. As a result, the treatment of mixed infections typically requires combination therapy. This not only increases the patient’s medication burden and risk of adverse reactions, but also easily induces the development of drug-resistant strains. Furthermore, traditional topical formulations often cause significant irritation, leading to poor patient compliance and resulting in limited treatment.

PL-18 is designed to exhibit both antibacterial and antifungal activity, to address the unmet medical need associated with the treatment of mixed infections. As a single-agent therapeutic, PL-18 differs from the compound formulations commonly used in current clinical practice for mixed bacterial and fungal infections. Our preclinical data indicate that PL-18 has demonstrated effective eradication activity against a range of common gynecological bacterial and fungal pathogens. By enabling the

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treatment of mixed infections with a single therapeutic agent, PL-18 is designed to reduce the need for combination therapy and to address a key clinical limitation associated with existing treatment approaches.

PL-18 currently utilizes a peptide suppository formulation tailored for localized gynecological treatment, and we are also conducting preclinical studies on a gel formulation of PL-18. Both formulations are intended to be gentle and non-irritating, allowing for direct action at the site of infection and enabling precise drug delivery with sustained release. This convenient administration method eliminates the need for concomitant medications, significantly reducing treatment complexity and psychological burden for patients, thereby improving treatment compliance and aligning well with the practical clinical requirements for the management of gynecological infections.

A differentiated product pipeline across multiple therapeutic areas with significant clinical needs, aiming to overcome the limitations of traditional therapies

Metabolism and Autoimmunity Product Candidate PL-MD-333

PL-MD-333 is a novel mimetic peptide drug candidate designed to combine the functional characteristics of peptides with certain advantages of small-molecule therapeutics, and is a potential first-in-class FGF19/FGF21 oral metabolic regulator for the treatment of obesity, according to Frost & Sullivan.

According to Frost & Sullivan, in China, obesity affected over 655.4 million adult patients in 2025. Existing clinical treatments face significant limitations: In the treatment of obesity, GLP-1-based therapies are primarily administered via injection and may be associated with adverse effects such as appetite suppression, muscle loss, depression, and potential cancer risks, and often lead to a weight-loss plateau.

Based on its differentiated mechanism of action, PL-MD-333 is designed to address certain limitations associated with existing therapeutic approaches. Preclinical data indicate that PL-MD-333 acts via multi-target mechanisms. In obesity models, it achieves fat loss while increasing muscle mass, without inducing appetite suppression-related side effects. In addition, when evaluated in combination with semaglutide, PL-MD-333 demonstrated synergistic effects in preclinical studies, including the potential to mitigate weight-loss plateaus observed with GLP-1-based therapies.

PL-MD-333's oral formulation is ideal for long-term treatment. The oral dosage form offers high convenience, eliminating the need for injections and significantly improving patient compliance. This profile aligns perfectly with the practical needs of long-term treatment for metabolic and chronic inflammatory diseases.

Independently developed core technology platforms, enhancing innovation competitiveness, empowering advancements across diverse therapeutic fields

We have developed four technology platforms to support the discovery, optimization and formulation development of our drug candidates. We initially developed AMPDDP as our antimicrobial peptide discovery and development platform for the rational design and optimization of peptide candidates. Building on our experience in peptide research, we subsequently developed PepMetrics to extend our technological capabilities from natural amino acid-based peptides to peptide mimetics as part of our molecular design strategy. As our research further advanced into metabolic and autoimmune therapeutic areas, we identified the applicability of PROTAC technology, which enables the use of peptides as targeting moieties for the conjugation of small molecules, and accordingly established PRONexTAC to support research and development in such therapeutic areas. We also established FDDP as our formulation development platform, which could further support the formulation development of drug candidates derived from these discovery platforms.

The AMPDDP

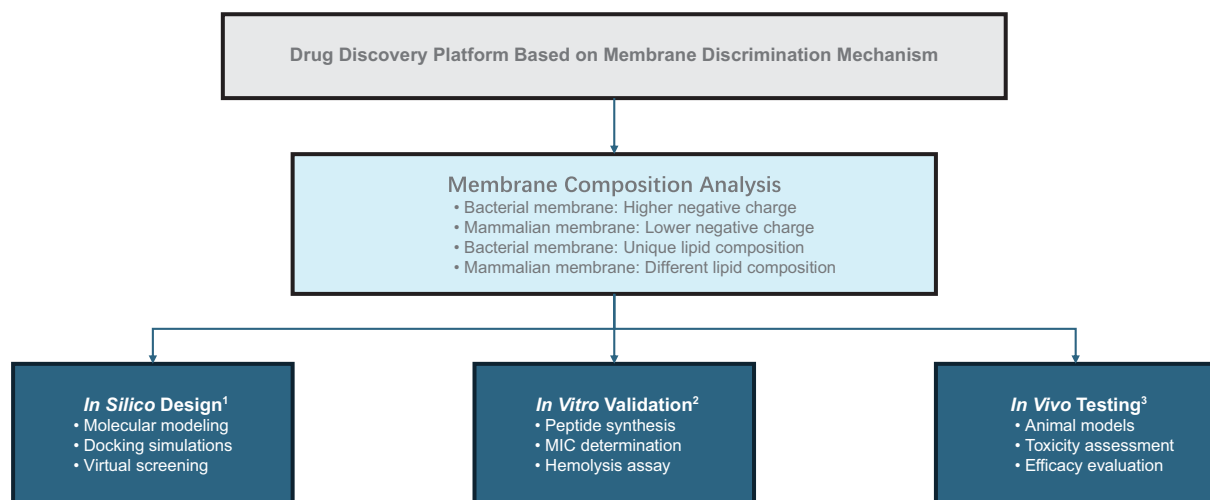
Among these platforms, AMPDDP serves as our discovery, design and molecular optimization platform for peptide candidates, and is primarily relevant to our Core Product, PL-5, and our key products, PL-18 and PL-3301. PL-5, PL-18 and PL-3301 were designed and optimized based on our continued research into the structural characteristics of antimicrobial peptides, Membrane

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Discrimination Mechanism and structure-activity relationships. Their molecular design logic and screening methods reflect the technical capabilities of AMPDDP in antimicrobial peptide sequence generation, rational modification, activity evaluation and lead compound screening.

Since microbial cell membranes and human cell membranes have different surface characteristics, including charge and lipid composition, we design and screen peptide molecules that are intended to attach to and disrupt microbial membranes while minimizing damage to human cells. The following workflow illustrates how the underlying technologies are applied in the design, validation and testing process.

Antimicrobial Peptide *De Novo* Design Process (AMPDDP)



Notes:

1. In the design stage, we use molecular modeling to construct and analyze the structures of AMPs and cell membranes. Docking simulations are generally used to predict how peptides with different amino acid sequences may bind to and insert into bacterial membranes. Virtual screening is generally used to compare a large number of peptide sequences based on parameters, such as hydrophobicity, amphipathicity, helicity, charge and predicted membrane-binding ability. Based on the screening results, we select peptide sequences for synthesis and validation.
2. In the *in vitro* validation stage, the selected peptides are produced through peptide synthesis. We conduct minimum inhibitory concentration (“MIC”) tests to determine the lowest concentration at which each peptide inhibits the growth of the relevant microorganism. We also conduct hemolysis assays to assess whether the peptide damages human cells. The results of the antibacterial and hemolysis tests are considered together to identify peptides that potentially demonstrate antibacterial activity at concentrations below those associated with material damage to human cells.
3. In the *in vivo* testing stage, the selected peptides are evaluated in animal infection models. We assess whether treatment reduces the relevant microbial burden and improves other disease-related indicators. Candidates demonstrating the desired efficacy and safety profile are selected for further preclinical development.

In particular, the AMPDDP stands out in the field of AMP development due to its efficiency and precision. Peptides designed using the platform have demonstrated low minimum inhibitory concentrations in preclinical studies against multidrug-resistant pathogens, such as *Acinetobacter baumannii*, *Staphylococcus aureus* and *Candida albicans*, with activity that is often comparable to or better than that of conventional antibiotics. It combines *de novo* design and membrane biology to deliver safe, effective solutions against infectious diseases. This platform not only accelerates our R&D efforts but also our efforts to address the growing global challenge of antimicrobial resistance.

The PRONexTAC

The PRONexTAC is an innovative computational and experimental framework developed by us to advance targeted protein degradation therapeutics. As an upgraded protein degrader platform based on traditional PROTAC technology, the PRONexTAC integrates advanced AI-driven design, high-throughput screening, and mechanistic insights to engineer bifunctional degraders that induce selective degradation of disease-associated proteins through the ubiquitin-proteasome system. In simple terms, instead of merely blocking a disease-related protein, this platform is designed to create molecules that help the body’s own protein disposal system recognize and remove such protein. This platform addresses limitations in conventional drug discovery by enabling the degradation of previously “undruggable” targets, such as those lacking enzymatic pockets, offering a transformative approach to

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treating cancers, neurodegenerative diseases, autoimmune disorders, and other conditions driven by aberrant protein activity. PRONexTAC supports the discovery and optimization of targeted protein degraders, particularly for disease-related proteins that may be difficult to address using conventional small-molecule inhibitors. It contributes to target selection, molecular design, activity screening and lead optimization for degrader candidates.

The PRONexTAC employs a modular, end-to-end workflow to streamline degrader development. The PRONexTAC excels in efficiency, versatility, and therapeutic potential, setting it apart from traditional small-molecule inhibitors. Unlike traditional inhibitors, which typically require sustained target occupancy to maintain therapeutic effect, degraders developed by our PRONexTAC are intended to function through a catalytic mode of action, whereby a single degrader molecule can induce the degradation of multiple target proteins via the ubiquitin-proteasome system. Based on preclinical observations, this mechanism may enable prolonged pharmacological activity at relatively low concentrations (often nanomolar to picomolar ranges), potentially reducing off-target effects and resistance risks. By focusing on degradation rather than inhibition, it unlocks new avenues for treating complex diseases, bringing us to innovate at the forefront of biomolecular engineering.

The PepMetrics

The PepMetrics is developed by us to support the identification of therapeutic candidates that address complex biological mechanisms, including protein-protein interactions (“PPIs”) that are traditionally considered challenging for conventional small-molecule approaches, according to Frost & Sullivan. Peptidomimetics are small molecules designed to mimic certain useful features of peptides, while aiming to improve properties such as oral administration, stability and manufacturability. This platform helps us borrow the biological “shape” or function of peptides and turn it into drug-like small molecules. By enabling the design of small-molecule compounds that mimic the structural and functional attributes of peptides, the PepMetrics is designed to bridge certain limitations between traditional small-molecule drugs and biologics. This platform facilitates the modulation of multiple disease-relevant targets across a range of therapeutic areas, including metabolic diseases, cancer, neurodegenerative disorders, and autoimmune conditions. By expediting the discovery and refinement of lead compounds, the PepMetrics is designed to support the advancement of differentiated and potentially first-in-class therapeutic candidates.

Our PepMetrics stands out for its innovative approach to overcoming limitations in conventional drug discovery, delivering superior efficiency and therapeutic potential. PepMetrics is aiming to support the design and optimization of peptidomimetic compounds, including candidates intended to act on challenging biological targets or protein interactions. It is expected to facilitate molecular design, synthetic route optimization, activity screening and improvement of drug-like properties. This platform embodies our dedication to pioneering peptidomimetic therapeutics, empowering the discovery of novel drugs that tackle complex biological challenges, and driving advancements in treating intractable diseases. It primarily supports the discovery and development of our PL-MD-333.

The FDDP

The FDDP is an integrated formulation and delivery system pioneered by us to support the development of pharmaceutical products, particularly peptide-based therapeutics. In simple terms, after a drug molecule is identified, FDDP helps us decide how the medicine should be made and delivered to the disease site, for example as thermosensitive oral gel, suppository, gel, inhalant or oral formulation. The platform uses formulation screening, excipient selection, stability testing, delivery-system design, process development and quality-control methods. By combining diversified formulation approaches with precision delivery technologies, the FDDP addresses key challenges in drug development, such as limited bioavailability, off-target exposure, and inter-patient variability. The FDDP leverages nanotechnology and biomaterials science to facilitate the design of customized drug delivery systems intended to enhance therapeutic performance while mitigating potential side effects. The FDDP supports a wide range of modalities, including peptides and small molecules, and is designed to enable efficient progression from formulation concept to clinical-ready drug candidates.

FDDP helps convert active drug molecules into practical dosage forms suitable for clinical use. It supports formulation optimization, drug stability, local retention at the intended treatment site, sustained release, patient convenience and manufacturability. It is particularly important for peptide drugs, which may be unstable or difficult to deliver without appropriate formulation design. The FDDP

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helps us overcome key technical challenges of formulation, such as the inherent instability of peptide molecules and the requirement to maintain a random coil structure to exert bactericidal activity. Through systematic screening and optimization, we develop formulations that preserve peptide stability and enhance activity. Leveraging the FDDP, we can also design specialized dosage forms tailored to the intended route of administration for specific indications, such as thermosensitive oral gels based on oral physiological conditions, which not only maintain peptide stability but also prolong oral residence time, thereby maximizing therapeutic efficacy.

Leveraging the FDDP, we have successfully advanced three differentiated peptide drug candidates, PL-5, PL-3301 and PL-18, into clinical development. This achievement demonstrates our fully integrated capabilities across the peptide drug development value chain, from target identification and molecule optimization to formulation development, and lays a solid foundation for subsequent clinical translation and pipeline expansion.

Overall, through these platforms, we are able to integrate drug discovery, molecular optimization, formulation development and preclinical evaluation within our in-house R&D system. For our AMP product candidates, AMPDDP supports the design and selection of antimicrobial peptide molecules, while FDDP helps translate such molecules into dosage forms suitable for administration at infected sites. We have continuously refined and optimized this integrated workflow alongside the research and development of PL5, PL18 and PL3301. For our other product candidates, PepMetrics supports the discovery and optimization of peptidomimetic candidates such as PL-MD-333, PROnexTAC supports the discovery and optimization of targeted protein degrader product candidates, and the FDDP facilitates the development of these products into suitable dosage forms for their respective routes of administration.

Advanced production capabilities enabling efficient transition from innovation to commercialization

We have advanced formulation production capabilities. We are in the process of expanding into active pharmaceutical ingredient (“API”) production and are planning on building our own API manufacturing facility in order to establish our fully integrated production capabilities. This system provides core support for the rapid translation of multiple potential first-in-class therapeutics, overcoming the industrial bottlenecks traditionally associated with the complex synthesis and specialized formulation of peptide drugs, according to Frost & Sullivan.

Established production technology for peptide APIs

Through our involvement in overseeing and guiding contract development and manufacturing organizations (“CDMOs”) in the production of peptide APIs, we have accumulated extensive practical experience in peptide API manufacturing, including process optimization, quality control and scale-up management. We are in the course of developing our core manufacturing capabilities for peptide drug APIs and will build our own peptide drug API manufacturing facility in the near future. The manufacturing capabilities for peptide drug APIs will enable us to tackle large-scale production challenges in peptide synthesis and ensure a stable supply of materials ranging from research samples to commercial-grade material. Our robust quality control system features standardized procedures for critical parameters, including impurity profiling and purity enhancement, to ensure that our peptide APIs meet applicable quality standards.

Industry-leading capabilities in specialized dosage form manufacturing

We have established our own global GMP-compliant manufacturing facilities in Jiangyin, Wuxi City (the “**Jiangyin Facility**”). For the specialized dosage forms in our pipeline, such as sprays, suppositories, and thermosensitive gels, we have built dedicated industrialization capabilities. These enable deep integration between formulation design and production processes. As of the Latest Practicable Date, our current manufacturing facilities for PL-5 have an annual capacity of 36 million bottles with reserved space to immediately double output. We have more than 2,300 sq.m. of cleanrooms equipped with advanced HVAC and purification systems, as well as an approximately 5,000 sq.m. warehouse featuring dedicated cold storage for peptide products to ensure supply chain integrity. We have overcome key technical hurdles in manufacturing these complex dosage forms, ensuring consistency between clinical performance and large-scale production to meet practical clinical application requirements.

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Parallel API and formulation development accelerating commercialization

We employ a highly efficient development model that advances API process optimization and dosage form industrialization research in parallel, in order to shorten the translation timeline from clinical development to commercialization. Our production system strictly adheres to all relevant compliance standards and incorporates a quality traceability framework that is in compliance with regulatory submission requirements, laying a solid foundation for product registration and commercial launch.

Management Team with Rich Industry Experience and Specialized Scientific Expertise

Since our inception, leveraging our fully integrated in-house innovation capabilities, we have rapidly advanced our product pipeline on an accelerated basis, with multiple drug candidates progressing from program initiation into clinical development within a relatively short timeframe. Concurrently, several potential first-in-class programs have entered clinical evaluation on a global basis.

We attribute this progress to the strategic leadership of our core executive team. Members of our management team possess deep expertise across multiple critical areas, such as underlying platform technology R&D, molecular design, and clinical operations. Their complementary proficiencies in R&D innovation, clinical execution, and corporate management enable us to set clear strategies that drive efficient technological iteration and pipeline advancement, and ensure alignment with clinical needs and applicable regulatory and compliance standards. Collectively, these capabilities constitute a key foundation supporting our rapid growth.

Our founder, chairman of the Board, executive Director, and chief executive officer, Dr. Chen Yuxin, possesses 30 years of experience in polypeptide drug research and development. During his tenure at the University of Colorado School of Medicine in the U.S., he co-developed the PL-5 AMP molecule and secured the related patent together with Dr. Robert Hodges, who was a Fellow of the Royal Society of Canada, former Chairman of the American Peptide Society, and recipient of the Bruce Merrifield Award for Lifetime Achievement in Peptide Research. In 2006, they together proposed the “Membrane Discrimination Mechanism,” which gained international recognition. As of the Latest Practicable Date, Dr. Chen has led the R&D of multiple innovative drugs that have entered clinical trial stages in China and/or the U.S., published over 60 scientific papers indexed by the Science Citation Index, and authorized or filed for more than 30 patents for drug molecules and formulations. Dr. Chen also has extensive experience in academia and industry organizations. He obtained a doctor of philosophy in biochemistry from the faculty of medicine, University of Alberta and conducted postdoctoral research in the department of biochemistry and molecular genetics at the University of Colorado. He served as a professor, doctoral supervisor, and academic leader at the Key Laboratory of Molecular Enzymology Engineering of the Ministry of Education at Jilin University for over 11 years and has served as a council member of the Peptide Branch of the Chinese Biochemical Pharmaceutical Association.

Dr. Zhu Xu, our vice president, is responsible for the overall management of the R&D of our product candidates. He is a seasoned pharmaceutical research executive with extensive international experience. Holding a Ph.D. from the University of Toronto, he spent nine years at Pfizer in the U.S.. He later served as the vice president of R&D at Axter Therapeutics in Beijing before joining us in 2023. Dr. Zhu brings with him over a decade of deep scientific expertise and leadership in drug discovery and development.

Our management team also includes other senior members who oversee functions including clinical science, regulatory affairs, commercialization, clinical operations, quality assurance, biostatistics, chemistry, manufacturing and controls (“CMC”), and project management, with extensive expertise in their respective areas.

OUR STRATEGIES

Accelerate global clinical advancement and commercialization of core pipeline

We will place significant strategic focus and resources on the rapid commercialization and clinical advancement of our lead assets. Our immediate priority is to finalize the regulatory and commercial preparations for the launch of PL-5 in China, ensuring a strong market entry. In tandem, we will aggressively drive the clinical development programs for PL-3301 and PL-18, aiming to achieve key

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trial milestones and generate robust datasets that reinforce their therapeutic value and potential. This concentrated effort on our most advanced programs is designed to create near-term value and establish a solid foundation in our core market.

To build a global footprint, we are executing a dual-path strategy for international development. We will proactively advance our overseas clinical trials to generate data that meets international regulatory standards. We plan to use [REDACTED] of approximately HK\$[REDACTED] from the [REDACTED] to fund our Phase II and Phase III clinical trials of PL-5 in the U.S. For details, please see “Future Plans and Use of [REDACTED].” Simultaneously, we will actively pursue strategic licensing out and collaboration opportunities with established global pharmaceutical partners. These partnerships are intended to provide critical regional expertise, co-development capabilities, and commercial infrastructure, thereby de-risking and accelerating the path to market access and patient reach across North America, Europe, and other key international territories.

Our commitment to long-term growth is underpinned by the steady progression of our preclinical pipeline. We are dedicating targeted resources to advance our most promising early-stage candidates toward clinical testing. A key near-term objective is the successful filing of an IND application for PL-MD-333. This involves meticulously completing all requisite preclinical studies, manufacturing process development, and regulatory documentation to ensure a compelling and compliant submission, thereby transitioning this promising asset into the clinical phase of development.

We recognize that compelling scientific data is fundamental to establishing credibility and driving adoption. We have a proactive plan to communicate the differentiated profile of our core products to the global scientific and medical community. This will involve strategically presenting key findings — particularly those highlighting unique advantages like a lack of observed drug resistance and synergistic efficacy — at leading international medical congresses and through publication in high-impact, peer-reviewed journals. This targeted communication strategy is essential to shape medical discourse, enhance our scientific reputation, and ultimately strengthen the market positioning of our innovative therapies.

We are also progressively building our commercialization capabilities to accelerate market entry, strengthen channel control, and optimize value realization across the product lifecycle. We plan to build our in-house sales and marketing team, and carry out various product commercialization and marketing network development activities, such as participating in academic forums and hosting academic conferences. We plan to invest RMB[REDACTED] in our commercialization and marketing network development, approximately HK\$[REDACTED] of which will from the [REDACTED] of the [REDACTED]. For details, please see “Future Plans and Use of [REDACTED].”

Deepen Technology Platform Iteration and Enrich Pipeline Portfolio

We will continue to refine our core technology by advancing the application of the “Membrane Discrimination Mechanism” in broader therapeutic contexts. By enhancing the precision and efficacy of AMPs in targeting specific bacterial membranes, we aim to extend their use beyond localized infections to systemic applications. This optimization will support the development of next-generation peptide-based therapies for severe systemic infections, addressing unmet medical needs while minimizing off-target effects and resistance development.

Building on our established platform, we are committed to improving our peptidomimetic molecular design capabilities to expand our pipeline in metabolic and autoimmune diseases. Through iterative design to combine the advantages of peptides and small molecules, we will generate novel candidate molecules with enhanced stability, bioavailability, and target specificity. This effort is geared toward identifying and advancing drug candidates into preclinical and clinical development, with the goal of delivering innovative treatments for complex chronic conditions.

We are strategically exploring new therapeutic areas and novel targets by leveraging our existing technology platforms. This includes investigating synergistic combinations of AMPs with other treatment modalities to enhance efficacy and overcome resistance. Additionally, we are expanding the application of PROTAC technology into oncology and autoimmune indications, aiming to develop targeted protein degradation strategies that offer new mechanisms of action and improved therapeutic outcomes in this challenging disease area.

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Complete Full Production Chain Integration and Strengthen Manufacturing Capabilities

We plan to commence construction of the API facility in the fourth quarter of 2026, with a phased completion schedule spanning until 2028. The facility is designed to meet stringent international GMP standards, with built-in flexibility for future capacity expansion.

The facility will target an annual production capacity sufficient to support our own commercial products while also meeting the needs of CDMO, our potential clients. This [REDACTED] will achieve full vertical integration for peptide synthesis, reducing dependency on third-party suppliers and improving our overall cost structure. We will develop a dedicated CDMO business unit to serve global biotech and pharmaceutical companies requiring specialty peptide manufacturing, positioning the Taizhou facility as a preferred partner for complex peptide APIs through competitive pricing and superior quality control.

We will upgrade the Jiangyin Facility with additional filling lines and enhanced quality control systems while concurrently developing proprietary formulation expertise in peptide sprays to ensure stability, consistent dosing, and patient acceptability. We will also perfect our thermosensitive gel process technology for targeted delivery applications, significantly improving patient compliance. Additionally, we will implement robust supply chain risk management strategies, including redundant sourcing and inventory optimization. By establishing quality-by-design frameworks, we will ensure batch-to-batch consistency and maintain strict regulatory compliance. Our objective is to achieve commercial-scale production capacity ahead of anticipated product launches to prevent supply constraints, while developing flexible manufacturing capabilities that can accommodate multiple product formulations and package configurations.

Deepen Global Strategic Partnerships and Maximize Commercial Value

We will proactively pursue strategic license-out agreements for PL-5 and PL-18 in key international markets. In parallel, we aim to establish a global co-development partnership with leading global pharmaceutical companies for PL-MD-333 to jointly advance its clinical development and commercialization worldwide. These efforts are designed to maximize the commercial potential of our pipeline through external expertise, shared resources, and accelerated global market penetration.

Domestically, we will strengthen collaborative synergies by working closely with Chia Tai Tianqing to jointly advance PL-5's inclusion in China's national reimbursement drug list and drive its scientific and medical promotion. We will also explore potential commercialization partnership models for follow-up assets, including PL-18 and PL-3301. Additionally, through collaboration with leading clinical key opinion leaders, we will actively support the inclusion of our products in clinical treatment guidelines, enhancing their adoption and positioning in the standard of care.

Furthermore, we may identify strategic investment and acquisition opportunities globally with a view to achieving synergies, broadening our product pipeline, enhancing the clinical value of our products and solidifying our market positioning. We may prudently conduct horizontal and vertical expansion along the AMP industry value chain to enhance our competitiveness and technological capabilities. We plan to use the [REDACTED] of approximately HK\$[REDACTED] from the [REDACTED] for potential strategic acquisitions, investment or collaboration which are in line with our growth strategies. For details, please see “Future Plans and Use of [REDACTED].” As of the Latest Practicable Date, we have not identified any specific acquisition or investment target, nor have we entered into any agreements, letters of intent, commitments or understandings with respect to any such transactions.

OUR PRODUCTS AND PIPELINES

Our Pharmaceutical Product Pipelines

Our pipeline mainly comprises (i) three clinical-stage candidates, including (a) PL-5, our Core Product, an α -helical antimicrobial peptide spray for the treatment of secondary wound infection and DFI, (b) PL-3301, an α -helical antimicrobial peptide oral thermosensitive gel and inhalant for the treatment of OPC and pulmonary infection and (c) PL-18, an α -helical antimicrobial peptide suppository and gel for the treatment of VVC, and (ii) one selected preclinical candidate, namely PL-MD-333, an oral small molecule FGF19/FGF21 inducer and lipid metabolism modulator for the treatment of obesity.

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PL-5 (Pecceleganan, α -Helical Antimicrobial Peptide), Our Core Product

Overview

PL-5 (Pecceleganan Spray) is an α -helical antimicrobial peptide (“AMP”) spray for the treatment of secondary wound infection and diabetic foot infections. The molecular name of the active ingredient is Pecceleganan, which is the first Ganan-class anti-infective drug in China to receive a WHO International Nonproprietary Name (“INN”), and it is the only approved Ganan-class anti-infective drug globally as of the Latest Practicable Date, according to Frost & Sullivan. The Pecceleganan Spray is a non-antibiotic antibacterial agent with a unique bactericidal mechanism, “Membrane Discrimination Mechanism” (膜區分機理), which targets the bacterial and fungal cell membranes. Based on our preclinical and clinical studies, PL-5 shows a broad antimicrobial spectrum and demonstrates strong bactericidal advantages against various drug-resistant bacteria, such as Methicillin-resistant *Staphylococcus aureus* (“MRSA”) and multidrug-resistant *Acinetobacter baumannii* carrying the NDM-1 gene. This antimicrobial peptide molecule was designed through our proprietary R&D platform, and we possess its global intellectual property rights.

The novelty of our Core Product primarily lies in its peptide molecular design, which gives rise to its distinctive molecular property of being inducible into an α -helical structure. The novelty of our Core Product does not solely refer to the disruption of microbial membranes by antimicrobial peptides.

As of the Latest Practicable Date, we have received the NDA approval in China, and a Phase II clinical trial in the U.S. is ongoing. According to Frost & Sullivan, this marks global first Ganan-class antimicrobial peptide innovative drug to receive NDA approval. We plan to commercially launch our PL-5 in China in the fourth quarter of 2026 and conduct a post market evaluation within five years of the commercialization of PL-5 in China to fulfill our statutory obligations under the Drug Administration Law. In the U.S., we are currently conducting a Phase II clinical trial and expect to finalize the trial by the third quarter of 2028, subject to the progress of the trial.

We have entered into exclusive commercial cooperation agreement with Chia Tai Tianqing to leverage its industry expertise and established distribution channels to better unleash the commercialization potential of PL-5. For details of such collaboration, see “— Our Collaborations And Licensing Arrangements — Exclusive Commercial Cooperation Agreement with Chia Tai Tianqing.”

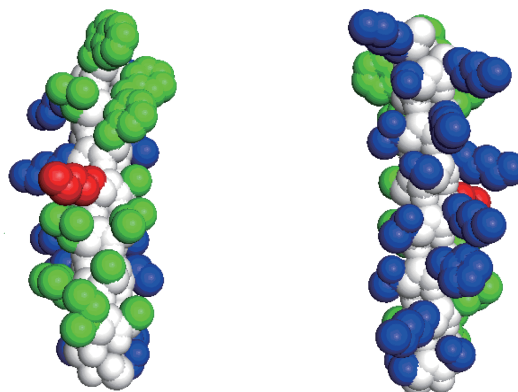
The period between the IND approval and the NDA approval of PL-5 is primarily due to the time required to complete Phase I to Phase III clinical trials, related pharmaceutical studies, regulatory communications and the NDA review process. According to Frost & Sullivan, given the complexity of antibacterial drug development, including relatively stringent eligibility criteria, recruitment challenges, complex efficacy and microbiological assessments, and required safety follow-up, it is not unusual for innovative antibacterial drugs in China to take about ten years from IND approval to NDA approval. During the interval between the IND approval and the NDA submission, the Company did not encounter any clinical hold, regulatory objection or litigation, and conducted the clinical trials on a back-to-back basis while ensuring trial quality. Based on the above, as advised by Frost & Sullivan, our Directors are of the view that, and the Sole Sponsor concurs, the overall development timeline is generally in line with industry norms. In addition, the period between the NDA submission in December 2024 and the NDA approval in June 2026 was approximately 18 months. According to Frost & Sullivan, based on its industry research, the typical period from NDA submission to NDA approval for comparable innovative drug products in China generally ranges from 14 months to 20 months. As such, the actual approval timeline of PL-5 falls within such typical range and is in line with the industry norm.

Drug Design and Mechanism of Action

Antimicrobial peptides (AMPs) are a class of naturally occurring antimicrobial molecules that form part of the innate defense systems across eukaryotes, bacteria and archaea, and they are produced by ribosomal or non-ribosomal pathways. AMPs exhibit direct and potent antimicrobial activity against a wide range of pathogens, including Gram-negative and Gram-positive bacteria, fungi and viruses, through different mechanisms of action. Among AMPs, “Ganan-class” antimicrobial peptide drugs are identified by the WHO INN as acting through an anti-infective mechanism that increases membrane permeability. This antibacterial mechanism not only confers potent broad-spectrum antimicrobial activity but also remains active against drug-resistant bacteria, and the development of resistance to membrane active peptides is not expected. Building on the established structural principles of “Ganan-class” antimicrobial peptides, PL-5 was designed to adopt an amphipathic α -helical

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conformation with a full hydrophobic face and a hydrophilic face, meaning that one side of the molecule is attracted to the lipid of bacterial membranes while the other side is attracted to water, as shown in the figure below.



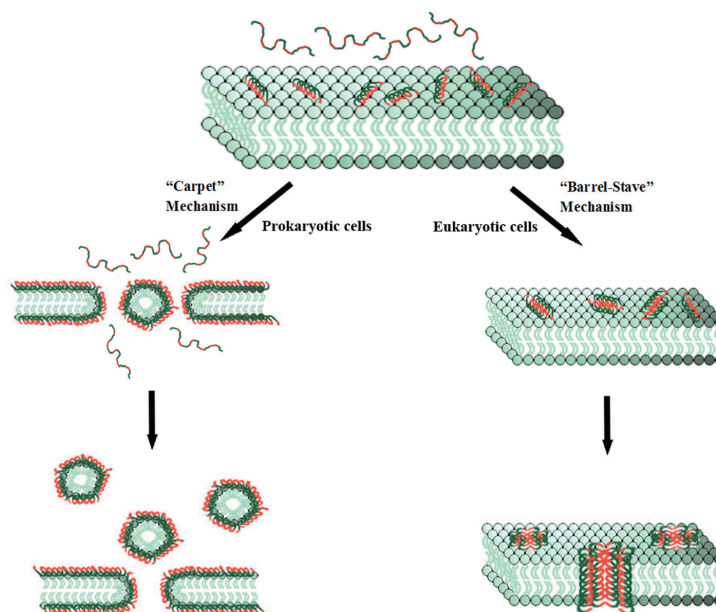
Source: Company

PL-5's mechanism of action is based on the “Membrane Discrimination Mechanism” (膜区分機理) and the membrane-induced activation mechanism. In simple terms, PL-5 works by taking advantage of a basic difference between bacterial cells and human cells. Bacterial cell membranes are enriched in negatively charged lipid, whereas human cell membranes or mammalian cell membranes are primarily composed of zwitterionic lipid. This difference in lipid composition results in a net negative charge on bacterial membranes, in contrast to the near-neutral charge of mammalian cell membranes. Therefore, as a positively-charged peptides, AMPs are preferentially attracted to the bacterial cell membrane and pass through the cell walls (the outer layer of the bacterial cell membrane) of Gram-positive and Gram-negative bacteria (which differ in cell wall structure) due to the electrostatic interactions, while exhibiting little to no affinity for human cells, which are largely electrically neutral in composition. This selective interaction with bacterial membranes also explains why PL-5 is expected to exert minimal toxic effects on normal human cells. In addition, although PL-5 may also act on commensal bacteria during the treatment period, it primarily addresses the pathogenic bacteria that are dominant in patients with active clinical symptoms. Following effective pathogen elimination, the commensal flora is expected to gradually recover toward a healthier balance through host immune regulation and microbiome self-adjustment.

When PL-5 reaches the surface of a bacterial cell, it changes from an unstructured form in solution into an active α -helical form. In this active form, it may disrupt the bacterial cell membrane in two related ways. One is the “barrel-stave” mechanism, in which PL-5 inserts into the membrane and forms pore-like openings. The other is the “carpet” mechanism, in which PL-5 covers the membrane surface and destabilizes it until the membrane breaks down. In both cases, the protective membrane of the bacterial cell is damaged, causing the cell to lose its integrity and die.

We refer to this mode of interaction of antimicrobial peptides, which combines the above two mechanisms, as a “Membrane Discrimination Mechanism”. The figure below illustrates this mechanism.

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Source: Company

The key highlight of our AMPs’ mechanism of action lies in its distinctive secondary-structure transition: it remains flexible and disordered in aqueous solution, but, upon contact with a target (such as a microbial membrane), it can be rapidly induced by the membrane hydrophobic environment to fold into an α -helix, thereby exerting its biological function. According to Frost & Sullivan, the advantages of this mechanism include:

- First, it significantly enhances selectivity and may help reduce toxicity. In an aqueous environment, the AMP remains in an inactive, disordered state and has relatively limited interaction with surrounding normal tissue cells. Through electrostatic interactions between negatively charged microbial membranes and positively charged AMPs, AMP molecules selectively move towards microbial membranes. Only upon encountering hydrophobic components characteristic of bacterial or fungal membranes does it fold into an α -helical structure with membrane-disruptive activity, thereby enabling more efficient killing at the site of infection.
- Second, its physical membrane-disruption mode of action may reduce the risk of resistance development. As the target is the physical structure of the membrane rather than a specific protein target, bacteria and fungi are less able to develop resistance through a single gene mutation.

Overall, based on its “Membrane Discrimination Mechanism”, PL-5 exhibits activity against a broad range of bacteria, including Gram-positive and Gram-negative bacteria. As this mechanism does not rely on a single enzymatic target or metabolic process, the development of resistance to membrane active peptides whose sole target is the cytoplasmic membrane is not expected.

Market Opportunity and Competition

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, 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. Conventional antibiotics have saved innumerable lives in the past decades. Nonetheless, the constant growth of antibiotic resistance has established a pressing demand for new

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molecules to be discovered or designed as new antimicrobial agents. According to Frost & Sullivan, antibiotics face substantial challenges due to bacterial resistance mechanisms, which can be intrinsic or acquired, underscoring the urgent need for novel drugs and strategies to combat resistant pathogens.

The global market size for peptide-based anti-infective drugs reached approximately USD2.0 billion in 2025, with the China market estimated at approximately USD0.2 billion in 2025, according to Frost & Sullivan. These figures are projected to grow to USD3.5 billion globally and USD0.4 billion in China by 2030, reflecting a continued upward trend. For details, please see “Industry Overview — Peptide-Based Anti-Infective Drug Market.”

As of the Latest Practicable Date, peptide-based anti-infective drugs remain scarce in both the U.S. and China, with only a limited number approved by the FDA and the NMPA and most approvals granted in earlier years, according to Frost & Sullivan. Certain marketed products that are sometimes categorised as AMPs, such as Polymyxin and Daptomycin, are in fact cyclic peptides and are structurally and mechanistically distinct from our linear α -helical, membrane-active AMPs. Polymyxin targets Gram-negative bacteria and is ineffective against Gram-positive bacteria, and its clinical use is associated with a risk of nephrotoxicity. Daptomycin acts against Gram-positive bacteria, but is associated with a risk of muscle toxicity, including elevated creatine phosphokinase levels, and is administered systemically by injection rather than via local topical application. Therefore, there is a need for anti-infective drugs with improved safety profiles and broader anti-infective spectra, according to Frost & Sullivan.

As of the Latest Practicable Date, there were six clinical-stage peptide-based anti-infective drug candidates under development overseas, whereas there were seven such candidates under development in China, according to Frost & Sullivan. Among the AMP candidates currently under development in China, there are notable differences in their mechanisms of action and molecular design strategies and formulation. For example, some candidates adopt a multi-target design approach that integrates both antibacterial and anti-inflammatory activities, aiming to indirectly ameliorate infection-related pathological conditions by modulating host immune responses and inflammatory pathways. Other candidates primarily focus on specific dermatological indications, with antibacterial effects derived from the interaction between naturally occurring peptides and bacterial membranes, and development efforts concentrated on topical administration settings. In addition, certain candidates are derived from well-defined antimicrobial peptide molecules, with research largely centred on their antibacterial and immunomodulatory activities; however, their structure-function relationships and modes of action in complex infectious environments remain predominantly at the basic research stage.

By contrast, PL-5 is designed as a linear, structurally inducible antimicrobial peptide. Its mechanism of action emphasises the formation of an α -helical conformation upon contact with bacterial membranes, leading to direct membrane disruption. This design strategy highlights mechanistic alignment between molecular structure and antibacterial function, thereby supporting a relatively clear and interpretable pharmacological pathway.

Secondary wound infection and secondary infection of burn wounds drugs in China

Secondary wound infection refers to microbial infection occurring in acute or chronic wounds caused by trauma, surgery, pressure injury or underlying diseases such as diabetes. It represents a broad spectrum of clinical conditions, including acute bacterial skin and soft tissue infections (“**ABSSSI**”), diabetic foot infections (“**DFI**”), burn-related infections, and post-surgical wound infections, among others. These infections may significantly delay wound healing and may lead to severe complications, including sepsis and amputation. Despite long-term reliance on conventional antibiotics, rising antimicrobial resistance and biofilm formation have substantially reduced treatment effectiveness, resulting in significant unmet clinical needs, according to Frost & Sullivan. In addition, certain existing formulation is inconvenient for administration (e.g., ointments or cream may cause secondary contamination or mechanical injury during application).

According to Frost & Sullivan, the global incidence of secondary wound infection increased from approximately 74.4 million cases in 2020 to 79.4 million cases in 2025, and is expected to reach 85.1 million cases by 2030. In China, incidence rose from approximately 16.8 million cases in 2020 to 18.9 million cases in 2025 and is projected to continue growing steadily. Correspondingly, the global secondary wound infection drug market reached approximately USD12.2 billion in 2025 and is expected to grow to USD14.1 billion by 2030. The China market was approximately USD0.9 billion in 2025 and

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is projected to expand to USD1.1 billion by 2030. In China, the incidence of secondary infection of burn wounds was 2.87 million cases in 2025 and is expected to remain approximately 2.92 million cases by 2030. The market for drugs used to treat secondary infection of burn wounds in China amounted to approximately USD0.15 billion in 2025 and is projected to remain approximately USD0.19 billion on a rounded basis by 2030.

As of the Latest Practicable Date, only three drugs have been approved for the treatment of secondary wound infections, including one drug specifically approved for secondary infections of burn wounds, and two drugs approved for ABSSSI and DFI, respectively, which represent certain subtypes within the broader category of secondary wound infections, according to Frost & Sullivan. Within the scope of pipeline programs active over the past three years, in China, only two pipeline candidates, MRX-4 and YB211, have been identified. Collectively, it indicates a limited approved and clinical-stage landscape in this field, underscoring the significant unmet medical need and development opportunity for differentiated therapies targeting secondary wound infections. For details, please see “Industry Overview — Secondary Wound Infection Drug Market.”

Diabetic foot infection drugs in the U.S.

According to Frost & Sullivan, DFI is one of the most severe and costly complications of diabetes mellitus. According to WHO, diabetic foot complications remain a major global health burden, with a lower-limb amputation occurring approximately every 20 seconds worldwide. DFIs are often polymicrobial infections, involving primarily Gram-positive bacteria, particularly *Staphylococcus aureus*, together with various Gram-negative bacteria, such as *Pseudomonas aeruginosa*, *Escherichia coli* and *Klebsiella pneumoniae*. The condition is typically associated with neuropathy, ischemia, and mixed microbial infections, making treatment complex and resource-intensive. Due to impaired microcirculation in the lower extremities, systemically administered antibiotics may not achieve adequate exposure at the infection site. Together with the colonization and invasion of multidrug-resistant pathogens, this may result in persistent or refractory infections and, ultimately, a substantially increased risk of amputation and even death. Effective anti-infective therapy for DFI requires broad pathogen coverage, including Gram-positive, Gram-negative, and mixed infections, while also addressing the high prevalence of multidrug-resistant microorganisms.

According to Frost & Sullivan, globally the number of patients with DFI increased from approximately 29.7 million in 2020 to 32.5 million in 2025, and is projected to reach 36.0 million by 2030. In China, patient numbers were approximately 10.7 million in 2025 and are expected to continue growing moderately. The global DFI drug market reached approximately USD3.1 billion in 2025 and is expected to grow to USD3.4 billion by 2030. The China market was approximately USD0.5 billion in 2025 and is projected to expand to USD0.7 billion by 2030.

As of the Latest Practicable Date, according to Frost & Sullivan, the FDA has approved only two drugs for DFI, although these products were not specifically developed for this indication. Both are systemically administered and have been reported to face drug-resistant bacterial strains and clinically significant systemic adverse effects, particularly in prolonged treatment settings. In addition, the overseas clinical pipeline for diabetic foot infection remains limited, with only two clinical-stage candidates identified worldwide, both in Phase II development. Collectively, these factors reflect a limited treatment and development landscape and underscore the substantial unmet medical need for safer and more effective therapies for diabetic foot infection. See “Industry Overview — Diabetic Foot Infection Drug Market”

Key Advantages

Strong Clinical Evidence Supporting Superior Efficacy and More Comprehensive Patient Benefits

Clinical results have demonstrated that PL-5 offers superior therapeutic efficacy compared to the positive control, 1% silver sulfadiazine (“SSD”) cream, which is a commonly used standard topical antibiotic treatment for infected wounds in the clinical practice, while also providing clinical evidence on wound healing. In our head-to-head Phase IIIa clinical trial (n=570), PL-5 (0.2% peceleganan topical spray) achieved a higher clinical efficacy rate on Day 8 than 1% SSD cream (90.4% vs. 78.7%; p=0.0006). In our Phase IIIb clinical trial (n=348), PL-5 (0.2% peceleganan topical spray) achieved a higher wound complete healing rate on Day 15 than placebo (64.3% vs. 43.1%; p=0.0002). These

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results support PL-5’s superior therapeutic efficacy against positive control and favorable wound healing profile compared with placebo. For further details, please see “— Summary of Clinical Trial Results” below.

About Drug-Resistance

- Active against antibiotic-resistant bacteria:** According to the World Health Organization’s *Bacterial Priority Pathogens List* (2024 update), which identifies certain “difficult-to-treat” antibiotic-resistant bacteria, our *in vitro* studies showed that PL-5 exhibited antibacterial activity against multiple resistant pathogens on the list, including *Acinetobacter baumannii* in the critical priority group, as well as *Pseudomonas aeruginosa* and *Staphylococcus aureus* in the high priority group. For example, PL-5 demonstrated comparable inhibitory effects against both antibiotic-susceptible and antibiotic-resistant strains of *A. baumannii*, supporting its antibacterial activity against antibiotic-resistant bacteria. The following table shows the *in vitro* efficacy data of PL-5 compared with two last-resort antibiotics — therapies used as a last-line defense in clinical practice for serious bacterial infections — vancomycin and imipenem.

Strain	Gram Stain Classification	Number of Strains	PL-5 MIC ₉₀ μM	Vancomycin MIC ₉₀ μM	Imipenem MIC ₉₀ μM
MRSA.	G+	130	2.3	0.69	—
MSSA.	G+	67	2.3	1.38	—
MRSCNS	G+	121	2.3	1.38	—
MSSCNS	G+	61	2.3	1.38	—
<i>Klebsiella pneumoniae</i> (ESBL-producing). . . .	G-	80	2.3	—	5.75
<i>Klebsiella pneumoniae</i> (non-ESBL-producing) .	G-	40	2.3	—	1.44
<i>Pseudomonas aeruginosa</i> (IPM-R)	G-	81	4.59	—	—
<i>Pseudomonas aeruginosa</i> (IPM-S).	G-	43	4.59	—	2.87
<i>Acinetobacter baumannii</i> (IPM-R).	G-	87	2.3	—	—
<i>Acinetobacter baumannii</i> (IPM-S).	G-	33	2.3	—	2.87
<i>Enterobacter cloacae</i>	G-	40	4.59	—	5.75
<i>Citrobacter freundii</i>	G-	20	4.59	—	22.99

Notes: As *Pseudomonas aeruginosa* (IPM-R) and *Acinetobacter baumannii* (IPM-R) are imipenem-resistant strains, the study design did not require the determination of the MIC of imipenem; “—” indicates no efficacy; ESBL: Extended Spectrum Beta Lactamases. MRSA: Methicillin-resistant *Staphylococcus aureus*. MSSA: Methicillin-susceptible *Staphylococcus aureus*. MRSCNS: Methicillin-resistant coagulase-negative staphylococci. MSSCNS: Methicillin-susceptible coagulase-negative staphylococci.

- No Inducible Drug Resistance:** Based on its antibacterial mechanism that primarily targets the bacterial cell membrane, we believe that PL-5 has a relatively low risk of inducing resistance upon repeated use. In our preclinical studies, under 15-passage induction conditions (repeated exposure designed to induce resistance), the minimum inhibition concentration (MIC) of PL-5 remained generally stable against bacteria (*E. coli*, *S. aureus*, and *P. aeruginosa*) and fungus (*C. albicans*). In contrast, the MIC of the antibiotics increased to approximately 44.28~44.29 μM for levofloxacin (bacteria) and 417.93 μM for fluconazole (fungus), suggesting a low risk of resistance induction for PL-5 in this *in vitro* model. In antibiotic resistance induction experiments, bacteria developed a 64-fold increase in levofloxacin resistance, and fungus developed an approximately 502-fold increase in fluconazole resistance. However, bacteria and fungus exhibit almost no resistance against PL-5.

Broad-Spectrum Antibacterial Activity

- Mechanistic basis for broad-spectrum activity:** We adopt a “Membrane Discrimination Mechanism” of action, under which our PL-5 can distinguish bacterial cell membranes from human cell membranes based on differences in membrane composition and surface charge, thereby exerting membrane-disruptive effects and causing bacterial death. Based on this mechanism, the development of resistance to membrane-active peptides, whose sole target is the cytoplasmic membrane, is not expected.
- Broad-spectrum activity supported by both preclinical and clinical data:** Our preclinical *in vitro* studies showed that PL-5 exhibited inhibitory and bactericidal activity against 1,102 clinically isolated strains across 13 bacterial species, including multiple Gram-positive and

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Gram-negative bacteria, with activity observed against both antibiotic-susceptible and antibiotic-resistant strains. In our Phase IIIa and Phase IIIb clinical trials, we observed antibacterial activity of PL-5 against a total of 2,242 clinically isolated strains, including, among others, strains of *Acinetobacter baumannii*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

High Effectiveness

- **Superior early clinical efficacy:** In our Phase IIIa clinical trial, PL-5 demonstrated higher clinical efficacy rates than SSD on Day 5 after administration in both the FAS and PPS populations, with statistically significant between-group differences. The clinical efficacy rates in the PL-5 and SSD groups were 59.2% and 49.2%, respectively, in the FAS population ($P=0.0252 < 0.05$), and 59.5% and 49.7%, respectively, in the PPS population ($P=0.0310 < 0.05$).
- **Reduced burden of resistance testing and culture:** In clinical practice, prescribing decisions often rely on culture and antimicrobial susceptibility testing before initiating therapy, which may delay treatment initiation and reduce prescribing efficiency in the early stage of infection. PL-5 may help address this, as its use may not require these tests and cultures before use, given its activity against antibiotic-resistant bacteria, no inducible drug resistance, and broad-spectrum antibacterial activity.

Proprietary Design and National Recognition

The drug’s high selectivity and stability are enabled by a proprietary AMP molecular design. This design avoids artificial cyclization, preserves the natural secondary structure of the peptide, and ensures reproducible biological activity across manufacturing batches. As China’s first Ganan-class antimicrobial peptide to receive an INN from the WHO, PL-5 represents a significant national innovation milestone. Its development has been consecutively supported by the Chinese Ministry of Science and Technology’s “Major New Drug Innovation” national science and technology major projects during both the 12th and 13th Five-Year Plan periods, underscoring its strategic importance.

Long-lasting Effect, Convenient Administration and Creating Moist Wound Healing Environment

PL-5 is formulated as a topical spray for direct administration to the wound surface. This route of administration is designed to achieve sustained local drug exposure and is less dependent on drug delivery through the local circulation, which may be impaired in certain chronic or complex wounds. In addition, spray application enables uniform coverage of irregular and complex wounds, providing painless administration and precise dosing while reducing the risk of mechanical injury and cross-contamination associated with repeated contact during topical application. Moreover, this formulation is also designed to maintain an appropriately moist wound microenvironment, which may promote granulation tissue formation, epithelial cell migration and re-epithelialization, while reducing wound desiccation and scab formation and minimizing mechanical damage to newly formed tissue during dressing changes, thereby creating favorable conditions for wound repair.

Clinical Development Plan

In China, PL-5 has completed its Phase III clinical trials, and received NDA approval from the NMPA in June 2026. We currently expect commercial launch in 2026. We also plan to conduct a post-market evaluation within five years thereafter to fulfill our statutory obligations under the Drug Administration Law. In the U.S., a Phase II clinical trial is ongoing and is expected to be completed by the third quarter of 2028, subject to trial progress. For the R&D expenses of our Core Product, please see “Financial Information — Cash Operating Costs — Research and Development Costs for Core Product.”

Summary of Clinical Trial Results

As of the Latest Practicable Date, we have completed six standalone clinical trials, including two Phase III trials, in China and are advancing one Phase II clinical trial in the U.S. for PL-5 Topical Spray. The table below sets out all the completed and ongoing clinical studies.

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Summary of Clinical Development of PL-5 Topical Spray

Phase	No.	Objective	Name	Participants	Dosage/ Exposure	Timespan	Status
IIIb	JSPL-PL-5-302	Safety, efficacy, PK	A multicenter, randomized, double-blind, placebo-controlled phase IIIb clinical trial evaluating the efficacy and safety of PL-5 AMP spray in the treatment of wound infection	Patients with Wound Infection	Once daily for 14 consecutive days.	June 2023 – August 2024 (LPO), November 2024 (CSR)	Completed in China
IIIa	JSPL-PL-5-301	Safety, efficacy	A multicenter, randomized, open-label, active-controlled phase III clinical trial evaluating the efficacy and safety of PL-5 AMP spray in the treatment of wound infection	Patients with Wound Infection	Once daily for 7 consecutive days.	August 2021 – July 2022 (LPO), February 2023 (CSR)	Completed in China
IIb	JSPL-PL-5-202	Safety, efficacy, PK	A multicenter, randomized, open-label, active-controlled phase IIb clinical trial evaluating the efficacy and safety of PL-5 AMP spray in the treatment of wound infection	Patients with Secondary Wound Infection	Once daily for 7 consecutive days.	July 2020 – May 2021 (LPO), July 2021 (CSR)	Completed in China
IIa	GQ-PL-5-201	Safety, efficacy	A randomized, open-label, active-controlled, dose-escalation clinical trial of PL-5 AMP spray for the treatment of wound infection	Patients with Wound Infection	Once daily for 7 consecutive days.	July 2018 – September 2019 (LPO), April 2020 (CSR)	Completed in China
Ib	GQ-PL-5-102	Safety, PK	A multiple-dose human safety and efficacy study of the PL-5 AMP spray	Healthy adults	Twice daily for 7 consecutive days (with only one dose administered on the morning of Day 7).	June 2017 – December 2017 (LPO), September 2018 (CSR)	Completed in China
Ia	GQ-PL-5-101	Safety, PK	A single-dose human tolerability study of the PL-5 AMP spray	Healthy adults	Single Administration	September 2016 – March 2017 (LPO), September 2017 (CSR)	Completed in China
II	JSPL-PL-5-203	Safety, efficacy	A multicenter, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of PL-5 AMP spray in patients with mild diabetic foot ulcer infection	Patients with IWGDF Grade II Diabetic Foot Ulcer Infection	Twice daily for 14 consecutive days.	January 2024 – 2028 Q3 (expected)	Ongoing in the U.S.

Notes: “Clinical trial completion” generally refers to the date on which the last subject completes the final protocol-specified visit or procedure in the relevant clinical trial, commonly understood as last patient out, last subject last visit or last participant last visit, with reference to ClinicalTrials.gov, the ICH E3 guideline and ChiCTR clinical trial registration practice.”

According to Frost & Sullivan, the use of relatively small sample sizes in early-stage clinical trials, such as Phase I and Phase IIa trials, is generally consistent with industry practice, as such trials are primarily designed to assess safety, explore preliminary efficacy signals and inform subsequent trial design.

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Phase III Clinical Studies in China

Two Phase III clinical studies have been completed for this product in China. The Phase IIIa clinical trial was designed as an open-label, active-controlled study primarily focused on infection control, using the clinical efficacy rate on Day 1 after completion of the last dose as the primary endpoint, which was intended to evaluate the anti-infective efficacy of PL-5. Given the particular considerations applicable to locally administered drugs with local therapeutic effects in clinical trial design and regulatory evaluation, regulatory authorities consider not only the anti-infective efficacy of such products, but also whether they may affect local tissue repair and wound healing. Although SSD was an appropriate positive control for assessing anti-infective efficacy, its cream formulation made blinding against the investigational spray impractical. In addition, SSD may itself affect wound healing. Therefore, a placebo-controlled design was considered more appropriate for evaluating wound-healing outcomes. We then conducted the Phase IIIb clinical trial as a double-blind, placebo-controlled study using wound complete healing rate on Day 1 after completion of the last dose as the primary endpoint to provide supplementary clinical evidence on wound healing, and the differences between the Phase IIIa and Phase IIIb trial designs were made pursuant to the CDE’s recommendation.

A Phase IIIa, Multicenter, Randomized, Open-Label, Active-Controlled Clinical Trial to Evaluate the Efficacy and Safety of Antimicrobial Peptide PL-5 Spray in Patients with Wound Infections.

Trial design

- **Enrollment and dosing regimen:** A total of 570 subjects with wound infection were enrolled, including 381 in the test group (PL-5 Spray) and 189 in the positive control group (SSD cream). Subjects in both groups received treatment once daily for seven days. Study visits were conducted at screening (Day -1 to Day 1), on Day 5 of dosing (“**Day 5**”), on Day 1 after completion of the last dose (“**Day 8**”), and on Day 7 after completion of the last dose.
- **Key eligibility criteria:** (i) Key inclusion criteria included: (a) age between 18 and 75 years; (b) the presence of an open wound with secondary infection, including burns, abrasions, cuts, lacerations, sutured wounds, traumatic ulcers, pressure ulcers, venous ulcers and Wagner Grade II diabetic foot ulcers, and satisfaction of the protocol-defined criteria relating to wound characteristics, infection severity, bacteriological findings and expected treatment approach during the study period; (c) collection of bacterial samples before enrollment and positive microscopic examination results; (d) agreement to adopt effective contraceptive measures, where applicable; and (ii) Key exclusion criteria included: (a) failure to collect bacterial culture samples before enrollment; (b) recent use of systemic antibacterial drugs or prior use of topical antibacterial therapy on the study wound, unless deemed ineffective by the investigator; (c) wound infections expected to require concomitant antibacterial therapy or surgical intervention during the study period; (d) wound infections known or suspected to be caused by non-bacterial pathogens, or acute severe infections requiring surgical management.
- **Primary and other endpoints:** The primary efficacy endpoint was the clinical efficacy rate on Day 8. Other key efficacy endpoints included minimum inhibitory concentration (“**MIC**”) analysis and subgroup efficacy analysis. Safety endpoints included adverse events (“**AEs**”), serious adverse events (“**SAEs**”), treatment-emergent adverse events (“**TEAEs**”), treatment-related adverse events (“**TRAEs**”), wound-related adverse events, laboratory tests, vital signs, physical examinations and electrocardiograms.

Efficacy Results

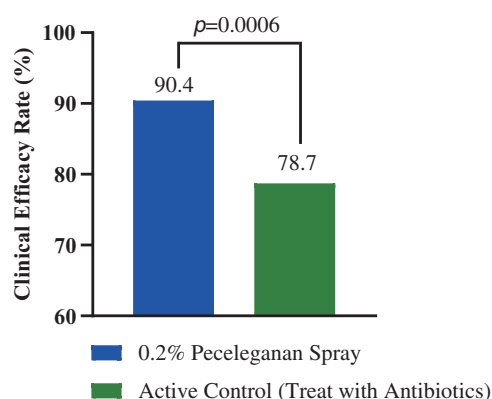
Efficacy was evaluated based on the protocol-specified analysis sets, including the full analysis set (“**FAS**”), the modified FAS (“**mFAS**”), and the per protocol set (“**PPS**”), as applicable.

- Clinical Efficacy Rate on Day 8

In the FAS, the clinical efficacy rate on Day 8 were 90.4% in the test group and 78.7% in the positive control group. The between-group difference was statistically significant (Chi-square test, $P = 0.0006 < 0.05$). The response clinical efficacy rate in the test group was 11.7% higher overall than in the control group. These results indicate that in the FAS population, the test group demonstrated superior clinical efficacy regarding wound outcome on Day 8 compared to the positive control group.

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Clinical Efficacy Rate on Day 8 (n=570)



• MIC Analysis

MIC testing was performed on 1,471 clinical isolates obtained from the mFAS subjects. The isolates comprised 526 *Staphylococcus aureus*, 231 *Staphylococcus epidermidis*, 159 *Pseudomonas aeruginosa*, 71 *Staphylococcus haemolyticus*, 70 *Klebsiella pneumoniae*, 63 *Enterococcus faecalis*, 54 *Escherichia coli*, 32 *Acinetobacter baumannii*, 31 *Proteus mirabilis*, and 26 *Enterobacter cloacae*. The table below summarizes the MIC ranges of PL-5 against selected resistant and intrinsically resistant isolates evaluated in this clinical trial.

Resistance Category	Representative Strains Included in Analysis	Number of Isolates Tested	MIC Range of PL-5
Ceftriaxone-resistant and intrinsically resistant strains	<i>P. aeruginosa</i> , <i>E. faecalis</i> , <i>K. pneumoniae</i> , <i>E. coli</i> , <i>A. baumannii</i> , <i>Corynebacterium striatum</i>	159, 63, 29, 25, 20, 13	1–32 µg/mL
Imipenem-resistant and intrinsically resistant strains	<i>P. mirabilis</i> , <i>A. baumannii</i> , <i>K. pneumoniae</i> , <i>Stenotrophomonas maltophilia</i> , <i>P. aeruginosa</i>	23, 18, 6, 5, 4	2–32 µg/mL for most common wound pathogens (excluding <i>P. mirabilis</i>)
Levofloxacin-resistant and intrinsically resistant strains	<i>S. epidermidis</i> , <i>S. aureus</i> , <i>S. haemolyticus</i> , <i>E. coli</i> , <i>P. aeruginosa</i> , <i>K. pneumoniae</i> , <i>E. faecalis</i> , <i>A. baumannii</i> , <i>P. mirabilis</i>	101, 72, 57, 34, 21, 18, 18, 15, 10	1–32 µg/mL for most common wound pathogens, excluding <i>E. faecalis</i> and some <i>P. mirabilis</i> strains

• Efficacy Analysis in the Burn/Scald Wound Infection Subgroup

In the burn/scald wound infection subgroup of the FAS, the clinical response rates on Day 1 after the last dose were 92.8% in the test group and 84.6% in the positive control group.

• Efficacy Analysis in the Physical Injury Wound Infection Subgroup

In the physical injury wound infection subgroup of the FAS, the clinical response rates on Day 1 after the last dose were 80.4% in the test group and 62.1% in the positive control group.

• Efficacy Analysis in the Diabetic Foot Ulcer Infection Subgroup

In the diabetic foot ulcer infection subgroup of the FAS, the clinical response rates on Day 1 after the last dose were 94.1% in the test group and 0.0% in the positive control group.

Safety Results

Safety was evaluated in the safety set (“SS”), which included 566 subjects, comprising 380 subjects in the PL-5 group and 186 subjects in the positive control group. The actual dosing duration was generally comparable between the two groups, with a mean exposure of 6.9 days in both groups.

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In the SS, the incidences of TEAEs, TRAEs and SAEs were generally comparable between the two groups. TEAEs occurred in 93 subjects (24.5%) in the PL-5 group and 44 subjects (23.7%) in the positive control group, while TRAEs occurred in 28 subjects (7.4%) and 13 subjects (7.0%), respectively. No TEAE or TRAE with an incidence of 5% or above was reported in either group. SAEs occurred in three subjects (0.8%) in the PL-5 group and three subjects (1.6%) in the positive control group.

AEs leading to drug discontinuation were reported in two subjects (0.5%) in the PL-5 group and two subjects (1.1%) in the positive control group. No death was reported in this study. Compared with baseline, no clinically significant changes were observed in laboratory parameters in either group.

Conclusion

PL-5 Spray demonstrated superior clinical efficacy in improving wound outcomes compared to the positive control drug, SSD cream. An independent comparative analysis of the eradication rates for key pathogens (*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Enterococcus faecalis*) in major wound types (burn/scald infections, physical injury infections) showed that the microbial eradication capability of Antimicrobial Peptide PL-5 Spray was comparable to that of SSD cream.

No new or unexpected safety concerns were identified in this study. The safety profile of Antimicrobial Peptide PL-5 Spray was similar to that of SSD cream. Therefore, Antimicrobial Peptide PL-5 Spray exhibits a favorable safety profile for the treatment of infected wounds.

A Phase IIIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Evaluating the Efficacy and Safety of Antimicrobial Peptide PL-5 Spray for the Treatment of Wound Infections.

Trial design

- **Enrollment and dosing regimen:** A total of 348 subjects were randomized in a 2:1 ratio to receive either PL-5 spray or placebo spray, including 232 subjects in the test group and 116 subjects in the placebo group. Subjects received treatment once daily for 14 days. Study visits were conducted at screening (Day-1 to Day 1), on Day 5 of dosing (Day 5), on Day 8 of dosing (Day 8), on Day 1 after completion of the last dose ("**Day 15**"), and on Day 7 after completion of the last dose ("**Day 21**").
- **Key eligibility criteria:** (i) Key inclusion criteria included: (a) age between 18 and 65 years; (b) the presence of a mildly infected secondary burn wound at screening; and (c) satisfaction of the protocol-defined inclusion criteria, including those relating to wound area, infection severity, bacteriological positivity, burn extent, expected treatment approach during the study period, protocol compliance and contraceptive measures, where applicable; and (ii) Key exclusion criteria included (a) failure to collect bacterial culture samples before enrollment; (b) recent use of systemic antibacterial drugs or prior use of topical antibacterial therapy on the study wound, unless such treatment was considered ineffective by the investigator; (c) wound infections expected to require concomitant antibacterial therapy during the study period; (d) wound infections known or suspected to be caused by non-bacterial pathogenic microorganisms.
- **Primary and other endpoints:** The primary efficacy endpoint was the wound complete healing rate on Day 15. Other key efficacy endpoints included the wound complete healing rates on Day 21, microbiological response rate on Day 15, and overall response rate on Day 15. Safety evaluations included AEs, SAEs, TEAEs, TRAEs, wound-related TEAEs, wound-related TRAEs, laboratory tests, vital signs, physical examinations and 12-lead ECGs.

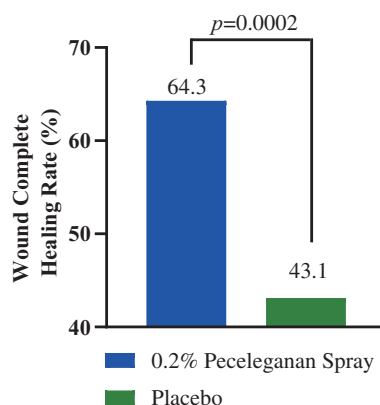
Primary efficacy endpoints

- Wound Complete Healing Rate on Day 15

Among subjects in the FAS, the wound complete healing rates on Day 15, were 64.3% in the test group and 43.1% in the placebo group, demonstrating a statistically significant between-group difference ($P=0.0002$). The healing rate in the test group was 21.2% higher than in the placebo group, indicating superior clinical efficacy.

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Wound Complete Healing Rate on Day 15 (n=348)



Key secondary efficacy endpoints

- Wound Complete Healing Rate on Day 21

The wound complete healing rates on Day 21 were 73.5% in the test group and 56.9% in the placebo group, with a statistically significant between-group difference ($P=0.0018$).

- Microbiological Response Rate on Day 15

The microbiological response rates on Day 15 were 72.3% in the test group and 50.5% in the placebo group, showing a statistically significant difference ($P=0.0001$).

- Overall Response Rate on Day 15

The overall response rates on Day 15 were 63.1% in the test group and 41.9% in the placebo group, with a statistically significant between-group difference ($P=0.0003$).

Safety results

Safety was evaluated in the SS, which included 347 subjects, comprising 231 subjects in the PL-5 group and 116 subjects in the placebo group. The actual dosing duration was generally comparable between the two groups, with a mean exposure of 11.3 ± 3.20 days in the PL-5 group and 11.6 ± 3.26 days in the placebo group.

In the SS, the incidence of TEAEs, TRAEs and SAEs were generally comparable between the two groups. TEAEs occurred in 60 subjects (26.0%) in the PL-5 group and 29 subjects (25.0%) in the placebo group, while TRAEs occurred in 11 subjects (4.8%) and five subjects (4.3%), respectively. No TRAE with an incidence of 5% or above was reported in either group. Grade 3 or above TEAEs occurred in three subjects (1.3%) in the PL-5 group and two subjects (1.7%) in the placebo group. No Grade 3 or above TRAE or wound-related TRAE was reported in either group. SAEs occurred in three subjects (1.3%) in the PL-5 group and one subject (0.9%) in the placebo group, and all SAEs in both groups were considered unrelated to the study drug.

No AEs of Grade 3 severity or higher leading to treatment discontinuation occurred in either the test or placebo group. No deaths were reported in this study. Compared to baseline, no clinically significant changes were observed in laboratory parameters for either group.

PK analysis

Based on the Pharmacokinetic Set (“PKS”), all plasma concentrations of Antimicrobial Peptide PL-5 at each visit were below the lower limit of quantification (“BQL”). No detectable plasma drug concentration was found in the subjects, confirming that the drug does not enter the systemic circulation.

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Conclusion

When administered for two consecutive weeks for the treatment of secondary infected wounds, Antimicrobial Peptide PL-5 Spray demonstrated superior clinical efficacy in improving wound healing compared to placebo. Its efficacy in eradicating wound infection pathogens was also superior to that of placebo. MIC results indicated that Antimicrobial Peptide PL-5 exhibits potent and broad-spectrum antibacterial activity against common clinical isolates from wound infections.

The safety profile of Antimicrobial Peptide PL-5 Spray was comparable to that of placebo, with a low incidence of various AEs. Therefore, Antimicrobial Peptide PL-5 Spray exhibits a favorable safety profile for the treatment of secondary infected wounds.

Following topical administration of Antimicrobial Peptide PL-5 Spray to the wound, no detectable plasma concentration of Antimicrobial Peptide PL-5 was observed, confirming that the drug does not enter the systemic circulation when applied locally.

Phase II Clinical Studies in China

Two Phase II clinical studies were conducted for PL-5 in China. The first was a Phase IIa randomized, open-label, active-controlled, dose-finding study (GQ-PL-5-201) in patients with wound infections, aiming to evaluate the safety and efficacy of Antimicrobial Peptide PL-5 Spray and explore its effective clinical dosage. The second, a Phase IIb randomized, open-label, active-controlled study (JSPL-PL-5-202), was also conducted domestically in patients with wound infections, with the objectives of assessing the efficacy and safety of Antimicrobial Peptide PL-5 Spray, exploring its optimal effective clinical dosage, and evaluating its pharmacokinetic (PK) profile following absorption through the wound surface.

Phase IIa (randomized, open-label, active-controlled, dose exploration)

- **Trial design:** 40 patients with wound infections; randomized and open-label; active-controlled; four parallel groups (active control, or PL-5 0.00625 mg/cm² (1%), 0.025 mg/cm² (4%), 0.0375 mg/cm² (6%)); 10 patients per group; all completed the study; all included in the FAS and SS.
- **Safety:** No SAEs/serious ADRs; no AEs/ADRs leading to drug discontinuation or study withdrawal.
- **Efficacy:** On Day 1 after the last dose, clinical effective rates were 70.0% (active control), 70.0% (1%), 90.0% (4%), and 100.0% (6%).

Phase IIb (multicenter, randomized, open-label, active-controlled)

- **Trial design:** Multicenter; randomized and open-label; Part I (efficacy/safety) and Part II (PK). Part I: 220 patients randomized to 1%, 2%, 4%, or active control (n=59/61/60/40); 211 completed. Part II: 6 patients enrolled for PK; 174 plasma samples collected.
- **Safety:** Part I AE incidence: 27.1% (1%), 34.4% (2%), 20.0% (4%), 23.7% (control). Important AE incidence: 10.2%, 14.8%, 11.7%, 15.8%, respectively (all Grade 1–2). One Grade 4 dyspnea in the control group led to discontinuation. Part II: no AE/ADR/SAE, and no events leading to discontinuation.
- **Efficacy:** In Part I FAS, effective rates on Day 1 after the last dose were 100.0% (1%), 96.7% (2%), 96.7% (4%), and 87.5% (control); Chi-square P<0.05.
- **PK:** In Part II, plasma PL-5 concentrations were below the LLOQ in all samples.

Phase I Clinical Studies in China

Following its NMPA clinical trial approval on May 4, 2016, two Phase I clinical studies were conducted for this product in China:

- *Single-dose escalation study (Phase I, healthy subjects)*

In a randomized, double-blind, placebo-controlled, single ascending dose study (n=40; five dose groups from 0.003125 to 0.0375 mg/cm²), PL-5 topical spray was safe and well-tolerated after a single administration. No drug-related AEs or SAEs were reported. For the highest dose group (0.0375 mg/cm²), plasma PL-5 concentrations in all samples were below the lower limit of quantification.

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- *Multiple-dose escalation study (Phase I, healthy subjects)*

In a randomized, double-blind, placebo-controlled, multiple-dose escalation study (n=24; two dose groups: 0.025 and 0.0375 mg/cm²), PL-5 topical spray was safe and well-tolerated with twice-daily administration for seven consecutive days. All AEs were assessed as unlikely to be related to PL-5. After multiple dosing at 0.0375 mg/cm², plasma PL-5 concentrations in all samples were below the lower limit of quantification.

Phase II Clinical Trial in the U.S.

Following FDA authorization on March 3, 2022, a Phase II, multicenter, randomized, double-blind, placebo-controlled clinical trial was initiated in the U.S. to evaluate the efficacy and safety of PL-5 Spray in patients with mild diabetic foot ulcer infections, with wound infection control as the primary endpoint, and the study is currently ongoing. As of the Latest Practicable Date, three clinical trial sites have been initiated, and is expected to be finalized by the third quarter of 2028.

Material Communications with Competent Authorities

We submitted the Investigational New Drug (“IND”) application in July 2014, and then obtained the approval (Acceptance No.: CXHL1400689-Ji; Approval No.: 2016L04635) from the NMPA on May 4, 2016. Following the completion of two Phase I clinical studies evaluating single and multiple doses in healthy subjects, a Type I meeting was held with the CDE on April 12, 2018, prior to the initiation of Phase II trials. This meeting primarily discussed and finalized the key design elements of the Phase IIa study, reaching consensus on aspects such as dose exploration, efficacy endpoints, the choice of active comparator, and open-label versus blinded design.

Upon completion of the Phase IIa trial, we submitted a request for a Type II meeting via the Applicant Window to discuss the design of the Phase IIb study, to which the CDE provided a written response confirming the proposal. After the Phase IIb trial was completed, the company requested another Type II meeting via the Applicant Window — an End-of-Phase II (EOP2) meeting — to present the accumulated clinical data to the CDE, discuss the design of the pivotal Phase III clinical trial, and explore the possibility of conditional approval. The aim was to seek the CDE’s opinions and recommendations regarding conditional market approval, and the agency subsequently provided a written reply.

On October 19, 2022, a Type II meeting was held with the CDE prior to the initiation of the pivotal Phase IIIb clinical trial. During this meeting, we sought the CDE’s advice on several key issues, including whether to conduct pharmacokinetic studies in Phase IIIb, the use of a placebo-controlled design, the selection of primary efficacy endpoints, and sample size calculation. A mutual agreement was reached with the CDE on these matters.

On July 13, 2023, we held a pre-New Drug Application (pre-NDA) meeting with the CDE. The CDE recommended completing the Phase IIIb clinical trial before proceeding with the NDA submission for this product, in light of the need to assess whether PL-5 would affect wound healing, and thereby, to further confirm that patients would derive an overall clinical benefit from the treatment. Subsequently, on September 18, 2023, a Type II meeting was conducted with the CDE during the pivotal clinical trial phase, focusing primarily on discussions related to pharmaceutical development, where consensus was also achieved.

All the mentioned clinical research activities in China have now been completed. The NDA was submitted for registration and was accepted by the NMPA on December 23, 2024. Following this, registration inspections were conducted in accordance with the review and approval process. During the review process, the registration testing was conducted by the National Institutes for Food and Drug Control, and the CDE provided standardization comments on certain descriptions in our proposed quality standards by reference to the Chinese Pharmacopoeia. Such comments were primarily wording-level revisions and did not involve additional studies, supplementary experiments or submission of new substantive technical data.

On June 17, 2026, we received the NDA approval for PL-5 (Pecelaganan Spray, 普亦克®) from the NMPA, for the treatment of secondary infection of burn wounds.

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As of the date of this document, we also have conducted multiple communications and technical exchanges with the FDA regarding PL-5 topical spray, including a Type B (Pre-IND) teleconference on July 13, 2021 to discuss our development plan for secondary wound infections. In such communications, the proposed indication was refined to mild infection of diabetic foot ulcers, which is within the scope of secondary wound infections, and the FDA provided comments on clinical strategy and trial design.

In March 2022, we received the FDA’s IND approval for a Phase II clinical trial without requiring a separate U.S. Phase I clinical trial, as Phase I clinical trial data generally provide preliminary overall safety information for the product, which had already been established in our prior clinical trials in China. The data submitted to the FDA mainly consisted of CSRs, with only a very limited amount of de-identified individual safety data, and the relevant transfer was completed in January 2022, when the relevant PRC laws had only recently come into effect and the detailed implementation rules for cross-border data transfer were not yet clear, and there were no clear and specific enforceable provisions in practice regarding the specific compliance pathways and procedures for cross-border data transfer, as the detailed implementation rules and regulatory guidance had not yet been developed or clarified at the relevant time. The Company has ceased such transfer after completion of the FDA submission and will comply with the applicable PRC requirements for any future cross-border data transfer.

PL-5 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED

PL-3301 (α -Helical Antimicrobial Peptide), Our Key Product

Overview

According to Frost & Sullivan, PL-3301 is potentially world’s first α -helical antimicrobial peptide-based drug formulated as a thermosensitive oral gel for the treatment of oropharyngeal candidiasis (“**OPC**”) and inhalant for the treatment of pulmonary infection. According to Frost & Sullivan, as a potential first-in-class, peptide-based broad-spectrum antifungal and antibacterial drug, PL-3301 was designed *de novo* and independently developed by us. PL-3301 is designed with a differentiated mechanism of action and a novel peptide sequence, and is formulated for local administration. It is intended to achieve therapeutic effects by a unique dosage form at a relatively low dose, and has demonstrated potent biological activity, high specificity, significant efficacy and a favorable safety profile in preclinical and clinical studies. This product is designed to act directly at the site of OPC infection, and based on its mechanism of action, the development of resistance to membrane active peptides whose sole target is the cytoplasmic membrane is not expected.

As of the Latest Practicable Date, we are advancing PL-3301 through parallel development in China and the U.S., (i) for OPC indication, (a) in China, we have completed Phase I clinical trials and expect to initiate a Phase II clinical trial in September 2026; and (b) in the U.S., the IND for OPC indication has been cleared, and we are pursuing ex-China partnerships to support the conduct of U.S. clinical trials; and (ii) for pulmonary infection indication, preclinical development is ongoing with an IND submission currently expected to be submitted by December 2027. Subject to successful clinical outcomes and relevant regulatory approvals, PL-3301 is expected to support a potential commercial launch within the next five years, alleviate the disease burden for a broad patient population, and offer an innovative solution to the risks of antibiotic resistance and misuse.

Drug Design and Mechanism of Action

PL-3301 was designed based on a similar concept to PL-5, while incorporating a distinct peptide sequence, and it exhibits a mechanism of action that is broadly consistent with that of PL-5.

Market Opportunity and Competition

Overview of Oropharyngeal Candidiasis

OPC is a fungal infection of the oral cavity and the oropharynx, primarily caused by *Candida* species, most commonly *Candida albicans*. OPC typically presents with white plaques or patches on the tongue, inner cheeks, palate and/or the oropharyngeal mucosa, and may be accompanied by mucosal erythema, pain and a burning sensation; in more severe cases, dysphagia may occur. Common risk factors include immunosuppression, diabetes, and the use of antibiotics or corticosteroids, according to Frost & Sullivan.

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Prevalence and Market Size of Oropharyngeal Candidiasis

According to Frost & Sullivan, the global prevalence of OPC was 580.9 million in 2025, including 81.7 million in China, and is expected to increase to 622.5 million globally and 85.3 million in China by 2030, indicating a sizeable and expanding patient population. The global market size for OPC drugs was approximately USD4.1 billion in 2025, while the Chinese market amounted to approximately USD0.5 billion in the same year, reflecting a meaningful commercial opportunity. The global and China markets are expected to grow to approximately USD4.6 billion and USD0.5 billion, respectively, by 2030, representing steady growth momentum and continued demand for OPC therapies. For details, please see “Industry Overview — Oropharyngeal Candidiasis Drug Market.”

Current Treatment Options and Unmet Needs

According to Frost & Sullivan, the current treatment options for OPC mainly include systemic oral fluconazole and topical therapies such as clotrimazole troches and oral nystatin: fluconazole inhibits ergosterol synthesis and is clinically superior to nystatin, with mycological efficacy better than clotrimazole, but resistance has been emerging in non-albicans species and its systemic exposure may be associated with gastrointestinal side effects and potential liver enzyme elevation; clotrimazole and nystatin are primarily topical with minimal systemic absorption and generally favourable tolerability, yet clotrimazole shows slightly lower clinical efficacy than fluconazole and lower mycological efficacy, while nystatin has lower and more variable clinical and mycological efficacy, and both typically require multiple daily dosing, which may limit adherence. Key unmet clinical needs therefore include achieving more consistent and higher clinical and mycological efficacy while maintaining low systemic exposure and good tolerability, improving coverage against non-albicans infections and addressing potential resistance risk, and reducing dosing frequency by enhancing mucosal retention and resistance to saliva washout to improve adherence and real-world outcomes.

Competitive Landscape

As of the Latest Practicable Date, according to Frost & Sullivan, (i) only three antifungal originator drugs have been approved for the treatment of OPC in each of the United States (miconazole, posaconazole, fluconazole) and China (posaconazole, itraconazole, fluconazole); and (ii) no clinical-stage pipeline candidates have been identified overseas with OPC, and only one active pipeline candidate (PL-3301) has been identified in China. For details, please see “Industry Overview — Oropharyngeal Candidiasis Drug Market.”

Key Advantages

PL-3301 is a potential first-in-class thermosensitive gel formulation developed for the treatment of OPC, according to Frost & Sullivan.

Targeting High-Burden Unmet Clinical Need

In addition to the large patient population as demonstrated above, OPC can cause extensive oral lesions, with severe cases leading to mucosal infection and pain that may impair eating or drinking. The disease severely affects immunocompromised populations, including cancer patients post-radiotherapy or chemotherapy, AIDS patients, and the elderly and children, with infection rates reaching 80% in post-chemotherapy leukemia and 96% in AIDS patients. The pathogen, *Candida albicans*, is a normal oral commensal that becomes pathogenic when host immunity weakens, leading to mucosal erosion and potential systemic complications. Current antifungal treatments may be constrained by emerging drug resistance and the oral cavity’s continuous salivary flow, which may reduce local drug retention and exposure at the infection site, according to Frost & Sullivan.

Innovative Thermosensitive Drug Delivery System

PL-3301’s peptide-based gel is liquid at room temperature but instantly solidifies at 30–35 °C upon contact with the oral mucosa. This forms a stable, adherent coating over lesions. Based on our preliminary data, drug remnants were still detectable at the mucosa site 24 hours after application, even while patients ate and drank freely. This technology enables long-lasting, local administration of the drug directly at the infection site.

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Potent and Broad-Spectrum Antimicrobial Activity

The gel has demonstrated more than 90% inhibition of *Candida albicans* in animal studies, confirming its potent therapeutic potential. Its active peptide is effective against both Gram-positive and Gram-negative bacteria, indicating broad-spectrum antimicrobial activity suitable for mixed or complex infections.

Engineered to Overcome Traditional Drug Limitations

PL-3301 is designed to overcome two major limitations of conventional and peptide-based therapies:

- (i) **No Inducible Drug Resistance:** The antimicrobial peptide (AMP) attacks the microbial cell membrane — a structure unchanged throughout evolution — making it theoretically impossible for pathogens to develop resistance. This contrasts with most antibiotics that target specific, mutable enzymes. Our resistance-induction experiments indicate that no resistance was observed against this peptide-based mechanism under the tested experimental conditions.
- (ii) **Resistance Against Protease Degradation:** The peptide is engineered by replacing standard L-amino acids with D-amino acids. This reverses its chirality, rendering it protease-resistant in oral environment while retaining full bioactivity, thereby increasing the drug’s stability in the oral cavity and prolonging its duration of action.

Favorable Safety and Stability Profile

Our product candidate is designed for topical administration and is intended to act primarily at the site of application, with the aim of reducing systemic exposure and thereby supporting a favourable systemic safety profile. Our preclinical data also show low systemic exposure following topical administration, which may help reduce systemic impact. In addition, our peptidomimetic design does not require artificial cyclisation and is intended to preserve the natural secondary structure, thereby supporting high selectivity and stability, as well as consistent and reproducible biological activity across different formulations, which may facilitate subsequent development and scale-up.

Summary of Clinical Trial Results

Currently, we have completed a Phase Ia clinical trial and a Phase Ib clinical trial of PL-3301 Oral Gel in China. In addition, we also have been granted an approval for a Phase I clinical trial in the U.S. The table below summarizes the clinical development of PL-3301 Oral Gel.

Summary of Clinical Development of PL-3301 Oral Gel

Phase	No.	Objective	Name	Participants	Dosage/ Exposure	Timespan	Status
I . . .	JSPL-PL-3301-101	Safety, PK	A Phase I clinical trial evaluating the safety, tolerability, and pharmacokinetic characteristics of PL-3301 AMP oral gel following a single topical oral administration in healthy adult study participants	Healthy adult	Single administration, crossover administration	October 2025 – March 2026 (LPO), June 2026 (CSR)	Completed in China
I . . .	JSPL-PL-3301-102	Safety, PK	A single-center, randomized, double-blind, dose-escalation, placebo-controlled Phase I clinical trial evaluating the safety, tolerability, and pharmacokinetic characteristics of PL-3301 AMP oral gel following multiple topical oral administrations in healthy adult study participants	Healthy adult	Multiple administrations: three times daily (q8h) for 7 consecutive days	May 2026 – July 2026 (LPO), September 2026 (CSR expected)	Completed in China
I . . .	JSPL-PL-3301-103	Safety, PK	A Phase I clinical trial evaluating the safety, tolerability, and pharmacokinetic characteristics of PL-3301 AMP oral gel following single and multiple topical oral administrations in healthy adult study participants	Healthy adult	SAD: Single Administration MAD: Multiple Administrations for 7 Consecutive Days	N/A	IND 170407; Phase I clinical trial application completed, SMP obtained in the U.S.

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Notes: “Clinical trial completion” generally refers to the date on which the last subject completes the final protocol-specified visit or procedure in the relevant clinical trial, commonly understood as last patient out, last subject last visit or last participant last visit, with reference to ClinicalTrials.gov, the ICH E3 guideline and ChiCTR clinical trial registration practice.”

The Phase Ia clinical trial and Phase Ib clinical trial of PL-3301 in the Chinese Mainland were designed as two early-stage clinical trials with different dosing regimens, and formed part of our planned early clinical development program for PL-3301. Although the two trials were submitted and conducted under two separate clinical trial numbers, they were submitted to, and approved by, the NMPA at the same time. Accordingly, the Phase Ib clinical trial was not an additional trial subsequently initiated upon completion of the Phase Ia clinical trial, nor was it conducted in response to any requirement or recommendation made by the NMPA after the Phase Ia clinical trial.

Specifically, the Phase Ia clinical trial primarily evaluated the safety, tolerability and pharmacokinetic characteristics of PL-3301 following a single topical oral administration in healthy adult subjects, while the Phase Ib clinical trial further evaluated such characteristics following multiple topical oral administrations in healthy adult subjects. The two trials therefore had distinct but complementary objectives in the early clinical development of PL-3301.

Phase Ia Clinical Trial in China

Trial Status

This trial was initiated in October 2025, and the LPO was achieved in March 2026, with CSR completed in June 2026.

Trial Design

This clinical trial is a randomized, double-blind, dose-escalation, and placebo-controlled study.

- **Enrollment and dosing regimen.** We enrolled 54 healthy adult participants. 52 participants received at least one dose of PL-3301 or placebo and were included in the FAS and SS, and 51 participants completed the trial. 46 participants were included in the PK concentration set and PK parameter set. Participants were enrolled sequentially into six single-dose cohorts of 2 mg, 4 mg, 8 mg, 12 mg, 16 mg and 20 mg. PL-3301 oral gel or placebo was administered locally to the buccal mucosa, with the number of sprays adjusted to achieve the target dose. The 4 mg and 8 mg cohorts adopt a two-period crossover design with a six-day washout period, while the 12 mg, 16 mg, and 20 mg cohorts include placebo controls. No dose escalation stopping criterion was met, and dose escalation was not suspended or terminated for safety reasons.
- **Key eligibility criteria.** (i) Key inclusion criteria include: (a) healthy male or female adults aged 18 to 50 years; (b) protocol-specified body weight and BMI requirements; (c) clinically acceptable findings in vital signs, physical examination, laboratory tests, 12-lead ECG and chest X-ray; (d) negative virology results; and (e) compliance with protocol-required contraception measures. (ii) Key exclusion criteria include: (a) clinically significant diseases or oral conditions that might affect study participation or oral dosing; (b) recent surgery, substantial blood loss, concomitant medications or prior trial participation; (c) smoking, alcohol, caffeine or restricted food intake above protocol-defined limits; and (d) allergy to the study drug or its components, pregnancy, lactation, history of substance and alcohol abuse.
- **Primary and secondary endpoints.** The primary endpoints are safety and tolerability following single local oral administration, including AEs, reported symptoms, and changes in laboratory tests, 12-lead ECG, vital signs, physical examination and local oral examination findings. The secondary endpoints are plasma PK parameters and salivary PK parameters, including C_{max}, T_{max}, t_{1/2}, AUC_{0-t} and other applicable PK measures.
- **Safety and Tolerability.** Among the 46 participants who received PL-3301, 14 participants (30.4%) experienced 21 TEAEs, and 12 participants (26.1%) experienced 19 TRAEs. No AEs were reported in the placebo group.

The more frequently reported TEAEs were sinus bradycardia in five participants (10.9%), increased basophil percentage in two participants (4.3%) and oral hypoesthesia in two participants (4.3%). All TRAEs were Grade 1, and the vast majority resolved without medical intervention.

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There were no SAEs, Grade 3 or higher TEAEs or TRAEs, AEs resulting in dosing interruption or death, or TRAEs resulting in permanent discontinuation or withdrawal from the trial. One participant in the 8 mg cohort experienced a Grade 2 infective febrile event and withdrew from the trial. The investigator considered this event possibly unrelated to the study product, and the participant subsequently recovered.

In the oral irritation assessment, more than 90% of participants had an overall score of at least 50, indicating favorable oral acceptability. Overall, a single topical oral dose of PL-3301 was well tolerated and demonstrated a favorable safety profile across the evaluated dose range of 2 mg to 20 mg.

- **Pharmacokinetic Results.** Following a single dose of PL-3301, plasma concentrations in all dose cohorts were BQL, indicating low systemic exposure following topical oral administration.

In saliva, PL-3301 reached its peak concentration at the first post-dose sampling time point, and Tmax ranged from approximately 0.146 to 0.177 hours. The mean residence time was approximately 1.62 to 2.42 hours, indicating a degree of local retention in the oral cavity. No clear dose-dependent relationship was observed between the administered dose and salivary exposure (Cmax & AUC) to PL-3301.

At the 4 mg dose level, bilateral administration, as compared with unilateral administration, resulted in an approximately 11.5% lower mean Cmax and approximately 13.7% and 14.0% higher AUC_{0-t} and AUC_{0-inf}, respectively. At the same 8 mg dose level, the 1% formulation, as compared with the 0.5% formulation, resulted in an approximately 89.3% higher mean Cmax and approximately 66.7% and 66.0% higher AUC_{0-t} and AUC_{0-inf}, respectively.

Urinary PL-3301 concentrations were low in participants receiving 8 mg or 20 mg PL-3301, and urinary pharmacokinetic parameters could not be calculated, indicating limited renal excretion.

Phase Ib Clinical Trial in China

Trial Status

This trial was initiated in May 2026, and the LPO was achieved in July 2026. The CSR is currently expected to be finalized by September 2026.

Trial Design

This clinical trial is a single-center, randomized, double-blind, dose-escalation and placebo-controlled study in healthy adult participants.

- **Enrollment and dosing regimen.** This study enrolled and randomized 21 participants, of whom 20 received PL-3301 or placebo. These 20 participants were allocated to two multiple-dose cohorts, with ten participants in each cohort, including eight in the PL-3301 group and two in the placebo group, with male and female participants equally represented. PL-3301 oral gel or placebo is administered locally to the bilateral buccal mucosa three times daily at eight-hour intervals from Day 1 to Day 6, with one additional morning dose on Day 7. Two dose levels are planned, namely 6 mg and 12 mg per administration, with the number of sprays adjusted to achieve the target dose. Dose escalation and any further dose exploration are determined based on cumulative safety and PK data.
- **Key eligibility criteria.** (i) Key inclusion criteria include: (a) healthy male or female adults aged 18 to 50 years; (b) body weight of at least 50.0 kg for males or 45.0 kg for females and BMI of 19.0 to 26.0 kg/m²; (c) clinically acceptable findings in vital signs, physical examination, laboratory tests, 12-lead ECG and chest X-ray; (d) negative virology test results; and (e) compliance with protocol-required contraceptive requirements, where applicable. (ii) Key exclusion criteria include: (a) clinically uncontrolled conditions, psychiatric disorders or oral pathological conditions that may affect study participation or oral administration; (b) recent surgery, substantial blood loss, blood transfusion, recent use of medications, or recent participation in another clinical trial; (c) smoking, alcohol, caffeine or restricted food intake above protocol-defined thresholds, or inability to abstain during the

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study; and (d) allergy to the investigational product or its components, pregnancy, lactation, history of substance or alcohol abuse, or any other condition considered by the investigator to make the patient unsuitable for the trial.

- **Primary and secondary endpoints.** The primary endpoints are safety and tolerability following multiple local oral administrations of PL-3301 oral gel, including AEs, reported symptoms, and changes in laboratory tests, 12-lead ECG, vital signs, physical examination and local oral examination findings. The secondary endpoints are plasma PK parameters and salivary PK parameters following multiple dosing. Exploratory endpoints include the effect of PL-3301 oral gel on oral mucosa and oral microbiota, as well as its immunogenicity.

Phase I Clinical Trial in the U.S.

This Phase I clinical trial will be a randomized, double-blind, placebo-controlled, single- and multiple-ascending-dose study in healthy adult participants. The study will consist of two parts, namely a SAD part and a MAD part. In the SAD part, approximately 40 participants will be enrolled. In the MAD part, approximately 24 participants will be enrolled. PL-3301 oral gel or placebo will be administered via the buccal mucosa, and dose escalation will proceed based on the review of cumulative safety and available PK data by the safety monitoring committee. The primary endpoints will be safety and tolerability following buccal administration of PL-3301 oral gel, including dose-limiting toxicities, maximum tolerated dose, AEs, clinical laboratory evaluations, vital signs, physical examination findings, local oral cavity examination findings and ECG results.

In light of the substantial funding requirements associated with U.S. clinical development, we are carefully assessing the optimal development strategy for PL-3301 in the U.S., including potential business development collaborations with suitable partners. We also believe that additional clinical data and regulatory feedback from our clinical development in China may further support the design of future U.S. clinical trials and help reduce clinical development risks. As such, we have not yet commenced clinical trials of PL-3301 in the U.S., as of the Latest Practicable Date.

Selected Preclinical Data

Based on preclinical studies, PL-3301 is an antimicrobial peptide that exerts antifungal activity by disrupting fungal cell membranes, demonstrating potent *in vitro* and *in vivo* efficacy against *Candida*, including fluconazole-resistant strains, with inhibition of biofilm formation. Following buccal administration, systemic exposure is low, distribution is mainly in the digestive tract with high plasma protein binding, and nonclinical evaluations showed negative genotoxicity, overall good local tolerance and safety profile under repeated dosing.

Material Communications with Competent Authorities

In the U.S., we (i) submitted the IND application on May 17, 2024; and then (ii) received a letter from the U.S. FDA on June 14, 2024, stating that we may proceed with our proposed clinical trial (IND 170407).

In China, we (i) submitted the IND application on April 10, 2025; and then (ii) obtained the IND approvals for our Phase Ia and Ib clinical trials (Approval Nos.: 2025LP01722, 2025LP01723) from the NMPA on July 3, 2025. According to these approval notices for PL-3301, as well as the applicable regulation and registration requirements, it is required to communicate with the CDE after completion of the Phase II clinical trial and before commencing the Phase III clinical trial, and a Pre-NDA meeting is also required prior to submission of the NDA application.

As of the Latest Practicable Date, we have not received any material objections to our clinical development plans from the relevant regulatory authorities.

PL-3301 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED

PL-18 (α -Helical Antimicrobial Peptide), Our Key Product

Overview

PL-18 is an α -helical AMP formulated as a vaginal suppository or gel for local gynecological administration. While its antimicrobial profile supports potential applications in colpomycolosis, bacterial vaginitis, and mixed vaginitis, our current clinical trial approvals are focused on vulvovaginal

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candidiasis (“VVC”) due to the requirements of CDE. Similar to our core product PL-5, PL-18 also exerts its antimicrobial effects primarily through the “Membrane Discrimination Mechanism”, whereby its amphipathic α -helical structure selectively interacts with microbial cell membranes, leading to membrane disruption and pathogen death.

As the most common form of colpomycolosis, VVC, formerly known as mycotic vaginitis, is primarily caused by yeasts, with *Candida albicans* being the predominant pathogen. According to Frost & Sullivan, VVC is the second most common cause of vaginitis after bacterial vaginitis, with approximately 75% of women experiencing at least one episode in their lifetime and 40%~45% developing recurrent infections. Clinically, VVC is characterized by symptoms including vulvar itching, burning sensation, dysuria and dyspareunia, with typical findings of vulvar erythema, adherent white plaques and thick, curd-like vaginal discharge. Current treatments mainly rely on azole antifungal agents, which are subject to limitations such as recurrence, reduced efficacy against non-albicans species and lack of activity against bacterial pathogens in mixed vaginitis, underscoring the need for locally administered therapies with broader antimicrobial coverage such as PL-18.

For suppository formulation, we have (i) completed a Phase I clinical trial in Australia, (ii) completed a Phase I clinical trial in China, (iii) completed a Phase Ib/II clinical trial in China and (iv) acquired an approval for a Phase II clinical trial from the FDA. For gel formulation, we expect to initiate a Phase II clinical trial in China by March 2027, subject to CDE’s approval. The current clinical trials for PL-18 are specifically focused on VVC as an indication, according to the requirements of CDE. However, considering its potential to be effective against a broad range of bacteria as well, we might plan to explore and develop additional indications in the future. But the subsequent steps will primarily depend on the specific indications officially approved by the CDE.

Drug Design and Mechanism of Action

The design concept of PL-18 is generally consistent with that of PL-5, while it is based on a distinct peptide sequence. The mechanism of action for PL-18 is also based on the Membrane Discrimination Mechanism.

Market Opportunity and Competition

Overview of Vulvovaginal Candidiasis

Vulvovaginal candidiasis (“VVC”) is a fungal infection caused by the overgrowth of *Candida* species (most commonly *Candida albicans*) in the vulva and vagina. VVC is common, with approximately 75% of women experiencing at least one episode in their lifetime and approximately 40%~45% experiencing at least two episodes; uncomplicated VVC accounts for approximately 49%, and recurrent VVC (“RVVC”) accounts for approximately 14.95%, according to Frost & Sullivan.

Prevalence and Market Size of Vulvovaginal Candidiasis

According to Frost & Sullivan, the prevalence of VVC increased from 445.0 million globally and 78.8 million in China in 2020 to 470.2 million globally and 80.0 million in China in 2025, and is expected to reach 494.2 million globally and 80.8 million in China in 2030. According to Frost & Sullivan, the global VVC drugs market was approximately USD5.6 billion in 2025 and is expected to reach approximately USD6.1 billion in 2030, while the VVC drugs market in China was approximately USD0.7 billion in 2025 and is expected to reach approximately USD0.7 billion in 2030.

Current Treatment and Unmet Needs

According to Frost & Sullivan, current treatment options for VVC mainly include oral azoles (such as fluconazole and itraconazole), topical azoles (such as clotrimazole or miconazole), and newer agents such as ibrexafungerp and oteseconazole, each with different efficacy, safety and convenience profiles. Fluconazole and itraconazole inhibit ergosterol synthesis and offer convenient oral administration, but may be associated with gastrointestinal AEs, elevations in liver enzymes, and emerging resistance in non-albicans species. Topical azoles also inhibit ergosterol synthesis and are generally well tolerated, but are typically administered as a 1-7 day topical regimen and may have reduced activity against certain non-albicans species. Ibrexafungerp, a triterpenoid glucan synthase inhibitor, provides a non-azole oral option with activity against azole-resistant and non-albicans species, although gastrointestinal tolerability and dosing considerations may affect its use in some patients.

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Oteseconazole, a next-generation azole designed for improved selectivity, remains within the azole class and involves a relatively complex dosing regimen, primarily for recurrent VVC rather than acute infection, according to Frost & Sullivan.

Accordingly, there remains an unmet medical need for VVC therapies that can (i) address real-world clinical scenarios where fungal infections may coexist with other vaginal infections, by providing coverage that reduces the need for multiple or sequential therapies and simplifies management in patients with complex or recurrent presentations; (ii) deliver effective local anti-infective activity with minimal systemic exposure, thereby improving tolerability and reducing systemic safety concerns; (iii) minimise irritation associated with traditional topical formulations to support adherence in real-world use; and (iv) offer convenient, short-course local administration with sustained local exposure, so as to reduce treatment complexity and patient burden and, in turn, improve compliance and clinical outcomes, particularly given the persistently high recurrence of VVC.

Competitive Landscape of Vulvovaginal Candidiasis

Based on publicly available information and Frost & Sullivan’s analysis, as of the Latest Practicable Date, the overseas identified programmes include BGY-1601 (Nexbiome Therapeutics; Phase I/II; indicated for bacterial vaginitis and VVC) and PL-18 (ProteLight; targeting Membrane Discrimination Mechanism; Phase I; VVC). In China, the identified programmes include WXSH0102 (Cisen Pharmaceutical; Phase II; VVC), PL-18 (ProteLight; targeting Membrane Discrimination Mechanism; Phase I/II; VVC) and GLS-W1100 (Hangzhou Grand Biologics; Phase I; VVC). Within this competitive landscape, PL-18 is differentiated by its proposed dual activity against bacterial and fungal pathogens through targeting Membrane Discrimination Mechanism, which is designed to address polymicrobial infections and reduce the need for combination therapy. PL-18 is also the only peptide-based anti-infective drug among the identified China pipelines for the treatment of VVC, and its localised administration is designed to support a favourable tolerability profile with minimal systemic exposure.

Key Advantages

Dual-Target Broad-Spectrum Efficacy.

PL-18’s primary advantage is its unique ability to simultaneously combat both bacterial and fungal pathogens. Unlike conventional agents that target only one type of microbe, PL-18 disrupts the fundamental structure of microbial cell membranes. This makes it effective for complex infections like mixed gynecological infections (e.g., bacterial vaginitis with VVC), where current single-target therapies fail, according to Frost & Sullivan.

Resistance-proof Mechanism.

The drug employs a theoretically resistance-proof strategy. By attacking the evolutionarily conserved cell membrane — a structure microbe cannot easily alter — it avoids the primary resistance mechanisms that plague traditional antibiotics (which target mutable proteins and enzymes). *In vitro* resistance-induction experiments confirm that bacteria do not develop resistance against this peptide-based mechanism, addressing the global crisis of multidrug-resistant pathogens.

Drug Stability and Topical Safety.

Through advanced molecular design, PL-18 overcomes the key limitations of natural antimicrobial peptides. By incorporating D-amino acids, it achieves complete protease resistance while maintaining full bioactivity. This molecular design ensures high selectivity and stable secondary structure without artificial cyclization. Formulated for local/topical delivery, it minimizes systemic exposure, resulting in a highly favorable safety profile with low systemic toxicity for applications like wound care and intravaginal use.

Clinical Development Plan

In China, subject to the regulatory approval for the formulation change, we expect to initiate a Phase II clinical trial for PL-18 Gel in the treatment of VVC by March 2027.

In the U.S., we expect to pursue ex-China partnerships to collaborate on and execute the clinical development of PL-18 Gel. As of the Latest Practicable Date, we have not identified such partner or entered into any collaborative arrangement.

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Summary of Clinical Trial Results

As of the Latest Practicable Date, for PL-18 Vaginal Suppositories, we have completed (i) a Phase I clinical trial in Australia and (ii) a Phase I clinical trial and a Phase Ib/II clinical trial in China. In addition, the FDA has cleared our Phase II clinical trial based on our Phase I clinical data generated in Australia and China. The table below summarizes the clinical development of PL-18.

Summary of Clinical Development of PL-18

Phase	No.	Objective	Name	Participants	Dosage/ Exposure	Timespan	Status
I . .	JSPL-PL-18-101	Safety, PK	A single-center, randomized, double-blind, dose-ascending, placebo-controlled phase I clinical trial evaluating the safety, tolerability, and pharmacokinetic characteristics of PL-18 AMP vaginal suppository following single and multiple administrations in healthy adult female volunteers	Healthy adult female	Single and multiple administration	June 2022 – March 2024 (LPO), July 2024 (CSR)	Completed in Australia
I . .	JSPL-PL-18-102	Safety, PK	a single-center, randomized, double-blind, dose-ascending, placebo-controlled phase I clinical trial evaluating the safety, tolerability, and pharmacokinetic characteristics of PL-18 AMP suppository following a single administration in healthy adult female volunteers	Healthy adult female	Single administration	March 2023 – July 2023 (LPO), November 2023 (CSR)	Completed in China
Ib+II .	JSPL-PL-18-103	Safety, efficacy	A randomized, double-blind, controlled phase Ib/II clinical trial evaluating the safety, tolerability, pharmacokinetic characteristics, and efficacy of PL-18 AMP suppository following multiple administrations in patients with vulvovaginal candidiasis (VVC)	patients with uncomplicated vulvovaginal candidiasis (VVC)	Multiple administration, dose escalation trial	Phase Ib: September 2023 – May 2024 (LPO) Phase II: September 2024 – October 2025 (LPO), April 2026 (CSR)	Completed in China
II . .	JSPL-PL-18-201	Safety, efficacy	A randomized, double-blind, placebo-controlled phase II clinical trial evaluating the safety and tolerability of PL-18 AMP suppository following multiple administrations in patients with vulvovaginal candidiasis (VVC)	patients with uncomplicated vulvovaginal candidiasis (VVC)	Multiple administration	NA	IND 171457; Phase II clinical trial application completed and SMP obtained in the U.S.

Notes: “Clinical trial completion” generally refers to the date on which the last subject completes the final protocol-specified visit or procedure in the relevant clinical trial, commonly understood as last patient out, last subject last visit or last participant last visit, with reference to ClinicalTrials.gov, the ICH E3 guideline and ChiCTR clinical trial registration practice.”

Phase Ib/II in China

In adopting a Phase Ib/II clinical trial design in patients, rather than conducting a standalone Phase I clinical trial in healthy subjects in China that comprised both single-dose and multiple-dose portions, we took into account that (i) early safety, tolerability and PK data had already been obtained from the Phase I clinical trial in healthy subjects in Australia under both single-dose and multiple-dose settings; and (ii) in China, the CDE had allowed us to enroll patients at the Phase I clinical stage to obtain preliminary efficacy data, thereby improving clinical development efficiency.

In this regard, the Phase I clinical development plan in China was designed as a stepwise clinical development strategy, under which the single-dose assessment was conducted in healthy subjects and the subsequent multiple-dose assessment was conducted directly in patients as part of the Phase Ib/II clinical trial.

- **Trial design:** This trial is a multicenter, randomized, double-blind, placebo-controlled Phase Ib/II trial conducted in China to evaluate the safety, tolerability and pharmacokinetics of PL-18 vaginal suppositories in patients with uncomplicated VVC. A total of 230 subjects were enrolled (30 in Phase Ib and 200 in Phase II) and randomized to receive PL-18 (2.5 mg, 5 mg or 10 mg) or placebo, administered once daily for six consecutive days.

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- **Key eligibility criteria.** (i) Key inclusion criteria include: (a) female patients aged 18 to 45 years in the Phase Ib stage, or 18 to 50 years in the Phase II stage; (b) diagnosis of uncomplicated VVC based on protocol-specified clinical and laboratory criteria; and (c) non-pregnant patients willing to comply with protocol requirements regarding sexual activity restrictions, avoidance of intravaginal products and contraception during the study, as well as no recent use of oral or topical agents for VVC treatment. (ii) Key exclusion criteria include: (a) complicated VVC, other causes of vulvovaginal discomfort, or recent genitourinary infections; (b) clinically significant viral, hepatic, metabolic, cardiovascular or other uncontrolled systemic diseases, psychiatric disorders, or abnormal protocol-specified laboratory or ECG findings; (c) recent use of antibiotics, antifungal agents, immunosuppressants or other prohibited medications, recent participation in other clinical studies, or recent vaginal or pelvic procedures; and (d) pregnancy, lactation, known or suspected hypersensitivity to the study drug or its components, caffeine or restricted food intake above protocol-defined thresholds, history of substance and alcohol abuse or any other condition considered by the investigator to make the patient unsuitable for the trial.

Phase Ib Clinical Trial Results

- **Primary endpoint: safety and tolerability**

In the SS, 12 subjects reported 17 TEAEs in the Phase Ib stage, including three subjects in the 2.5 mg group, four subjects in the 5 mg group, three subjects in the 10 mg group and two subjects in the placebo group. The incidence of TEAEs in the PL-18 dose groups did not show an apparent increase as compared with placebo, nor did it show an apparent dose-dependent trend. All TEAEs in the Phase Ib stage were Grade 1 or Grade 2. No Grade 3 or above TEAEs, SAEs, TEAEs resulting in early withdrawal from the trial, or TEAEs resulting in death.

- **Key secondary endpoints: PK and preliminary efficacy**

Based on the FAS, VVC clinical scores decreased from baseline in all PL-18 dose groups at D13 and at 28 days after the last dose. For mycological outcomes, the *Candida* negative conversion rates at D13 were 62.5%, 37.5%, 50.0% and 83.3% in the 2.5 mg, 5 mg, 10 mg and placebo groups, respectively. At 28 days after the last dose, the corresponding rates were 75.0%, 25.0%, 50.0% and 50.0%, respectively.

Phase II Clinical Trial Results

- **Primary endpoint: clinical cure rate at D28**

Clinical cure was defined as disappearance of VVC symptoms and signs, namely a VVC clinical score of 0. Based on the FAS, the proportions of subjects achieving clinical cure at D28 were 28.6%, 38.8%, 34.7% and 26.0% in the 2.5 mg, 5 mg, 10 mg and placebo groups, respectively. The clinical cure rates in the 5 mg and 10 mg groups were numerically higher than that in the placebo group.

- **Key secondary endpoints**

Clinical Cure Rate at D13. Based on the FAS, at D13/early withdrawal, the proportions of subjects achieving clinical cure were 26.5%, 32.7%, 28.6% and 26.0% in the 2.5 mg, 5 mg, 10 mg and placebo groups, respectively. The clinical cure rate in the 5 mg group was numerically higher than that in the placebo group.

Mycological Cure Rate. Based on the FAS, at D13/early withdrawal, the mycological cure rates were 22.4%, 26.5%, 18.4% and 18.0% in the 2.5 mg, 5 mg, 10 mg and placebo groups, respectively. At D28, the mycological cure rates were 22.4%, 30.6%, 38.8% and 22.0%, respectively. The mycological cure rates in the 5 mg and 10 mg groups at D28 were higher than that in the placebo group.

Composite Efficacy Rate. Based on the FAS, at D13/early withdrawal, the composite efficacy rates were 10.2%, 16.3%, 12.2% and 8.0% in the 2.5 mg, 5 mg, 10 mg and placebo groups, respectively. The composite efficacy rates in all PL-18 dose levels at D13/early withdrawal were numerically higher than that in the placebo group. At 28 days after the last dose, the corresponding rates were 14.3%, 18.4%, 20.4% and 16.0%, respectively. The composite efficacy rates in the 5 mg and 10 mg groups at 28 days after the last dose were higher than that in the placebo group.

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Clinical Response Rate. Based on the FAS, at D13/early withdrawal, the proportions of subjects achieving clinical response, defined as a reduction of at least 75% in VVC clinical score from baseline, were 49.0%, 55.1%, 53.1% and 42.0% in the 2.5 mg, 5 mg, 10 mg and placebo groups, respectively. At D28, the corresponding rates were 57.1%, 53.1%, 59.2% and 38.0%, respectively. The clinical response rates in all PL-18 dose groups were numerically higher than that in the placebo group.

Safety and Tolerability. Based on the SS, 89 subjects reported 135 TEAEs, including 27 subjects in the 2.5 mg group, 16 subjects in the 5 mg group, 23 subjects in the 10 mg group and 23 subjects in the placebo group. The incidence of TEAEs in the PL-18 dose groups did not show an apparent increase as compared with placebo, nor did it show an apparent dose-dependent trend. Most TEAEs were Grade 1 or Grade 2. One SAE, cholecystitis, occurred in the placebo group and was assessed by the investigator as unrelated to the study drug. No deaths were reported during the study.

Phase I in China (SAD; placebo-controlled)

- **Trial design:** Single-center, randomized, double-blind, dose-ascending, placebo-controlled Phase I single-administration study in healthy adult female volunteers (n=42). Subjects were allocated to PL-18 1, 2.5, 5, 10, or 15 mg or placebo. Primary endpoints were safety, tolerability following a single dose, with serial plasma sampling. The secondary endpoints were PK parameters and vaginal microbiota modulation/Impact on vaginal flora.
- **Safety:** Generally well tolerated; TEAEs were predominantly CTCAE Grade 1–2. No Grade ≥3 TEAEs, deaths, SAEs, or AEs leading to early withdrawal. TEAE incidence in PL-18 groups was not significantly higher than placebo; no clear dose relationship.
- **PK:** Systemic exposure was low. Detectable plasma concentrations were observed at individual time points in some subjects in the 5 mg, 10 mg, and 15 mg cohorts, while concentrations in other samples were below the LLOQ (lower limit of quantification). Median Tmax was approximately 4–8 hours.

Phase II in the U.S.

This study received FDA IND approval on October 25, 2024. It is planned to be conducted in the U.S. to evaluate the efficacy and safety in approximately 150 VVC patients. As of the Latest Date, the study has not yet been initiated, and the sponsor is currently seeking international development partners for collaboration.

Phase I in Australia (SAD + MAD; placebo-controlled)

- **Trial design:** Single-center, randomized, double-blind, placebo-controlled Phase I in healthy adult females (n=42). PL-18 vaginal suppository dose cohorts (1-15 mg) and placebo. Combined single ascending dose followed by multiple ascending doses: one single dose, then once-daily dosing for six consecutive days, with sentinel dosing at each dose level. Primary endpoints were safety, tolerability, and pharmacokinetics, with monitoring including PK sampling, physical exams, vital signs, labs, and ECG.
- **Safety:** Generally well tolerated; most TEAEs were CTCAE Grade 1–2. One subject (2.4%) in the 5 mg cohort had a Grade 3 ALT increase considered related. No deaths, SAEs, or important AEs; no clear dose-related trend; no significant increase during MAD.
- **PK:** Systemic exposure was low. Detectable plasma PL-18 concentrations were observed at individual time points in a limited number of subjects in the 10 mg and 15 mg cohorts; due to sparse and inconsistent detectability, PK parameters based on individual plasma profiles were not representative.

The data obtained from the Phase I clinical trial in Australia provided support for our subsequent application to the FDA to conduct a Phase II clinical trial of PL-18 in the U.S. For clarification, such Australian clinical trial data were not submitted to the NMPA as part of the IND application materials in China, but we have taken and will continue to take them into account, from a clinical development perspective, in designing clinical trial protocols to improve clinical development efficiency.

Material Communications with Competent Authorities

In China, we submitted the IND application in November 2022 and subsequently obtained the IND approval (Approval Nos.: CXHL2200882 to CXHL2200886) from the NMPA on January 13, 2023. According to these approval notices for PL-18 Vaginal Suppository, as well as the applicable regulation and registration requirements, it is required to communicate with the CDE after completion of the Phase

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II clinical trial and before commencing the Phase III clinical trial, and a Pre-NDA meeting is also required prior to submission of the NDA application. We did not submit any Australian Phase I clinical trial data to the NMPA as part of the IND application materials for PL-18. For clarification, under the current drug clinical trial review and approval regime in China, clinical trial applications for new drugs are subject to one-time approval and are no longer subject to phase-by-phase application, review and approval, as set out in the Announcement on Several Policies for Drug Registration Review and Approval issued by the former China Food and Drug Administration on November 11, 2015 (Announcement No. 230 of 2015). Accordingly, the Phase Ib/II clinical trial of PL-18 in China was not separately applied for or separately approved after completion of the Phase I clinical trial in China, but formed part of the clinical development plan covered by the relevant IND approval.

In July 2026, following the CDE’s preliminary review of the relevant materials regarding the proposed change of PL-18 from a suppository to a gel formulation, the CDE indicated that the formulation change should be submitted through the supplemental application procedure. This indicates that the change may be pursued under the existing IND without the need to submit a new IND application. This communication was conducted on the basis that the gel formulation would proceed directly into Phase II clinical development. The CDE did not require a new Phase I clinical trial for the gel formulation and recommended that the Phase II trial include a comparison with an existing therapy in addition to a placebo control. We expect to submit the supplemental application and supporting materials relating to the formulation change to the CDE by October 2026. Subject to regulatory approval, we expect to initiate a Phase II clinical trial of the PL-18 gel formulation by March 2027.

In Australia, the Phase I clinical trial for PL-18 Vaginal Suppository was reviewed by the ethics committee in March 2022 and formally approved in April 2022, leading to the initiation of a Phase I clinical trial. The relevant Clinical Trial Notification (“CTN”) was submitted to the Therapeutic Goods Administration (“TGA”) later in April 2022.

In the U.S., based on our Phase I clinical data generated in China and Australia, an application was submitted to the FDA in 2024, which granted approval (SMP approval) on October 25, 2024, authorizing the commencement of a Phase II clinical trial for PL-18 Vaginal Suppository.

As of the Latest Practicable Date, we have not received any material objections to our clinical development plans from the relevant regulatory authorities.

PL-18 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED PL-MD-333 (FGF19/FGF21 Inducer and Lipid Metabolism Modulator)

Overview

PL-MD-333 is a preclinical-stage oral peptidomimetic FGF19/FGF21 inducer and lipid metabolism modulator drug being developed for the treatment of obesity, metabolic dysfunction-associated steatohepatitis (“MASH”), and ulcerative colitis (“UC”).

Key Advantages

Superior and Complementary Efficacy

The investigational compound PL-MD-333 presents a potentially superior efficacy and safety profile compared to standard therapies. A key distinguishing feature is its tissue-selective action; unlike semaglutide, which reduces both fat and muscle mass, PL-MD-333 preferentially reduces adipose tissue while preserving or even increasing lean muscle mass. In terms of potency, at a lower dose (20 mg/kg/day), PL-MD-333 leads to moderate and steady weight loss. At a higher dose level (40 mg/kg/day), the reduction in body weight was greater than that observed in the semaglutide group. Furthermore, its use in combination therapy with semaglutide shows promising additive or synergistic weight-loss effects. This combination not only yields significantly greater weight reduction than either monotherapy when initiated concurrently but also appears to prevent the weight-loss plateau observed with long-term semaglutide use.

Enhanced Safety and Patient Convenience

PL-MD-333 also exhibits a potentially improved safety and tolerability profile. In our preclinical study, at 20 mg/kg/day, PL-MD-333 appeared to result in less appetite suppression than semaglutide, which may enhance patient quality of life and adherence. Beyond safety, the drug offers significant convenience as an orally administered agent, providing a clear practical advantage over injectable GLP-1 agonists.

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Broad Therapeutic Potential

The therapeutic potential of PL-MD-333 extends broadly across metabolic health. While initially targeted for obesity, ongoing studies suggest efficacy in MASH, hyperlipidemia, and other disorders of lipid metabolism, positioning it as a versatile candidate for a range of cardiometabolic conditions.

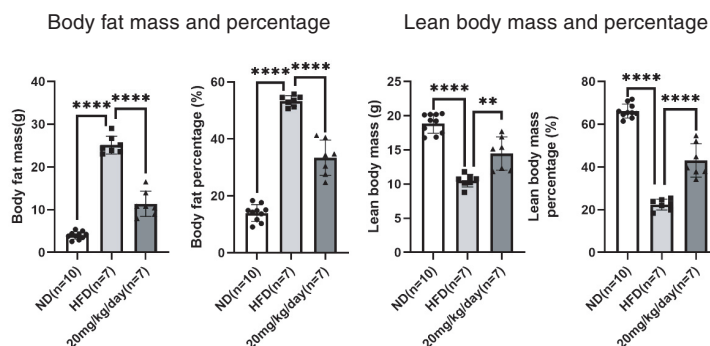
Clinical Development Plan

Our development strategy for PL-MD-333 is advancing across multiple indications. For obesity, the program is in the preclinical stage, with an IND application expected to be filed by March 2027, and IND-enabling studies have already commenced. Both UC and MASH indications are also in preclinical stage, with an IND application targeted for October 2027 and December 2027, respectively. Furthermore, we plan to expand into additional critical metabolic indications, including hyperlipidemia and other lipid metabolism disorders, with specific IND filing timelines to be determined.

Selected Preclinical Data

Obesity Indication

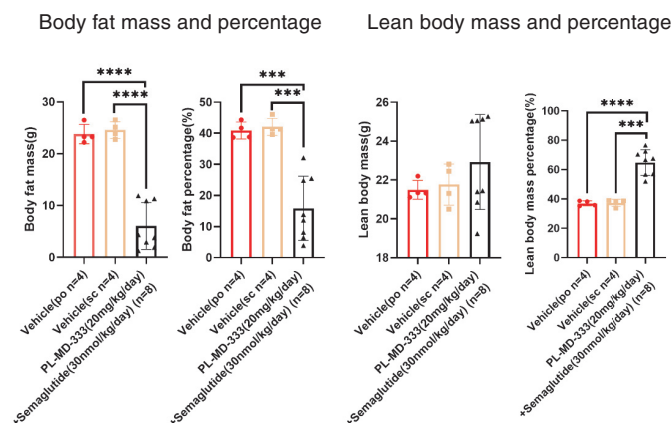
Monotherapy. In preclinical obesity mouse models, PL-MD-333 demonstrated beneficial effects on body weight and composition. Oral dosing of PL-MD-333 at 20 mg/kg/day for 50 days attenuated high-fat diet–associated body weight gain, with an approximate 26% lower mean final body weight versus the high-fat diet (“HFD”) control group ($P<0.001$). Concurrently, mice receiving PL-MD-333 at 20 mg/kg/day for 50 days displayed a statistically significant increase in lean body mass percentage versus the HFD control group ($P<0.001$), likely attributable to preserved absolute lean mass amid reduced adiposities. Taken together, these findings indicate that PL-MD-333 may support favorable body composition outcomes in preclinical models of diet-induced obesity by reducing weight gain while increasing lean body mass percentage. The following charts illustrate body fat mass and lean body mass results of this study:



Note: “ND” refers to normal diet; “HFD” refers to high-fat diet; “body fat mass” refers to the mass of adipose (fat) tissue; “lean body mass” refers to non-fat body mass, including muscle, organs, bone, and body water.

Combination with Semaglutide. We also evaluated PL-MD-333 in combination with semaglutide in obesity mouse models. Compared with the vehicle control groups, the combination group (PL-MD-333 plus semaglutide) showed a statistically significant decrease in body weight ($P<0.001$). These data advocate for additional investigation of PL-MD-333 in combination with semaglutide. The following charts delineate body fat mass and lean body mass results from this study:

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Note: “Vehicle” refers to the administered solvent without PL-MD-333; “p.o.” denotes per os (oral) administration (oral gavage); “s.c.” refers to subcutaneous injection.

PL-MD-333 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED

PL-AC-2001 (Selective PARP-1 degrader)

Overview

PL-AC-2001 is a preclinical-stage oral selective PARP-1 degrader for the treatment of hematologic malignancies and solid tumors. According to Frost & Sullivan, it is potentially the first selective PARP-1 degrader developed using PROTAC technology.

Key Advantages

According to Frost & Sullivan, PL-AC-2001 offers a transformative approach by overcoming a key limitation of existing oncology treatments. Current PARP inhibitors (PARPi), such as Olaparib and Talazoparib, are standard-of-care drugs that function by blocking the enzymatic activity of PARP proteins, exploiting synthetic lethality in cancers with homologous recombination deficiencies. However, resistance to these catalytic inhibitors can emerge. As highlighted in publications such as *Nature Reviews Drug Discovery* (2021) and *Science Translational Medicine* (2022), a PARP-1 degrader like PL-AC-2001 is considered capable of addressing this challenge by removing the entire protein, thereby eliminating not only its catalytic function but also its non-enzymatic scaffold roles. This complete protein clearance is hypothesized to overcome resistance mechanisms associated with traditional inhibitors and could provide broader efficacy in tumor models where resistance or incomplete PARP trapping limits current therapies.

In addition to its novel mechanism, PL-AC-2001 exhibits exceptional *in vitro* potency. It has demonstrated activity at the picomolar level (10^{-12} M), which represents a significant increase in strength compared to most previously reported PARP-1 inhibitors, which typically operate in the nanomolar range (10^{-9} M), according to Frost & Sullivan. This combination of a superior mechanistic profile and profound biochemical potency supports the continued development of PL-AC-2001 as a next-generation therapeutic candidate.

PL-AC-2001 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED

Our Other Products

Since our establishment, we have always been primarily focused on the research and development of innovative pharmaceutical products, including our Core Product and other drug candidates. However, the development of innovative pharmaceutical products requires substantial investment in terms of capital, time, personnel, and other resources. In order to generate some revenue and positive cash flows to support the continuing research and development of our Core Product and other product candidates, we developed and commercialized several daily-care products, leveraging certain technologies that we developed during the process of developing our pharmaceutical products.

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Our daily-care products primarily comprise professional-grade topical solutions formulated for antibacterial, antifungal, and mosquito bite management. We offer a portfolio of over 20 daily care products across three series, namely the Wenning Series (蚊寧), the antibacterial care series, and the cleaning & daily chemical series. Unlike other daily care products that rely on synthetic surfactants and chemical preservatives, our daily care products are distinguished by our AMP technology. Leveraging pharmaceutical-grade R&D and a mechanism of physical membrane disruption, our peptide-based formulations provide broad-spectrum inhibition of pathogenic bacteria without inducing microbial resistance or compromising the skin’s commensal flora. Furthermore, the inherent bioactivity of these peptides enables a self-preserving system that minimizes the use of common sensitizing agents, thereby offering high biocompatibility and tolerance for sensitive and compromised skin.

These daily-care products comply with relevant quality standards and have passed necessary quality tests and deliver rapid antibacterial, antifungal, and anti-pruritic effects. All our daily-care products are developed with a high safety margin and contain no alcohol, hormones, antibiotics, or pesticides, ensuring a comfortable, non-irritating experience for users. Going forward, we plan to keep our daily care products business as it is currently. Given that we will continue focus on our innovative pharmaceutical products in the future, our daily care products will remain as our supplementary business.

As of the Latest Practicable Date, none of our pharmaceutical products was commercialized yet. Therefore, we generated all our revenue from sales of our daily-care products during the Track Record Period. We recorded revenue generated from sales of daily care products of RMB5.2 million in 2024, RMB3.3 million in 2025 and RMB2.2 million in the six months ended June 30, 2026, respectively. Our gross profit margin from sales of daily-care products were 41.9% in 2024, 39.3% in 2025 and 47.9% in the six months ended June 30, 2026, respectively.

OUR COLLABORATIONS AND LICENSING ARRANGEMENTS

Licensing arrangements with the University of Colorado regarding certain intellectual property rights in relation to our Core Product

All the key technologies in relation to our Core Product and other product candidates were developed by us in-house, and substantially all the IP rights in relation to our Core Product and other product candidates were granted by relevant regulatory authorities to, and are currently owned by us. For details, please see “— Intellectual Property.”

However, the “Membrane Discrimination Mechanism” was co-proposed by our founder, Dr. Chen, when he was conducting his postdoctoral research at the University of Colorado (the “**University**”) and Dr. Robert Hodges (who was Dr. Chen’s mentor at the University), and the underlying antimicrobial peptide molecule of PL-5 was co-developed by Dr. Chen and Dr. Robert Hodges, as principal inventors, together with the three other co-inventors (who primarily provided experimental support for the invention and were involved on a collaborative basis). Following the University’s policies regarding discoveries and inventions, the initial compound patents in relation to such antimicrobial peptide, namely the Chinese patent ZL200580047492.9 (the “**Chinese Compound Patent**”) titled “Antimicrobial Peptides and Methods of Use,” which is the corresponding granted patent in the Chinese mainland arising from PCT/US2005/45393, and the U.S. patent, US8,252,737B2 (the “**U.S. Compound Patent**”), titled “Antimicrobial Peptides and Methods of Use,” were owned by the University.

The PL-5 licensing agreements, comprising the 2007 Agreement and the 2021 Agreement (both as defined below), were principally negotiated and finalized between Dr. Chen and the University. Dr. Hodges and the co-inventors are neither licensors nor licensees under the agreement, and the agreements do not grant them any direct authority, in their personal capacities, over the execution of the agreements or decisions relating to commercialization. ULE Holdings, a non-profit entity affiliated with the University, acted as the recipient of an equity interest in our Company on behalf of the University, and did not participate in the negotiation of the specific terms of the agreements.

Both agreements reserve for the University the right to practice and use the licensed patent rights (and related know-how/licensed products) for non-commercial purposes, including educational and research activities and industry-sponsored research. Accordingly, the University’s retained rights related to the licensed patents and non-commercial use thereof; there were no retained commercial rights by the University with respect to the Core Product. The 2021 Agreement expressly extends that reserved non-commercial use rights beyond the University to future not-for-profit employers of the inventors and

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other not-for-profit academic and research institutions. Likewise, these reserved use rights are limited to educational, research, and other non-commercial purposes and do not include any commercial exploitation rights of the Core Product.

We believe that, based on the contractual framework, the reserved rights do not and will not constitute any material commercial competition with our Core Product for the following reasons: (i) the reserved rights granted to the University, Dr. Hodges, and the co-inventors are strictly limited to non-commercial purposes, including educational, research and clinical use, and do not permit any manufacture, sale or other commercial exploitation; (ii) all exclusive commercialization rights in respect of the core product, including manufacturing, use, sale and importation, have been exclusively granted to us; (iii) while certain permitted activities, such as clinical use, industry-sponsored research and academic publication, may generate publicly available scientific information or research outputs, any third party would remain subject to our exclusive license under the 2021 Agreement; and (iv) although the 2007 Agreement and the corresponding patent in China have expired, we have established a robust and effective defensive moat for our Core Product through five patents in China and one patent in Japan covering the specific sequence-related formulation used in PL-5, all of which have been granted directly to us and will remain valid until 2041. For details, please see “— INTELLECTUAL PROPERTY.”

Neither agreement confers on the University any right to amend, determine or intervene in the clinical trial design or other day-to-day R&D activities relating to our Core Product, and full R&D control and decision-making authority rests solely with us as the licensee. While we are required to provide the University with periodic updates summarizing completed R&D activities, clinical trial progress and future development plans within specified timelines under the relevant agreements, such obligations are purely for information disclosure and milestone compliance monitoring purposes. As such, we are the sole sponsor responsible for all clinical trials and the marketing authorization holder for PL-5, our Core Products, in both the PRC and the United States. We have not engaged, and have had no plans to engage, the University in any post-licensing collaborations as of the Latest Practicable Date.

Although the two compound patents relating to PL-5 in China and the U.S. that we in-licensed from the University previously formed part of our patent portfolio, the Chinese Compound Patent expired in December 2025. As of the Latest Practicable Date, we retain only one effective compound patent license in the U.S. in respect of the Core Product, which is the U.S. Compound Patent. Notwithstanding the expiry of the Chinese Compound Patent, as of the Latest Practicable Date, we solely own five formulation patents in China and one formulation patent in Japan covering PL-5, all of which are expected to remain valid until 2041. These formulation patents cover PL-5 across multiple dosage forms, including sprays, creams, gels, paints and lyophilized formulations. We solely own all patents relating to the Core Product, except for the Chinese Compound Patent, which expired in December 2025, and the U.S. Compound Patent that is subject to the licensing arrangements under the 2021 Agreement. Compound patents and formulation patents afford different scopes of protection. While compound patents protect the peptide molecule itself, formulation patents protect specific formulations, dosage forms and methods of delivery incorporating the peptide. We rely on a layered and integrated “composition — formulation — application — commercialization pathway” patent strategy to protect the IP rights in respect of our Core Product. According to Frost & Sullivan, our patent strategy is consistent with industry practice, and, from an industry perspective, the formulation patents provide adequate protection for our commercial rights and market position against potential generic competition. For further details of our patent strategy, see “— Intellectual Property.”

The 2007 Exclusive License Agreement (Greater China)

In May 2007, we entered into an exclusive license agreement with the University (the “**2007 Agreement**”).¹ Pursuant to this agreement, the University granted us an exclusive, royalty-bearing license, which include the right to grant sublicense, to Chinese patents and applications that emerge from PCT Application PCT/US2005/45393, titled “Antimicrobial Peptides and Methods of Use Thereof” (the “**Chinese Patent Rights**”), including the Chinese Compound Patent which emerged from such PCT application.

Under the license, the University granted us an exclusive, royalty-bearing license to make, use, import, offer to sell or sell (i) any product or part thereof that is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Chinese Patent Rights and (ii) product, apparatus, or part thereof that is manufactured or discovered by using a process or is employed to

¹ The signing parties to the 2007 Agreement were Changchun ProteLight and the Regents of the University of Colorado.

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practice a process which is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Chinese Patent Rights (the “**Chinese Licensed Product(s)**,” which shall not include a new patentable enhancement, modification, purification, optimization, or affinity maturation of the Chinese Patent Rights that does not require practice of the Chinese Patent Rights to make, use or sell) in Greater China (including Chinese Mainland, Hong Kong, Macau and Taiwan). No joint steering committee or other similar joint decision-making mechanism was established pursuant to such license agreement. The University only retains the right to practice the Chinese Patent Rights for its own internal research and educational purposes and did not have any control over the R&D, clinical development and commercialization of products independently developed by us based on the Chinese Patent Rights. Under the University policies, the inventors would be rewarded by the University for such discovery.

At the time of entering into the 2007 Agreement, the relevant technology had only just emerged from the laboratory, and our core product had not entered any substantive stage of clinical trials. Only patent application PCT Application PCT/US2005/45393 had been filed, and no patent had yet been granted. There was no clear pathway as to how the patented compound could be advanced into a drug candidate, nor was there any established methodology available. Subsequently, the pre-clinical development of PL-5, as well as the maintenance of the relevant patent in the PRC (including responding to office actions and payment of related fees), were carried out by us in the PRC. Following our licensing-in of the patent, we undertook drug development efforts and the University was not involved in the process.

Other key terms of this agreement are summarized below:

Equity Consideration: In exchange for the license, we issued ULE Holdings an equity interest of 7% in Changchun ProteLight. Following a series of equity transfers among the then shareholders of Changchun ProteLight in 2009, Changchun ProteLight was wholly owned by our Company, and ULE Holdings became a shareholder of our Company in 2011. The equity ownership of ULE Holdings in our Company were later diluted as a result of our subsequent financing rounds. See “History, Development and Corporate Structure — Major Shareholding Changes of Our Group” for more information regarding their current equity ownership in our Company.

Milestone Payments: The University is also entitled to receive milestone payments based on the stage of clinical development of any Chinese Licensed Product. The total milestone payments are subject to a maximum amount, with the highest single milestone payment being USD50,000 and the aggregate milestone payments being capped at USD125,000. Milestone payments are triggered upon the occurrence of certain development and commercialization events, including (i) USD15,000 upon first dosing in humans of any Chinese Licensed Product, (ii) USD25,000 upon initiation of Phase II (or its PRC equivalent) clinical trials, (iii) USD35,000 upon initiation of Phase III (or its PRC equivalent) clinical trials, and (iv) USD50,000 upon first commercial sale of any Chinese Licensed Product in the PRC. During the term of the 2007 Agreement, the Company achieved the first three milestones in relation to PL-5 under the 2007 Agreement and made aggregate payments of USD75,000. The fourth milestone payment was never triggered because the relevant development milestone was not achieved prior to the expiry of the 2007 Agreement.

Sublicense: Under the 2007 Agreement, we were permitted to grant sublicenses to third parties (the “**Sublicensees**”) only with the University’s prior written consent, which could not be unreasonably withheld.

Royalties: We are required to pay royalties at 1.0% of net sales of the Chinese Licensed Products, triggered upon the generation of net sales in a given year and payable in the beginning of each year. We are also required to pay sublicensing royalties based on income received from Sublicensees, at rates ranging from 10% to 20% depending on the timing of the sublicense agreements entered into after the effective date.

Diligence Report: We are subject to periodic R&D reporting obligations, including annual R&D and business reports detailing the development of the Chinese Patent Rights in China and our financial condition, and milestone completion reports on each anniversary of the effective date of the agreement, specifying whether the R&D milestones have been achieved.

Governing Law and Dispute Resolution: The agreement is governed by the laws of the State of Colorado, and exclusive jurisdiction for any disputes lies with a court of competent jurisdiction in the State of Colorado.

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Subsequent Amendments: We and the University further amended the 2007 Agreement, in July 2009 and July 2013, respectively, to extend certain development milestones set forth in the agreement, such as the completion of animal toxicity studies and preclinical experiments. In addition, Changchun ProteLight, Jiangsu Protelight Pharmaceutical & Biotechnology Co., Ltd. and the University entered into an assignment and novation agreement on February 24, 2017, in which Changchun ProteLight transferred all its rights, liabilities, duties and obligations under the 2007 Agreement to Jiangsu Protelight Pharmaceutical & Biotechnology Co., Ltd. and the University approved such transfer.

Termination: The 2007 Agreement (as amended) was terminated in December 2025, following the expiration of the corresponding patent term of the Chinese Compound Patent in China. By the time of the termination, no Chinese Licensed Product was commercialized yet. As such, no royalty was payable, and we did not pay any royalty, under this agreement. Accordingly, we had no outstanding payment obligations under the 2007 Agreement upon its expiry.

The 2021 Exclusive License Agreement (U.S.)

From August 2017 to December 2021, the University granted us an exclusive option to negotiate a worldwide, exclusive license for two U.S. patents, namely, the U.S. Compound Patent and U.S. 9346865B2, a process patent directed to the method of producing the compound, which expired in 2025 (the “**U.S. Patent Rights**”). By 2021, we had initiated Phase III clinical trials of PL-5 in the PRC, and the drug had demonstrated significant potential. Accordingly, we sought to acquire the relevant rights in the U.S. and to advance our R&D activities in the U.S. on that basis. In December 2021, we decided to exercise the aforesaid option and entered into another exclusive license agreement with the University (the “**2021 Agreement**”).² Pursuant to this agreement, the University granted us an exclusive, royalty-bearing license to make, use, import, offer to sell or sell any product, service or process that would infringe a valid claim of the U.S. patents, or any product manufactured or service rendered using a process that would infringe such a valid claim (the “**U.S. Licensed Product(s)**”).

At the time of execution of the 2021 Agreement, the core product underlying the relevant licensed patents had not yet been the subject of an IND filing in the U.S. and remained entirely at the pre-clinical development stage. We independently undertook all R&D efforts in advancing PL-5 from the pre-clinical stage to the clinical stage in the U.S..

The license applies to all fields of use and is limited to the territory of the U.S. We are permitted to grant sublicenses without obtaining the University’s prior written consent, provided that such sublicenses comply with the terms of the agreement. No joint steering committee or other similar joint decision-making mechanism was established pursuant to such license agreement. The University retains the right to practice the licensed patents for educational, research, clinical, and other non-commercial purposes, and did not have any control over the R&D, clinical development and commercialization of products independently developed by us based on the patents. Under the University policies, the inventors would be rewarded by the University for such discovery.

We are required to use commercially reasonable efforts to develop and commercialize the U.S. Licensed Products. The agreement specifies development diligence milestones, including securing certain amount of fund in financing IND submission and clinical trials, submitting an IND application initiating U.S. clinical trials, and completing the first commercial sale.

License Fee: We were required to pay an upfront license fee of USD25,000 and subsequent annual license maintenance fees. The annual license maintenance fee is USD20,000 on each of the first and second anniversaries of the agreement, USD35,000 on the third anniversary, and USD70,000 on the fourth anniversary and each anniversary thereafter, and was creditable against the royalties on net sales payable by us for the annual period commencing from the relevant anniversary.

Milestone Payments: The University is entitled to receive milestone payments based on the stage of clinical development of any U.S. Licensed Product. The total milestone payments are subject to a cap, with the highest single milestone payment being USD500,000 and the aggregate milestone payments being capped at USD850,000. Milestone payments are triggered upon the occurrence of key regulatory and clinical development events, including (i) USD50,000 upon submission of an IND application to the FDA, (ii) USD100,000 upon first dosing of a patient in a clinical trial in the United States, (iii) USD200,000 upon first dosing of a patient in a Phase III clinical trial in the United States,

2. The signing parties to the 2021 Agreement were Jiangsu ProteLight Pharmaceutical & Biotechnology Corporation, Ltd. and the Regents of the University of Colorado.

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and (iv) USD500,000 upon acceptance by the FDA of an NDA for the first licensed product. As of the Latest Practicable Date, we have made payments for the first two milestone payments, with an aggregate amount of USD150,000.

Sublicense: We and our affiliates may grant sublicenses, including through multiple tiers, to third parties (the “**Sublicensees**”) without obtaining the University’s prior written consent.

Royalties: We are required to pay royalties equal to 2% of net sales of the licensed products, payable on a quarterly basis upon generation of net sales. We are also required to pay sublicensing royalties based on income received from Sublicensees for granting the sublicenses, at rates ranging from 10% to 20% depending on the timing of the sublicense agreements entered into after the effective date.

Diligence Report: We are required to submit diligence reports to the University, including disclosures of R&D data and results comprising the initial development plan, annual diligence reports, future R&D plans, and detailed explanations for any changes to the product development plan.

Governing Law and Dispute Resolution: The agreement is governed by the laws of the State of Colorado, and exclusive jurisdiction for any disputes lies with the state and federal courts located in Colorado.

Termination: The 2021 Agreement will be terminated after the expiration of the corresponding patent terms in the U.S. (currently expected in 2028).

As of the Latest Practicable Date, none of the two license agreements covered any product that was commercialized during the term of the relevant license agreement. Therefore, we did not pay any royalties to the University during the Track Record Period and up to the Latest Practicable Date.

Exclusive Commercial Cooperation Agreement with Chia Tai Tianqing

In December 2022, we entered into an exclusive commercial cooperation agreement (the “**Cooperation Agreement**”) with Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (“**Chia Tai Tianqing**”) for sales of PL-5 in Chinese Mainland (the “**Licensed Territory**”). As the subsidiaries of Sino Biopharmaceutical Limited, Chia Tai Tianqing are highly regarded cooperation partners in China’s pharmaceutical industry with strong R&D heritage and well-established nationwide commercial network.

Our collaboration with Chia Tai Tianqing is designed to accelerate the commercialization of our core product PL-5 in the Licensed Territory through its mature commercial infrastructure. We will retain responsibility for the research, global clinical trials, and registration strategy of PL-5, as well as all commercialization rights outside the Licensed Territory.

Sales: Chia Tai Tianqing shall, in each calendar year, prompt us to sell PL-5 to customers within the region such as the distributors appointed by Chia Tai Tianqing in accordance with this Cooperation Agreement. Chia Tai Tianqing is responsible for comprehensively formulating nationwide and regional market strategy analysis reports and market strategy execution reports for PL-5. By December 31 of each calendar year following the launch of PL-5, it shall submit such nationwide reports to us. The parties may discuss these reports, and our reasonable suggestions shall be duly considered and incorporated.

Service Fees: We are required to settle service fees with Chia Tai Tianqing on a quarterly basis, based on the service fees payable for each calendar quarter, and to conduct an annual settlement to reconcile and adjust the total annual service fees against the quarterly amounts already paid. The service fees are calculated based on the difference between (i) the calculation price, being the market selling price after deducting the agreed channel discount and VAT, and (ii) the applicable base settlement price determined with reference to the relevant base settlement discount rate, multiplied by the actual shipment volume (measured in vials). The applicable base settlement discount rate may be adjusted depending on the actual shipment volume and the achievement of sales targets by Chia Tai Tianqing. As PL-5 had not yet been commercialized as of the Latest Practicable Date, no service fees were paid during the Track Record Period and up to the Latest Practicable Date.

Exclusivity Terms: Under the exclusivity terms, we are restricted from selling the product directly or authorizing any other third party to do so and is required to enter into distribution agreements exclusively with distributors appointed by Chia Tai Tianqing. In terms of market access and pricing, Chia Tai Tianqing leads initiatives related to National Reimbursement Drug List (the “**NRDL**”) negotiations.

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Regulatory Approvals: We shall obtain and maintain all governmental approvals necessary for the sale of PL-5 within the Licensed Territory, including but not limited to securing and retaining marketing authorization and passing inspections conducted by regulatory authorities.

Product Supply: We shall deliver PL-5 within five calendar days upon receipt of an order from Chia Tai Tianqing or its appointed distributors. Unless otherwise agreed in writing by the parties, we shall be responsible for all procedures and costs (including shipping and insurance) incurred prior to the delivery of PL-5 to the distributor.

Product Liability: We are responsible for handling and bearing all costs and liabilities arising from disputes, returns or complaints relating to quality issues in the manufacture of the Core Product, adverse reactions, medical incidents or safety issues, including, without limitation, compensation for personal injury to patients.

Joint Steering Committee: We and Chia Tai Tianqing shall establish a joint steering committee ("JSC") composed of an equal number of representatives from each party, serving as the platform for exchanging product data, information, and market strategy plans. The JSC shall be responsible for overseeing the overall performance of this Cooperation Agreement and for facilitating communication on matters such as production, supply, launch plans, tendering, distribution, promotion, and performance review of PL-5.

Pursuant to the Cooperation Agreement, the parties have established a tiered escalation and consultation mechanism that provides a clear framework for resolving any disagreements that may arise in the course of the cooperation. If the JSC is unable to reach a consensus on any matter within the designated period, such matter will be escalated to the respective designated representatives of the parties for resolution. The designated representatives of Chia Tai Tianqing and us shall seek to resolve the relevant disputed matter through good-faith discussions and by using their best efforts within the applicable designated period following receipt of the escalation request. If a matter remains unresolved at the JSC level or by the designated representatives of the parties, such matter may be further escalated to the management of the respective parties for discussion and resolution. If the management of both parties is still unable to reach a consensus, the parties may mutually agree to terminate this agreement.

NRDL Matters: Chia Tai Tianqing is responsible for leading the NRDL access, inclusion and price negotiation matters, while we are required to provide necessary cooperation and jointly participate in on-site NRDL negotiations through designated representatives where permitted by the applicable authorities. Pricing strategy and final pricing decisions are subject to mutual consultation and approval by the JSC. We are responsible for completing the application for NRDL application and coding after the agreement becomes effective and within two months after the relevant product is approved for marketing and sale in the Licensed Territory.

Commercialization Strategies and Activities: We have granted Chia Tai Tianqing exclusive rights to promote and commercialize the product within the Licensed Territory. Chia Tai Tianqing is responsible for managing distribution channels in the Licensed Territory, including the appointment and management of distributors, inventory management, and compliance oversight, and shall submit a list of distributors to us for record-filing. In the event of any objection, the matter shall be referred to the JSC for discussion.

Chia Tai Tianqing shall take the lead in national and provincial tendering and procurement processes with our cooperation to the extent permitted by applicable regulations. Product pricing shall be determined through mutual consultation and subject to approval by the JSC. Chia Tai Tianqing is also responsible for facilitating market access to medical institutions within the Licensed Territory, and we will provide reasonable assistance. We are responsible for regulatory filings and maintenance, manufacturing, quality control, supply and inventory, pharmacovigilance and adverse event handling, as well as regulatory-required medical studies.

In terms of marketing and branding, Chia Tai Tianqing is responsible for the formulation and execution of national and regional marketing strategies and shall submit relevant materials to us for record-filing in accordance with the agreement; our reasonable suggestions shall be adopted. The product name, trademarks and packaging design will be led by Chia Tai Tianqing, subject to mutual agreement and approval by the JSC, with final decision-making authority resting with us.

Intellectual Property Rights: All copyrights, trademarks, patents, and other intellectual property rights owned by us and our affiliates prior to the execution of this Cooperation Agreement shall remain the exclusive property of us and our affiliates, unaffected by the signing of this Cooperation Agreement. Accordingly, we retain full ownership and control of all intellectual property and proprietary technology

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related to PL-5, and such rights are not transferred or diminished as a result of this Cooperation Agreement. We may also continue to conduct research, development, and commercialization activities for PL-5 outside the licensed territory in accordance with our global strategy.

Term and Termination: Unless earlier terminated in accordance with the terms of the Cooperation Agreement, the initial cooperation period under this Cooperation Agreement shall last until the date that is ten years after the commercial launch of PL-5. Upon expiration of this period, the parties may renegotiate the commercial terms based on their respective circumstances, including but not limited to the cooperation duration, service fee structure, and shipment sales targets. This Cooperation Agreement may be terminated immediately upon mutual written agreement of the parties. Following expiration or early termination of the Cooperation Agreement, the exclusive commercialization rights granted to Chia Tai Tianqing within the territory shall cease as stipulated therein.

Future Commercialization Plans (Overseas)

We intend to seek and license out the overseas development and commercialization rights of our Core Product and other drug candidates to potential partners outside the PRC. As of the Latest Practicable Date, we had not identified or secured any definitive U.S. commercialization partner, sales channel, pricing strategy or market access pathway for the commercialization of our Core Product in the U.S. We have, however, been engaging with a pharmaceutical company in Brazil and another in India, and have entered into confidential disclosure agreements with both parties in relation to potential collaboration regarding our Core Product. As of the Latest Practicable Date, we had not entered into any definitive agreement with either party. We will continue to actively explore and pursue collaboration and commercialization opportunities with suitable partners in the U.S. and other overseas markets to facilitate the commercialization of our Core Product.

RESEARCH AND DEVELOPMENT

Research and development supports our ability to foster innovation, advance pipeline assets, and maintain a competitive edge in the global pharmaceutical market. We conduct research and development activities primarily through our in-house scientific and development teams, supplemented by CDMOs, CROs and SMOs engaged from time to time to support preclinical research and clinical trials.

We have been primarily engaged in research and development for the purpose of developing our Core Product, and have continued such research and development efforts throughout the Track Record Period. In 2024, 2025 and for the six months ended June 30, 2026, our research and development expenses accounted for 71.5%, 60.9% and 50.4% of our total operating expenses (defined as the sum of research and development expenses, selling and distribution expenses and administrative expenses). Our research and development expenses for the Core Product accounted for 52.5%, 31.5% and 33.4% of our research and development expenses in 2024, 2025 and for the six months ended June 30, 2026, respectively. With respect to the research and development expenses incurred for the Core Product, we recorded RMB42.4 million in 2024, RMB18.0 million in 2025 and RMB8.2 million in the six months ended June 30, 2026, respectively. The decrease is primarily because our Core Product PL-5 received acceptance notice for application of its NDA in China in December 2024 and received NDA approval in China in June 2026. Currently, we are conducting a Phase II clinical trial of our Core Product PL-5 in the U.S. for the treatment of diabetic foot infections, which is expected to be finalized by the third quarter of 2028. Furthermore, we may also be required to conduct Phase III clinical trial of our Core Product PL-5 in the U.S. for the treatment of diabetic foot infections in order to apply for NDA in the U.S. As such, we expect our research and development expenses will continue to increase, which could satisfy the paragraph 7 of Chapter 2.3 of the Guide. Our R&D centers, located in Jiangyin, Wuxi City and Nanjing with an aggregate gross floor area of approximately 2,000 sq.m., are equipped with advanced laboratories and state-of-art equipment and instruments.

In-house R&D Team

As of the Latest Practicable Date, we have established a dedicated in-house R&D team of 36 members with an average of more than eight years of industry experience and more than 86.0% of our R&D team members held master’s or above degrees. For our Core Product PL-5, we have a dedicated team of 13 core R&D personnel as of the Latest Practicable Date covering the complete drug development lifecycle of PL-5. The team is headed by our CEO, Dr. Chen Yuxin and the remaining 12 members consist of specialized experts across key functions: clinical & regulatory affairs, pharmacovigilance, clinical & medical, preclinical, CMC & formulation and analysis & quality control. All these 13 aforementioned core R&D personnel remained continuously employed by us throughout the Track Record Period and up to the Latest Practicable Date.

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Our R&D team consists of experienced scientists with strong expertise and extensive development experience in, backed by years of work in drug development, medical practice and strategic planning. Below set forth our R&D team, who play key roles in leading the development of our drug candidates as of the Latest Practicable Date.

Ms. Chen Mingxia, our Vice President, is responsible for the R&D of clinical trials. A highly capable and experienced leader responsible for all clinical trials, regulatory submissions, intellectual property, and pharmacovigilance. She previously worked on new drug R&D and registration at Joinn Laboratories and joined the company in 2009, bringing extensive expertise to her role.

Dr. Zhu Xu, our Vice President, is responsible for the Preclinical R&D. A national-level talent recognized under the “Qiming Plan.” Before joining the company in January 2023, he spent nearly nine years in innovative drug R&D at Pfizer’s U.S. headquarters. Under his leadership, multiple drug candidates have advanced rapidly.

Dr. Sun Ping, our Head of Medicinal Chemistry. He returned to China after completing his PhD in Germany, where he specialized in PROTAC research. He designed the PROTAC-based molecules and PL-1001 and later took over the optimization of PL-MD-333, demonstrating excellent performance in structure-based drug design.

Dr. Yip Wan Kong, our Head of Biology. He held a PhD in Immunology from the University of Alberta Faculty of Medicine in Canada and is an expert in immunology and related biological research.

Dr. Yao Wenjun, our Head of Formulation. He held a PhD in Pharmaceutics from China Pharmaceutical University and previously served as the formulation lead at a company listed on the Shenzhen Stock Exchange, where he oversaw more than 70 generic drug bioequivalence studies. He has led the development of advanced formulations, including the thermo-sensitive gel formulation for PL-3301.

All core R&D personnel are bound by non-compete agreements upon departure, and no prior non-compete restrictions apply to their current roles. We confirmed that the departure of the predecessors of Dr. Zhu Xu, Dr. Sun Ping, Dr. Yip Wan Kong and Dr. Yao Wenjun did not have any material impact on the R&D of the Core Product since we have strict project management process and intellectual property protection policies and comprehensive transition arrangement to ensure steady and smooth handover process.

Drug Discovery and Preclinical Development

Prior to project initiation, our scientists leverage deep domain expertise to systematically identify, screen, and evaluate both validated and novel targets. In alignment with evolving GLP and GMP regulatory trends, we prioritize strategic imperatives such as minimizing drug-related adverse effects while maximizing therapeutic potential. Following rigorous scientific research, epidemiological analysis, market opportunity forecasting, and competitive landscape assessment, we prepare a comprehensive project proposal. This dossier outlines the technical approach, market potential, competitive positioning, implementation plan, and budget. Only after thorough internal review and approval do we formally initiate lead discovery efforts.

Once a target is validated, we advance to systematic drug discovery, which includes structure-based rational design, and iterative medicinal chemistry optimization. Candidate selection rigorously balances potency, selectivity, and drug-like properties to prioritize molecules suitable for oral delivery and further development.

In the preclinical phase, we conduct pharmacokinetics (PK), toxicology, and pharmacology studies — both *in vitro* and *in vivo* — to achieve critical milestones toward clinical readiness. Drug metabolism and PK evaluations quantify parent compounds, metabolites, and key biomarkers, informing human dosing projections. Toxicology teams design and interpret GLP-compliant safety studies to ensure robust data for IND submission. Concurrently, biomarker development enables target-engagement assays, efficacy predictions, and safety monitoring. Clinical pharmacology experts apply appropriate analysis, population PK/PD modeling, and exposure-response simulations to refine first-in-human trial designs.

To support IND submission, our CMC teams collaborate closely with contract development and manufacturing organizations (CDMOs) for drug substance and drug product activities. For the drug substance, we manage API process development, scale-up manufacturing, analytical method validation, and impurity profiling to guarantee quality, stability, and compliance with GMP standards. For the drug product, we advance formulation optimization, excipient compatibility testing, and clinical batch

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production, including stability assessments and packaging strategies. This partnership-driven approach ensures comprehensive CMC documentation, mitigates supply chain risks, and facilitates a seamless transition to clinical stages.

Looking ahead, we plan to integrate artificial intelligence technologies and leverage our AI technology platform across discovery and preclinical workflows. AI-driven virtual screening via this platform will accelerate identification of novel targets and lead chemotypes, enhancing hit-to-lead efficiency and reducing cycle times. By embedding the AI technology platform into our existing R&D system, we aim to streamline early-stage screening, prioritize high-value candidates and further boost the productivity of our drug-discovery engine.

Clinical Development

Our medical and clinical development team leads the strategic design and efficient execution of our clinical programs, managing end-to-end trial operations with the assistance of CROs, including site selection and activation, drug supply chain management, collection and analysis of study data, and preparation of clinical study reports (CSR).

Our trial momentum is powered by deep therapeutic expertise, scientifically rigorous protocols, a multi-center trial strategy in close collaboration with clinical principal investigators (PIs), and efficient trial execution. Anchored in a clinical-need-driven R&D philosophy, we strategically design the clinical trials of our drug candidates, critically select the registration pathways, diligently conduct our clinical trials to ensure speed of execution and data quality, and maintain constructive dialogues with the regulatory authorities to achieve optimal clinical efficacy, and accelerate the approval timelines and maximize the commercial potential of our drug candidates.

Critically, we retain full control over trial site selection-evaluating institutions based on patient access, therapeutic specialization, historical performance, and geographic reach. Through our established network of high-performing hospitals and PIs across diverse regions, we can rapidly enroll patients, run multiple trials in parallel, and execute large-scale studies with speed and reliability. The size and the geographic diversity of these institutions provide us with a significant advantage in implementing large-scale clinical trials and also enable us to conduct multiple clinical trials concurrently. This infrastructure not only de-risks our development timeline but also positions us to efficiently expand into new indications and markets.

Collaborations with Clinical Trial Sites

The NMPA maintains a catalog of hospitals that it has approved as clinical trial centers, from which we select a number of leading hospitals with desirable expertise, patient samples, technology and equipment to conduct our clinical trials. We meet with the selected participating hospitals to discuss the trial’s goals and requirements, as well as to select the leading institutions for the trials, which typically are the largest and best-equipped hospitals of the participating hospitals.

We typically enter into an agreement with each selected hospital for each clinical trial, under which we and the participating hospitals prepare a clinical trial protocol following GCP standards that describes in detail the goal of the clinical trial, the risks involved, the overall design, the methods and the procedures of the trial. We submit documents, including our clinical trial protocol and draft informed consent to be filled out by patients, to the ethics committee of each participating hospital for review. The ethics committees may ask us to revise the clinical trial protocol or other documents before their approval. Once the protocol is approved, any amendment thereafter is required to be reviewed and consented to by the ethics committees and the clinical trials are required to be conducted strictly pursuant to the approved protocol. The hospital provides the foundational medical services required for the trial, including supplying facilities, equipment, and qualified personnel that meet GCP requirements. In this capacity, the Principal Investigators (“PIs”) are responsible for screening subjects according to the protocol, obtaining legally valid signed informed consent, making critical medical decisions, and providing timely treatment for any adverse events or serious adverse events that occur during the study. They must also strictly manage the collection, storage, and testing of biological samples in compliance with ethical approvals and relevant genetic resource regulations.

Collaborations with PIs

In addition to our collaboration with clinical trial institutions, we also maintain continuous communications with lead principal investigators, who are informed of our latest research and development progress. The PIs we work with include reputable physicians who work at leading Class III hospitals and are responsible for the implementation, quality and safety of clinical trials. They not only provide us with important feedback on clinical needs but also present the clinical use of our

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products in academic settings, which we believe can invite wider discussion of our drug candidates and in turn contribute to our research and development efforts. Furthermore, we have presented our products in multiple industry conferences, where we keep industry participants updated on our latest research and development progress. In addition, PIs bear additional leadership and coordination responsibilities. In this role, they need to assist in coordinating the screening and mobilization of other participating research centers across the country. Their administrative and scientific duties include hosting investigator meetings to communicate the research background, supervising the overall enrollment speed and protocol adherence of the participating centers, and providing expert scientific advice to interpret trial results and review the final statistical analysis and clinical summary reports.

Key terms of agreements that we typically enter into with clinical trial sites and PIs are set forth below:

- **Services.** We are responsible for providing GMP-compliant investigational drugs, the clinical trial protocols, and relevant regulatory approval documents. The clinical trial sites are responsible for the execution of specific study activities, including subject screening and enrollment, administration of investigational drugs, safety and efficacy assessments, biological sample collection and management, adverse event reporting, and source data recording in accordance with GCP and the protocols.
- **Terms.** The term of services for each project varies depending on the trial phase and enrollment plan. In general, it should cover the period from the effectiveness of the agreement until the completion of the clinical trial and the full discharge of all parties’ rights and obligations.
- **Payment.** Clinical trial study fees are generally structured as milestone-based payments, with final settlement based on the actual number of enrolled subjects and completed study visits.
- **IP rights.** All the intellectual property rights in relation to the clinical trial are either owned by us or by the participating institutions. The use of clinical trial results for academic activities or patient care purposes is generally allowed but may require our prior approval, subject to the specific terms.
- **Confidentiality.** Except as necessary for performance of the agreement or as required by regulatory authorities or ethics committees, no party shall disclose any confidential information to any third party without the prior written consent of the counter-party.

Collaboration with CROs and SMOs

To improve research and development efficiency, control costs, and accelerate the commercial launch of our drug candidates, we have adopted a collaborative R&D model comprising our core in-house team alongside external CROs and SMOs. Under this model, we firmly retain all core decision-making authority, including trial protocol design, medical strategy formulation, data ownership, and regulatory filings, while our engaged CROs and SMOs act solely as executing parties. Our in-house R&D team leads the core stages of our development programs and oversees the entire project lifecycle. During the clinical stage, their responsibilities include determining clinical trial protocols, maintaining relationships with Key Opinion Leaders (KOLs), communicating with regulatory authorities, and managing product registrations. Furthermore, our in-house team establishes a pool of qualified suppliers, selects and evaluates CROs and SMOs through a competitive bidding process, to ensure effective execution and quality compliance. During the clinical trial, We would organize monitoring steps at each milestone, and will engage independent clinical trial audit institutions to issue independent clinical audit report.

We engage CROs and SMOs to serve as the executing parties for our clinical trials. CROs primarily provide specialized clinical execution services, which include conducting clinical site monitoring, providing pharmacovigilance services, and managing electronic data capture systems. SMOs primarily provide clinical trial site management services. They assist the clinical research institutions and principal investigators with the day-to-day operations and specific on-the-ground execution of our clinical trials at the study sites.

We select CROs and SMOs based on professional qualifications, relevant research experience, service quality, efficiency, industry reputation, and costs. We typically enter into the master service agreement with CROs and SMOs under which we execute a separate work order which define the scope of work, sample size, procedures, deliverables, timelines, and payment terms for each preclinical or clinical research project. CROs are required to comply with all applicable laws and regulations and adhere to our established protocols, ensuring the accuracy and authenticity of clinical trial results. To

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maintain data integrity and regulatory compliance, we also exercise oversight of our CROs and SMOs partners. This includes regular progress meetings, execution reviews, and periodic audits, ensuring adherence to our protocols and regulatory requirements. Our proactive management approach reinforces the quality and reliability of data generated from our trials, supporting the advancement of our pipeline and strengthening our overall clinical development strategy.

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

- **Services.** In line with industry practice, CROs support us in matters such as trial design, site selection, trial execution, data management and analysis, and compliance with regulatory requirements. According to China’s GCP common practice, we also engage SMOs, working together with trial sites in trial site management, including assisting in recruiting trial participants, coordinating site staff to confirm site process compliance, collecting clinical trial documents and maintaining data integrity at each site.
- **Term.** The CROs and SMOs are required to perform their services and complete the research project within the prescribed time limit set out in each agreement or work order, usually on a project basis.
- **Payments.** We are required to make payments to the CROs and SMOs in accordance with the payment schedule agreed by the parties.
- **Intellectual property rights.** We own all intellectual property rights arising from the clinical research projects conducted by the CROs and SMOs within the stipulated work scope.
- **Confidentiality.** Our CROs and SMOs are not allowed to disclose confidential information, including but not limited to, any information or data related to research, development, processes and protocols as specified in the agreement, and such obligation generally survives for a specified period.
- **Risk allocation.** We are generally responsible for the risks associated with the research project, while the CROs and SMOs should indemnify us for losses caused by their fault or gross negligence.

During the Track Record Period, we engaged with (i) five, six and three CROs in 2024, 2025 and the six months ended June 30, 2026, respectively; and (ii) one, two and one SMOs in 2024, 2025 and the six months ended June 30, 2026, respectively. The aggregate expenses incurred in relation to the (i) engaged CROs amounted to approximately RMB28.5 million, RMB18.8 million and RMB9.0 million in 2024, 2025 and the six months ended June 30, 2026, respectively; and (ii) engaged SMOs amounted to RMB0.3 million, RMB0.2 million and 46.4 thousand in 2024, 2025 and the six months ended June 30, 2026, respectively.

Given that our core competencies, including clinical development strategy, trial protocol design, medical oversight, data ownership, and regulatory submissions, are firmly retained by our in-house R&D team. Our CROs and SMOs are engaged solely for the operational execution of these internally driven strategies. Furthermore, the market for CROs and SMOs services is highly competitive and abundantly supplied with qualified alternative service providers. We maintain a robust supplier management system and engage multiple vendors concurrently. We can readily replace any existing CRO or SMO with comparable third-party service providers on commercially reasonable terms without experiencing material disruptions, delays, or significant additional costs to our clinical development programs if necessary. Ultimately, our engagement of these third parties reflects a standard industry practice optimized for operational efficiency, rather than a dependency. Therefore, our Directors are of the view that we do not have any reliance on any individual CRO or SMO for our research and development activities.

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Collaboration with CDMOs

In the biotechnology industry, CDMOs are specialized service providers that offer comprehensive drug development and manufacturing solutions, including the synthesis of raw materials. During the Track Record Period, to support the research, development, and clinical trials of our drug candidates, we procured some raw material, namely peptide APIs, from external CDMOs. During the Track Record Period, we cooperated with two, three and two CDMOs in 2024, 2025 and the six months ended June 30, 2026, respectively, with corresponding expenses of approximately RMB2.9 million, RMB3.5 million and RMB3.0 million. Key terms of agreements that we enter into with our CDMOs include:

Services. Responsibilities of CDMOs typically include API production, process validation, stability testing, as well as the preparation and submission of API registration applications.

Term. The CDMOs are required to perform their services within the time limits prescribed in the respective agreements.

Payment. Payments are made upon the completion of milestones as set forth in the respective agreements.

Confidentiality. Our CDMOs are not allowed to disclose confidential information, including but not limited to, any information or data related to drug application and relevant technical documents, and such obligation generally survives for a specified period.

Intellectual property. We own all new technical achievements relating to the relevant products generated from the CDMOs’ contracted manufacturing.

CMC AND MANUFACTURING

Our CMC team

Our CMC team provides strong support throughout the drug development process. Our CMC team, is responsible for, among other relevant functions, process development, formulation development, analytical method development and validation, technology transfer, GMP-compliant manufacturing, quality control and quality assurance. Our CMC team is led by Mr. Liu Chunmeng, our Operation senior director and Mr. Feng Shangbin, our quality director, who boast extensive experience in this regard.

Manufacturing Facilities

We have established our own Chinese GMP-compliant manufacturing facilities in Jiangyin (“**Jiangyin Facilities**”), Wuxi City, China, which meet both clinical and commercial production demands for quantity, quality and dosage form of our drug candidates and daily-care products. Our Jiangyin Facilities have a total gross floor area of approximately 12,000 sq.m. We primarily utilize these facilities to manufacture PL-5 and our daily-care products. Additionally, as of the Latest Practicable Date, we also conduct small-scale production of our key products at this site to support our ongoing research and development activities.

Drug Candidates

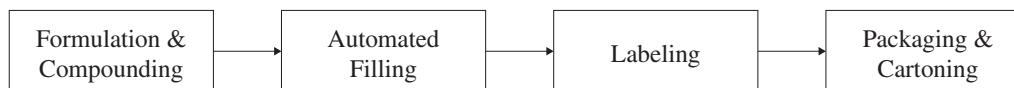
We strategically front-loaded our production capacity infrastructure in a relatively cost-efficient manner. As compared with production outsourcing, our robust independent production capability guarantees a stable and sufficient supply of drug candidates and future commercialized drugs with more manageable production costs and guaranteed quality.

During the Track Record Period, we have successfully completed nine production batches of our PL-5, which fulfilled the needs for preclinical studies, pilot production and clinical trials. As of June 30, 2026, the total production volume of our pipeline product PL-5 (spray dosage form) reached 117,364 bottles and all produced batches achieved a 100% product release success rate.

Our PL-5 production line utilizes an automated workflow designed for high-efficiency pharmaceutical manufacturing, moving seamlessly from bulk formulation to final packaging. The process begins with a 300L stainless steel compounding tank capable of producing 200L per batch, which equals a substantial output of 40,000 bottles per batch. Following formulation, the system transitions to a comprehensive filling stage, which comprises automatic bottle unscrambling, filling, and capping, and should be able to operate at a design speed of 120 bottles per minute. This is immediately followed by the S-500 labeling unit, which applies labels at a rate of 125 bottles per minute. The line

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concludes with a high-capacity automated cartoning station capable of processing 145 bottles per minute, ensuring that downstream packaging capacity effectively supports the line’s continuous high-speed operation. The following diagram shows the production process of our PL-5:



Daily-care Products

During the Track Record Period, we currently have three production lines for our daily-care products up to a total capacity of 20.2 million units. The table below sets forth the production details of our daily-care products as of June 30, 2026:

	For the Year Ended December 31, 2024			For the Year Ended December 31, 2025			For the Six Months Ended June 30, 2026		
	Production capacity ⁽¹⁾	Production volume	Utilization rate ⁽²⁾	Production capacity ⁽¹⁾	Production volume	Utilization rate ⁽²⁾	Production capacity ⁽¹⁾	Production volume	Utilization rate ⁽²⁾
		(Unit)		(Unit)	(Unit)				
Product line A ⁽³⁾	9,000,000	899,561	10.0%	9,000,000	415,058	4.6%	4,500,000	227,483	5.1%
Product line B ⁽³⁾	2,160,000	57,528	2.7%	2,160,000	60,910	2.8%	1,080,000	23,647	2.2%
Product line C ⁽⁴⁾	9,000,000	103,078	1.1%	9,000,000	79,926	0.9%	4,500,000	10,676	0.2%

Notes:

1. Production capacity is calculated as the full production rate of various machines in a production facility operating 300 days for a year. If a production facility commences or ceases operation in the middle of the year, the actual days from its production commencement to the last day of such year, or the actual days from the first day of such year until the date it ceases production, is used instead.
2. Utilization rate refers to the percentage of production volume to production capacity over the respective period.
3. Production line A and Production line B represent our gel daily-care products in different specification.
4. Production line C represents our liquid daily-care products.

We expect to devote our productive forces to our own drug candidates and products as our clinical trials progress and after our commencement of commercialization.

API Manufacturing Facility

In December 2025, we acquired a parcel of land in Taizhou Bay through our own fund and we are constructing our own API manufacturing facility on this site, which is expected to be completed in 2029. The designed annual production capacity of our Taizhou Bay API manufacturing facility is expected to be approximately 160 kg, which will mainly support the upcoming commercialization of our Core Product, PL-5, and the research and development of other product candidates, such as PL-18 and PL-3301. As a national-level economic and technological development zone located in Linhai City, Zhejiang Province, Taizhou Bay has vigorously fostered the pharmaceutical and chemical industry, attracting various enterprises and establishing a complete industrial chain covering intermediates, APIs, and formulations. In addition, Taizhou Bay enjoys a strategic location with convenient transportation links, and offers well-established infrastructure and utility services. Such land is categorized as Class III industrial land, a classification that complies with national requirements for land that may be used for the construction of API manufacturing facility. We view it as a key component of our supply chain integration strategy, designed to: (i) mitigates the risk of supply chain by ensuring a stable and reliable supply of high-quality APIs, timely delivery, and effective cost control; (ii) maintain in-house production enables us to better protect our proprietary manufacturing technologies and minimizes the risk of process know-how and trade secret leakage associated with reliance on third-party manufacturers; and (iii) allow us to maintain stringent oversight over process stability and batch-to-batch consistency for our innovative drugs and formulations, ensuring that our impurity profiling and control strictly comply with the relevant regulatory and registration requirements. We do not allocate any portion of the [REDACTED] to the construction or development of our API manufacturing facilities, as we intend to fund the expenditure primarily through our internal financial resources.

Our CMC activities and capabilities

CMC refers to activities that define methods for manufacturing processes, product testing and releasing, product storage, ensuring that a pharmaceutical product is safe, effective, and consistent across batches.

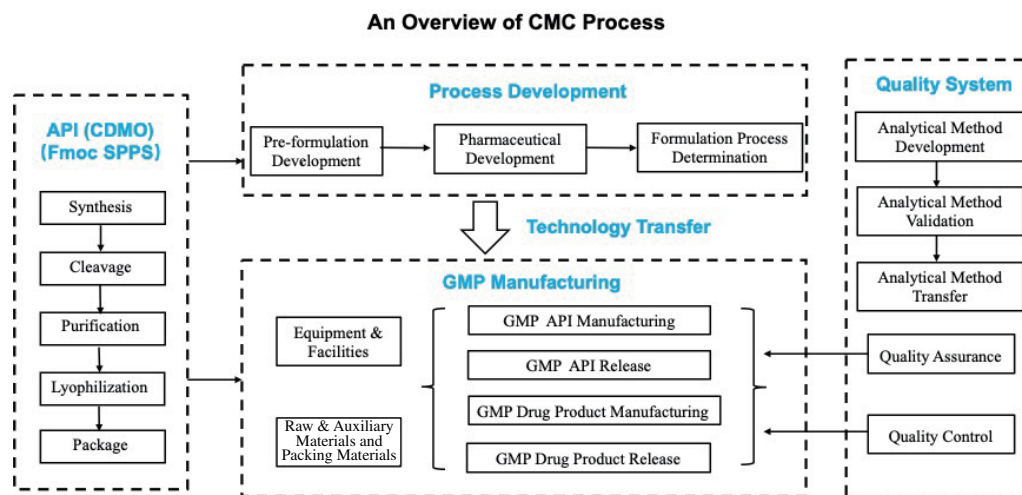
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Due to the complexity of therapeutic molecules, such as the various stages of peptides, including crude peptide syntheses, cleavage, purification and lyophilization, and GMP-compliant manufacturing, are critical for the successful development of peptide drugs. We cooperate closely with certain listed peptide CDMO companies to manufacture peptide pharmaceutical ingredient (API), which focus on developing and synthesizing active ingredient, expediting the scale-up of compounds for early developmental activities in drug safety and pharmaceutical sciences, and fulfilling in a timely and efficient manner the requests for drug substance supply to support pre-clinical study pipelines, and also focus on manufacturing GMP-compliant API for clinical studies and commercial supplement. Our CMC team have the capability to ensure that the production qualifications, facilities and processes of our CDMOs comply with the applicable regulatory requirements and our internal guidelines and quality standards.

As for drug product, our CMC capability includes the following functions:

- (i) Formulation development: our formulation development team focuses on developing dosage forms of toxicology evaluations and preclinical trials and clinical studies; our experienced team integrates formulation process development, technology transfer, and contract manufacturing technical support, leveraging advanced facilities and technology to significantly reducing cycle times while ensuring adherence to the most stringent quality standards and rigorous manufacturing practices.
- (ii) Manufacturing facilities: we have established robust pilot manufacturing capabilities to support the clinical development. Notably, we also have a GMP-compliant manufacturing facility to support commercial supplement of our drug candidates. Our GMP-compliant manufacturing factory in Jiangyin, Wuxi City, Jiangsu Province has a total GFA of more than 12,000 m².
- (iii) Analytical sciences: our analytical science team implements a science-driven, clinical and commercial production-oriented approach to the development and application of both classic and state-of-the-art analytical techniques and tools throughout the life cycle of each of our drug candidates, including but not limited to development and validation of analytical methods for API and drug product, technical transfer of process and analytical methods, establishment of specifications, testing and releasing of each batch of API;
- (iv) Quality control and assurance: with a well-documented and comprehensive quality system, the quality control and assurance team is responsible for testing and verifying the product quality with predefined standards to assure the quality of all the batches, manufactured at every stage of processing API and manufacturing drug products.

The following figure shows an overview of our CMC process:



QUALITY CONTROL AND ASSURANCE

Quality control and quality assurance are critical to our continued success. We are committed to ensuring the quality of our operations through a comprehensive quality management system that spans all key stages of our R&D and manufacturing processes, which is meticulously established in

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accordance with rigorous regulations and guidelines in China. We closely monitor evolving cGMP standards and regulatory developments in the market, continuously updating our internal procedures to adhere to the highest international standards for patient safety and regulatory compliance.

Our dedicated quality management team are dedicated to ensuring the quality systems cover all key stages of product development. All team members possess the work experience and knowledge background that match their positions, and the necessary qualifications that meet the requirements of our quality management activities.

We have established comprehensive quality control and assurance procedures to ensure compliance with relevant regulatory requirements and our internal quality standards, primarily including control and inspection of raw materials, management of each step of the development procedures, inspection of samples, establishment of internationalized product release standards, and risk evaluation during the process of product development.

COMMERCIALIZATION

Since our establishment, we have always been primarily focused on the research and development of innovative pharmaceutical products, including our Core Product and other product candidates. As of the Latest Practicable Date, we had not established a large in-house sales and marketing team yet, and our limited commercialization efforts during the Track Record Period were primarily in relation to the sale of our daily-care products, which has never been, and will not be, our core business. We believe that such strategy has afforded us significant advantages in terms of economic viability and operational efficiency, and allowed for the swift development of our core technologies and our pharmaceutical product candidates.

In the near term, we expect that we will continue to be primarily focused on research and development. Instead of expending extensive resources on establishing a large sales and marketing team within a short timeframe, we plan to cooperate with leading industry players, leveraging their established distribution channels, robust sales and marketing capabilities, capital resources and market intelligence and insights to achieve fast market access for our products in a cost-effective way. Following such strategy, we entered into the exclusive commercial cooperation with Chia Tai Tianqing, in anticipation of the upcoming commercialization of PL-5 in China, which could enable us to rapidly penetrate the domestic market by leveraging Chia Tai Tianqing established commercial infrastructure and extensive industry network. In terms of market access and pricing, Chia Tai Tianqing will also lead initiatives related to National Reimbursement Drug List (the “NRDL”) negotiations. Our Phase III clinical data demonstrate that PL-5 possesses broad-spectrum efficacy against over 2,200 bacterial strains, including antibiotic-resistant pathogens. Beyond its clinical efficacy, PL-5 offers a strong pharmacoeconomic advantage by delivering rapid bactericidal action within 15 to 90 minutes, by passing the prolonged regimens typical of conventional antibiotics. Notably, its unique “Membrane Discrimination Mechanism” is not expected to induce drug resistance, thereby mitigating the need for time-intensive and costly pre-treatment susceptibility testing. This streamlines clinical workflows reduces diagnostic overhead and enables the immediate initiation of targeted therapy to accelerate patient recovery. In light of these demonstrated clinical benefits and cost-saving efficiencies, our Directors are of the view that the inclusion of PL-5 in the National Reimbursement Drug List (NRDL) is strategically and commercially feasible. For details, please see “— Exclusive Commercial Cooperation Agreement.”

For the U.S. market, we intends to adopt a collaborative commercialisation strategy as well. We are actively exploring opportunities to cooperate with prospective overseas partners to jointly commercialize PL-5 in the U.S. Accordingly, the definitive sales and distribution pathways in the U.S., encompassing potential engagements with local hospitals or clinics will be strategically determined and deployed in conjunction with such partners upon the formalisation of these collaborative arrangements. As of the Latest Practicable Date, our key products remain in the clinical development stages. Given that the preliminary phase of their clinical progression of our key products, we have not formulated any definitive commercialization strategy as of the Latest Practicable Date.

Going forward, as our Core Product and other drug candidates approach commercialization, we plan to progressively strengthen our commercialization capabilities through a combination of internal sales and marketing resources and external marketing and distribution partnerships, with the goal of achieving broader patient access and maximizing the value of our product pipeline.

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SALES AND MARKETING

Sales

During the Track Record Period, all our sales efforts were conducted in relation to our daily-care products. We sold such products in China, either directly by ourselves, or indirectly through distributors.

Distributors

During the Track Record Period, we primarily sold our daily care products through the network of third-party distributors which include typical buy-out distributors and consignment distributors. To the best of our Directors’ knowledge, all of our distributors are Independent Third Parties, and none of them were controlled by our current or former employees. These distributors are typically established entities with major business in retail of pharmaceuticals and daily necessities, possessing the requisite business licenses and established sales network to penetrate regional markets effectively. We select our distributors based on a rigorous set of criteria, including their creditworthiness, geographical coverage, market reputation, and historical sales performance. We benefit from our distributors’ established distribution channels and local resources, which enable us to save costs and increase the effectiveness of launching and selling our daily-care products in our target markets within a short period of time. We have been selling daily-care products to distributors in China since 2015. As of June 30, 2026, we had 97 distributors in China. To the best knowledge of our Directors, during the Track Record Period, all of our distributors were Independent Third Parties. In 2024, 2025 and the six months ended June 30, 2026, the revenue attributable to our distributors was RMB3.6 million, RMB1.9 million and RMB0.7 million, accounting for 69.7%, 57.3% and 31.4% of the revenue generated from sales of daily-care products in China, respectively. Our gross profit margin from sales of daily-care products by distributors 37.4% in 2024, 24.3% in 2025 and 27.5% in the six months ended June 30, 2026, respectively. We either have a seller-buyer relationship or a consignment sales relationship with our distributors.

We generally enter into distribution agreements with our distributors. The principal terms of our distribution agreements with buy-out distributors are substantially similar to those with our consignment distributors, with the only material distinction being the transfer of title to and risk of our products. Under the consignment model, title to and risk of our products remain with us until the products are ultimately sold to the end-customers. Conversely, our arrangement with buy-out distributors operates on a principal-to-principal basis, where title and risk transfer to the buy-out distributors upon their acceptance of the products. According to Frost & Sullivan, it is not uncommon to adopt a hybrid distribution model that utilizes both buy-out distributors and consignment distributors in order to optimize market penetration and adapt to the diverse procurement preferences. Individual sales contracts or purchase orders are generally separately entered into or placed for each purchase. Key terms of our distribution agreements include:

Term	Typically one to three years.
Designated distribution area	Distributors are generally not allowed to sell or distribute our products outside of their designated distribution areas.
Price and payment methods	Our selling prices and payment methods are typically specified in the distribution agreements
Resale price management	We generally do not allow malicious underpricing and require our distributors to follow our recommended retail price.
Exclusivity	Some distributors are granted the distributorship of specific specifications of products agreed upon in the distributor agreements in their designated distribution areas on an exclusive basis, while other distributors are generally granted the distributorship on a non-exclusive basis.

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Inventory level	We generally do not require our distributors to maintain a minimum inventory level.
Return of products	We generally do not allow product returns except for defective products.
Sub-distributors	We do not have contractual relationships with sub-distributors engaged by our distributors, nor do we manage such sub-distributors directly.
Minimum purchase amount	Minimum purchase amount is 100 bottles per order in general.
Confidentiality	We generally specify the term of confidentiality in the distribution agreements.
Termination	We may terminate the distribution agreements in the event of, among others, any material breach by our distributors, such as sales outside of their designated distribution areas.

Selection and Management of Distributors

We select our distributors based on their proven sales capabilities, knowledge of their target markets, warehouse management, financial stability, credit records and expertise and experience of their management teams. We require all our distributors to possess all licenses and permits necessary for the sales and distribution of our daily-care products. We require our distributors to meet our annual sales targets during their term of engagement. Our annual sales targets may vary among distributors based on factors such as general market conditions, economic development levels, our market penetration, and estimated customer demand in the designated distribution area as well as historical performance of the distributors.

The table below sets forth the number of our distributors and their movements for the periods indicated.

	Year Ended December 31,		Six Months Ended June 30,
	2024	2025	2026
Number of distributors at the beginning of the year/period	137	123	86
Number of new distributors during the year/period	39	20	15
Number of terminated distributors during the year/period	53	57	4
Number of distributors at the end of the year/period	123	86	97

In 2024, 2025 and the six months ended June 30, 2026, we terminated the relationship with 53, 57 and four distributors. During the Track Record Period, we terminated our business relationships with certain distributors primarily due to: (i) their failure to meet the sales targets during our performance assessments; (ii) severe operational or financial difficulties of the distributors (including prolonged delays in settling outstanding payments to us); and (iii) violation of our sales and pricing policies as discovered through our regular on-site spot checks and random checks conducted on e-commerce platforms.

In order to manage the risk of cannibalization of sales among our distributors, we specify the designated geographic area for which our distributors are responsible in our distribution agreements with them. The agreements also prohibit distributors from distributing our products outside their respective designated geographic areas. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any material cannibalization or competition among our distributors within the same geographical area. Our Directors are of the view that the above measures are sufficient to mitigate potential cannibalization and competition among distributors.

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Some of our distributors may engage sub-distributors within their respective designated distribution areas and channels. To the best of our knowledge, some of our distributors have engaged sub-distributors during the Track Record Period. In line with the market practice, as confirmed by Frost & Sullivan, we do not enter into contractual relationships with sub-distributors engaged by our distributors, and our distributors select and enter into separate agreements with the sub-distributors. Consequently, we do not exercise direct control over the sub-distributors and mainly rely on our distributors to manage and control their sub-distributors in accordance with regulatory requirements, the terms of the distribution agreements we entered into with our distributors and our policies and measures that our distributors agree to comply with. Although we primarily rely on our distributors to directly control their sub-distributors, we have adopted a special code system (pursuant to which each of our products carry a special code which contain information including the specific distributor who purchases such product from us). We conduct random purchases of products suspected of channel diversion or price violations and trace the distributors by tracking the special codes. Through which, we are able to identify and assess whether a given product was sold by the corresponding distributor within the designated distribution area or channel.

Furthermore, we have implemented the following policies and measures to mitigate the risk of inventory accumulation in the distribution channels. For consignment distributors, we usually conduct settlements with them periodically, for instance, monthly or quarterly; therefore, it is less likely to have inventory accumulation issues. For buy-out distributors, they are required to provide us with information, including but not limited to sales and inventory data of our product. We monitor our distributors’ inventory level through regular on-site visit. We also review and evaluate sales data of our distributors on a regular basis, which enables us to make periodic assessments of actual market demand for our products. We actively adjust our sales strategy and geographic or product coverage of each distributor based on market demand and each distributor’s capacity. During the Track Record Period and up to the Latest Practicable Date, we did not notice any abnormally high inventory level of our distributors.

Direct Sales

We also directly sell daily-care products to consumers in China through e-commerce channels and have established our online channels, primarily through the opening of online stores on Tmall, JD.com, Douyin, Pinduoduo and other e-commerce platforms since 2016 in China. As of June 30, 2026, we had 11 direct sales online stores in China. In 2024, 2025 and the six months ended June 30, 2026, the revenue attributable to our direct sales customers was RMB1.6 million, RMB1.4 million and RMB1.5 million, accounting for 30.3%, 42.7% and 68.6% of the revenue generated from sales of daily-care products in China, respectively. Our gross profit margin from sales of daily-care products through direct sales 52.2% in 2024, 59.3% in 2025 and 57.2% in the six months ended June 30, 2026, respectively.

Marketing

Our in-house sales and marketing team is primarily responsible for the promotion of our daily-care products through various marketing activities and sales through different channels in China. As of the Latest Practicable Date, our in-house sales and marketing team included 11 employees, with an average of approximately eight years of daily-care products industry-related experience. Our in-house sales and marketing personnel are required to strictly adhere to our detailed procedures, policies, and guidelines, including but not limited to a code of conduct on interacting with, and promoting our products to, healthcare professionals. For details, please see “— Risk Management and Internal Control.”

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business, and we are committed to the development and protection of our intellectual properties. We rely on a combination of patent and other intellectual property rights, as well as confidentiality procedures, non-disclosure agreements, employee non-disclosure and invention assignment agreements, and other contractual restrictions to establish and protect our commercially important technologies, inventions and know-how related to our business.

We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 71 issued patents in China, (ii) two issued patents and one licensed-in patent in the U.S., (iii) three issued patents in other jurisdictions, including Japan and

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Europe, and (iv) 27 pending patent applications, including 16 in China, two in the U.S., one under the Patent Cooperation Treaty (PCT) which has not entered into national phases, and eight in other jurisdictions. As our IP Counsel advised, except for the compound patents in China and in the U.S., we own all patents in relation to our Core product.

In December 2025, a Chinese patent we licensed from the University of Colorado covering the underlying antimicrobial peptide compound of our Core Product expired, and a U.S. patent we licensed from University of Colorado covering the same compound is expected to expire in October 2028. Despite the expiration (and expected expiration) of these patents, we believe we have established a robust and effective defensive moat for our Core Product. As of the Latest Practicable Date, with respect to our Core Product, PL-5, we owned five patents in China, and one patent in Japan, covering the specific sequence-related formulation used in PL-5. These patents have all been granted directly to us, and will remain valid until 2041. As confirmed by our IP Counsel, such patent portfolio covers almost all the possible principal topical routes of administration of PL-5, including spray (suitable for large-area or pain-sensitive wounds), cream (suitable for superficial infected wounds), gel (suitable for infected wounds with slough that require maintenance of a moist environment), topical solution/liquid (suitable for wound irrigation and wet dressing applications), and lyophilized formulations (suitable for scenarios requiring a reconstituted antimicrobial solution with high concentration and high activity for complex wounds or drug-resistant infections), which represent the most commonly used and principal conventional dosage forms for treating secondary wound infections as confirmed by Frost & Sullivan. We believe that this multi-dosage-form coverage enables us to address different wound types and clinical use scenarios, and forms an effective barrier to deter competition from generic drugs. In addition to the above-mentioned issued patents, as of the Latest Practicable Date, we also had four pending patent applications in relation to PL-5, including one in China, one in the U.S., and two in other jurisdictions, namely Japan and the European Union.

We believe our multi-dosage form, multi-jurisdictional and regionally diversified patent portfolio serves as a defensive moat for our Core Product, based on the following considerations:

First, we own five patents in China and one patent in Japan covering PL-5 which will remain valid until 2041, and such patent portfolio covers PL-5 across multiple dosage forms, including sprays, creams, gels, paints and lyophilized formulations (the “**Relevant Patents**”). We understand that, in light of considerations relating to the stability, developability, and compatibility with excipients of the PL-5 compound, the Relevant Patents cover almost all topical dosage forms that may be applicable to PL-5 so that we have sufficient coverage for the dosage forms of PL-5.

Second, each of these patents specifies formulation compositions and methods of use for specific types of infections, wound types, or drug-resistant scenarios in its patent specification. In particular, we have defined suitable concentration ranges for the key ingredients of each dosage form, reflecting data collected during our R&D process and taking into account considerations relating to stability, developability, and compatibility with excipients, based on the nature of the PL-5 compound. As a result, it would be difficult for competitors to develop commercially competitive drug products based on the PL-5 compound without infringing or circumventing our patents.

Third, we have also filed four patent applications in relation to PL-5, including two divisional applications based on existing patents and two patent applications filed in Europe and the United States. As confirmed by our Intellectual Property Legal Advisor, these patent applications may further expand our existing patent coverage in terms of both geographical scope and formulation specifications. In addition, we continue to carry out ongoing R&D of PL-5 and may, based on new technical ideas or developments arising from such R&D activities, apply for further patents in the future.

In summary, our PL-5 patent portfolio not only provides protection at the level of individual inventions, but also, through a multi-dimensional combination of dosage forms, indications, administration regimens and multi-jurisdictional coverage, establishes a layered and integrated “composition–formulation–application–commercialization pathway” patent barrier, thereby supporting the long-term competitiveness and commercial value of our Core Product. In addition, following the NDA approval, PL-5 was granted a six-year drug trial data protection period, during which other applicants for generic or improved new drugs may not rely on our protected trial data and would generally need to independently generate the relevant clinical data, thereby providing an additional layer of regulatory protection for PL-5.

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According to Frost & Sullivan, our patent strategy is in line with industry practice, and our formulation patents can fully protect our commercial rights against potential generic drug developer from an industry perspective.

Based on the above, our Directors believe, and the Sole Sponsor concurs, that the expired PRC patent and the U.S. patents which are nearing expiry do not have, and will not have, any material impact on our R&D activities or the commercialization of the Core Product.

As of the Latest Practicable Date, (i) we have one PCT patent application and one issued patent in China regarding our key product PL-3301; and (ii) we have three issued patents in China, the U.S. and the European Union, respectively and no patent application regarding our key product PL-18.

The following table sets forth the portfolio of patents and patent applications material to our business operations as of the Latest Practicable Date:

Product	Key Technologies	Patent Number	Patent Type	Patentee	Jurisdiction	Patent Status	Patent Grant Date	Patent Expiration*
PL-5	Antimicrobial peptides and methods of use ⁽²⁾	US8,252,737B2	Invention	University of Colorado	U.S.	Granted	2012.08.28	2028.10.13
PL-5	An antibacterial peptide liquid composition and its preparation ⁽¹⁾	ZL202110068276.3	Invention	Our Group	China	Granted	2024.04.09	2041.01.19
PL-5	An antibacterial peptide liquid composition and its preparation ⁽¹⁾	特許第7731153號	Invention	Our Group	Japan	Granted	2025.08.21	2041.01.19
PL-5	An antibacterial peptide cream and its preparation methods ⁽¹⁾	ZL202110472836.1	Invention	Our Group	China	Granted	2024.05.10	2041.04.29
PL-5	A topical antibacterial peptide gel and its preparation methods ⁽¹⁾	ZL202110472490.5	Invention	Our Group	China	Granted	2023.10.31	2041.04.29
PL-5	An antibacterial peptide coating and its preparation methods ⁽¹⁾	ZL202110482050.8	Invention	Our Group	China	Granted	2024.06.07	2041.04.30
PL-5	An anti-infective antibacterial peptide lyophilized preparation and its preparation methods ⁽¹⁾	ZL202110483679.4	Invention	Our Group	China	Granted	2022.07.29	2041.04.30
PL-3301	An anti-infective antibacterial peptide and its use	ZL201510403782.8	Invention	Our Group	China	Granted	2018.06.19	2035.07.13
PL-18	An antibacterial peptide, its preparation methods and use	ZL201110095737.2	Invention	Our Group	China	Granted	2013.03.20	2031.04.18
PL-18	An antibacterial peptide, its preparation methods and use	US9,273,095B2	Invention	Our Group	U.S.	Granted	2016.03.01	2032.01.17
PL-18	An antibacterial peptide, its preparation methods and use	EP2735570B1	Invention	Our Group	EU	Granted	2018.01.03	2032.01.17
PL-MD-333 . .	Ethylenediamine derivatives, its preparation method and use	ZL202211660703.8	Invention	Our Group	China	Granted	2025.04.11	2042.12.23
PL-5	Antimicrobial peptide liquid composition and its preparations	CN202410305699.6	Invention	Our Group	China	Pending	N/A	N/A

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Product	Key Technologies	Patent Number	Patent Type	Patentee	Jurisdiction	Patent Status	Patent Grant Date	Patent Expiration*
PL-5	An antimicrobial peptide liquid composition and its preparations	特願2025-134445	Invention	Our Group	Japan	Pending	N/A	N/A
PL-3301 . . .	Antimicrobial peptides	PCT/CN2021/072665	Invention	Our Group	PCT	Pending	N/A	N/A
PL-AC-1001. .	Process for preparing trans-vinyl sulfones	CN202411063528.3	Invention	Our Group	China	Pending	N/A	N/A
PL-AC-1001. .	Pyrimidine compounds, preparation method and use	CN202510419797.7	Invention	Our Group	China	Pending	N/A	N/A

Note:

* *Patent expiration date does not include any applicable patent term extensions.*

- (1) Specific sequence-related formulation patents used in PL-5
- (2) The “Antimicrobial Peptides and Methods of Use” license is in-licensed from the University of Colorado. We originally acquired two licenses in relation to the compound patents of PL-5, namely the “Antimicrobial Peptides and Methods of Use” in China and the U.S. However, the “Antimicrobial Peptides and Methods of Use” in China expired in December 2025. Therefore, as of the Latest Practicable Date, we only have one effective license in the U.S. regarding the “Antimicrobial Peptides and Methods of Use”.

In addition to patents, we also rely on trade secrets, unpatented know-how, and proprietary information to maintain our competitive position, and as confirmed by Frost & Sullivan, it is inherently difficult for competitors to reverse engineer the formulation of our Core Product and other product candidates and develop a drug that would be bioequivalent to our Core Product.

Furthermore, our market position is reinforced by significant regulatory barriers. According to Frost & Sullivan, under the Administrative Measures for Drug Registration and related PRC regulations, any competitor seeking to develop a new formulation based on the PL-5 sequence would be required to complete a lengthy and costly process of IND filings and clinical trials. As of the Latest Practicable Date, we are not aware of any third parties who have completed, or are currently conducting, such clinical research. Therefore, we believe that our comprehensive patent portfolio across China, the U.S., and other key jurisdictions integrated with these stringent regulatory requirements establishes a robust and effective defensive moat for our Core Product.

The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends on many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular jurisdiction, and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug candidates and methods of manufacturing the same. For a detailed description of risks related to our intellectual property, please see “Risk Factors — Risks Relating to Our Intellectual Property Rights.” According to the freedom-to-operate (“FTO”) search and analysis conducted by our IP counsel on our Core Product and key products in China and U.S., our Directors and our IP counsel believe that (i) we can implement the product technology of all of Core Product and key products in China and U.S. without any material risk of patent infringement; (ii) given that we do not have plan to commercialize our Core Product in Australia as of the Latest Practicable Date, our Directors are of the view that the FTO search and analysis in China and the U.S. should be sufficient to prevent potential risks in relation to the infringements of IP rights.

As of the Latest Practicable Date, we have not applied for any key IP rights in relation to our technology platforms, as they primarily consist of know-how and proprietary technology and, given their confidential nature, patent protection is less likely to be suitable.

As of the Latest Practicable Date, we had 75 registered trademarks in China and we are also the registered owner of two domain names.

We enter into license and collaboration agreements and other relationships with biopharmaceutical companies and other industry participants, through which we may grant access to our own intellectual property, or gain access to the intellectual property of others. For details, please see “— Our Collaborations and Licensing Arrangements.”

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

SUPPLIERS AND PROCUREMENT

During the Track Record Period, our suppliers primarily consisted of CROs, SMOs, and suppliers of R&D materials. Purchases from our five largest suppliers for the year ended December 31, 2024 and 2025 and the six months ended June 30, 2026 were RMB43.7 million, RMB22.0 million and RMB14.1 million, respectively, representing 54.7%, 45.9% and 52.7% of our total purchases for the respective years/period. Purchases from our single largest supplier for the year ended December 31, 2024 and 2025 and the six months ended June 30, 2026 were RMB21.5 million, RMB16.0 million and RMB6.1 million, respectively, representing 27.0%, 33.3% and 22.6% of our total purchases for the respective years/period.

We select our suppliers based on their quality, costs, delivery standards, industry reputation and compliance with or qualification under relevant regulations and industry standards. We believe that we maintain strong and stable relationships with our major suppliers. During the Track Record Period, we did not experience any material disputes with our suppliers, difficulties in the procurement of raw materials or services, disruptions to our operations due to a shortage of or delay in supply of raw materials or services, or significant fluctuations in raw material and/or service prices. For the summary of the key terms of our suppliers, please see “— Research and Development — Collaboration with CROs and SMOs” and “— Research and Development — Collaboration with CDMOs.”

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

Supplier	Supplier background	Registered capital	Products/service purchased	Credit term	Year of commencement of business relationship	Payment method	Purchase amount (RMB'000)	% of total purchases
For the Six Months Ended June 30, 2026								
Supplier A	A HKEX-listed company located in Zhejiang and primarily engaged in medical research and experimental development, providing full-process services for pharmaceutical R&D, including Phase I-IV clinical trials, data management and statistical analysis, and regulatory filing.	RMB861 million	CRO Services	Installment payments to be made within 30 days upon completion of milestones, as applicable	2019	Bank transfer	6,059	22.6
Clinical Service Center Co., Ltd. (蘇州科林利康醫藥科技股份有限公司)	A Jiangsu company primarily engaged in medical research, technical services, as well as sales of Class I medical devices and mechanical equipment.	RMB10 million	CRO Services	Installment payments to be made within 15 days upon completion of milestones, as applicable	2025	Bank transfer	2,923	10.9
Joinn Laboratories (China) Co., Ltd. (北京昭衍新葯研究中心股份有限公司)	A Hong Kong-listed company, which also listed on the Shanghai Stock Exchange, headquartered in Beijing and specialised in non-clinical safety assessment of pharmaceuticals, providing comprehensive services across the drug development value chain.	RMB749 million	Animal Studies Execution Services	30% to 70% advance payment within 10 days upon execution of the contract, with the balance to be paid within 10 days upon completion of milestones, as applicable	2020	Bank transfer	2,110	7.9
Supplier H	A Sichuan professional peptide drug R&D and manufacturing company whose core business covers full industry chain services for peptide APIs, formulations, and innovative drugs from the preclinical stage to industrialization.	RMB50 million	CDMO Services (Polypeptide API)	Installment payments to be made within 15 days upon completion of milestones, as applicable	2011	Bank transfer	1,770	6.6

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Supplier	Supplier background	Registered capital	Products/service purchased	Credit term	Year of commencement of business relationship	Payment method	Purchase amount (RMB'000)	% of total purchases
Pharmaron Beijing Co., Ltd. (康龍化成(北京)新藥技術股份有限公司)	A company dually listed in SSE and HKEX, offering end-to-end drug discovery, development and manufacturing services across small-molecule, biologics and cell and gene therapy modalities.	RMB178 million	CDMO Services	31.32% to 50% advance payment within 10 to 20 days following the receipt of the invoice upon execution of the contract, with the balance to be paid within 10 to 20 days following the receipt of the invoice upon completion of milestones, as applicable	2025	Bank transfer	1,278	4.7
							14,140	52.7
For the year ended December 31, 2025								
Supplier A	A HKEX-listed company located in Zhejiang and primarily engaged in medical research and experimental development, providing full-process services for pharmaceutical R&D, including Phase I-IV clinical trials, data management and statistical analysis, and regulatory filing.	RMB861 million	CRO Services	Installment payments to be made within 30 days upon completion of milestones, as applicable	2019	Bank transfer	15,963	33.3
Supplier H	A Sichuan professional peptide drug R&D and manufacturing company whose core business covers full industry chain services for peptide APIs, formulations, and innovative drugs from the preclinical stage to industrialization.	RMB50 million	CDMO Services (Polypeptide API)	Installment payments to be made within 15 days upon completion of milestones, as applicable	2011	Bank transfer	2,516	5.3
Supplier E	A Nanjing company primarily engaged in the development, construction, operation, and management of university science and education innovation parks, focusing on the establishment of technology innovation platforms, industrial incubation, and the integration of industry-university-research resources.	RMB1,977 million	Property leasing service	Payments to be made semi-annually within 10 days prior to each due date	2020	Bank transfer	1,472	3.1
Clinical Service Center Co., Ltd. (蘇州科林利康醫藥科技股份有限公司)	A Jiangsu company primarily engaged in medical research, technical services, as well as sales of Class I medical devices and mechanical equipment.	RMB10 million	CRO Services	Installment payments to be made within 15 days upon completion of milestones, as applicable	2025	Bank transfer	1,112	2.3
Guangzhou Huayin Medical Research Institute Co., Ltd. (廣州華銀醫學研究所有限公司)	A Guangdong company primarily engaged in third-party medical testing services with pathological diagnosis at its core, covering clinical testing, telepathology, and specialized technology platforms, while providing scientific research support.	RMB5 million	CRO Services	10% to 30% advance payment to be made within 30 days upon execution of the contract, and the balance to be paid within 60 to 90 days after reconciliation every 1 to 3 months	2020	Bank transfer	888	1.9
							21,951	45.9

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Supplier	Supplier background	Registered capital	Products/service purchased	Credit term	Year of commencement of business relationship	Payment method	Purchase amount	% of total purchases
							(RMB '000)	
For the year ended December 31, 2024								
Supplier A	A HKEX-listed company located in Zhejiang and primarily engaged in medical research and experimental development, providing full-process services for pharmaceutical R&D, including Phase I-IV clinical trials, data management and statistical analysis, and regulatory filing.	RMB861 million	CRO Services	Installment payments to be made within 30 days upon completion of milestones, as applicable	2019	Bank transfer	21,533	27.0
Supplier B	A U.S.-based contract research organization (CRO) specializing in biopharmaceutical outsourcing, providing comprehensive clinical research, medical communications, consulting, commercialization, and advanced technology products to the global pharmaceutical, biotechnology, and medical device industries, with specific services covering clinical trial management, observational studies, data management, biostatistics, epidemiology, health economics/outcomes research, pharmacovigilance, medical communication, clinical pharmacology, patient recruitment, post-marketing surveillance, regulatory product development, and commercialization consulting.	USD0.5 million	CRO Services	Installment payments to be made within 30 days upon completion of milestones, as applicable	2023	Bank transfer	11,827	14.8
Supplier C	A Shanghai company primarily engaged in the R&D, manufacturing, and sales of electronic products, focusing on smart hardware and solutions.	RMB20 million	Laboratory Equipment	90% prepayment to be made before shipment and the balance within 30 days after inspection and acceptance	2024	Bank transfer	4,478	5.6
Supplier H	A Sichuan professional peptide drug R&D and manufacturing company whose core business covers full industry chain services for peptide APIs, formulations, and innovative drugs from the preclinical stage to industrialization.	RMB50 million	CDMO Services (Polypeptide API)	Installment payments to be made within 15 days upon completion of milestones, as applicable	2011	Bank transfer	2,922	3.7
Supplier D	A Jiangsu company engaged in construction engineering	RMB10 million	Building Construction and Maintenance	Installment payments to be within 7 days upon acceptance of the completed work	2023	Bank transfer	2,898	3.6
							43,658	54.7

To monitor the quality of supplies, we implement rigorous supplier qualification and selection standards. We verify the qualifications, licenses and permits of our suppliers each time before entering into procurement agreements. For suppliers of raw materials and key equipment, we also conduct rigorous audits prior to procurement. We maintain a list of qualified key suppliers, which is subject to regular review and update.

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All of our five largest suppliers in each year during the Track Record Period were Independent Third Parties. None of our Directors or their close associates or, to the knowledge of our Directors, any Shareholder with over 5% of the share capital of our Company has any interest in any of our five largest suppliers in each year during the Track Record Period.

Raw Materials

During the Track Record Period, the raw materials we purchased and consumed for (i) our daily care products amounting to RMB2.0 million, RMB1.3 million and RMB0.9 million in 2024, 2025 and the six months ended June 30, 2026, respectively, accounting for 66.7%, 65.0% and 81.8% of our cost of sales in the respective years/period; and (ii) our drug candidates amounting to RMB7.4 million, RMB8.4 million and RMB5.7 million in 2024, 2025 and the six months ended June 30, 2026, respectively, accounting for 9.2%, 14.6% and 23.4% of our research and development expenses in the respective years/periods. During the Track Record Period, we did not experience any significant fluctuations in raw material prices or delays that had a material impact on our results of operations or financial position. The raw materials for our drug candidates to be used in clinical trials as well as materials for our laboratory use are generally readily available in the market through multiple suppliers.

CUSTOMERS

Our core pharmaceuticals have not yet been launched, nor have we generated any revenue from patent licensing. Our current customer base contained daily-care products customers only. Therefore, for salient terms of the agreements typically entered into with our customers, see “— Sales and Marketing — Sales — Distributors.”

In 2024, 2025 and the six months ended June 30, 2026, revenue generated from our five largest customers in each year/period amounted to RMB1.9 million, RMB1.1 million and RMB0.4 million, representing 36.9%, 32.9% and 20.2% of our total revenue for the respective years/periods, respectively. Revenue generated from our single largest customer in each year/period amounted to RMB0.6 million, RMB0.4 million and RMB0.2 million, representing 11.5%, 13.5% and 10.8% of our total revenue for the respective years/periods, respectively. The following table sets forth details of our five largest customers in each year/period during the Track Record Period:

Customer	Customer background	Registered capital	Products/service purchased	Credit term	Year of commencement of business relationship	Payment method	Revenue contribution (RMB'000)	% of total revenue
For the Six Months Ended June 30, 2026								
Hunan Mingyulongxing Pharmaceutical Sales Co., Ltd. (湖南名裕龍行醫藥銷售有限公司). . . .	A Hunan company primarily engaged in the wholesale and retail of pharmaceutical products and medical devices, and also in the provision of professional pharmaceutical distribution, marketing, and supply chain services.	RMB30 million	Daily-care products distributor	Payment to be made within 45 days after reconciliation and settlement	2019	Bank transfer	236	10.8
Nanjing Cixi Technology Co., Ltd. (南京賜禧科技有限責任公司). . . .	A company primarily engaged in the sale of daily necessities, disinfection products and hygiene products.	RMB1 million	Daily-care product distributor	Shipment to be made upon full payment	2024	Bank transfer	61	2.8
Shaanxi Pharmaceutical Holdings PaiAng Pharmaceutical Co., Ltd. (陝西醫藥控股集團派昂醫藥有限責任公司). . . .	A Shaanxi company primarily engaged in the wholesale and distribution of pharmaceuticals and the operation and sale of medical devices, together with the wholesale and sale of health food and Chinese medicinal herbs.	RMB188 million	Daily-care product distributor	Payment to be made within 37 days from the invoice date	2018	Bank transfer	56	2.5

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Customer	Customer background	Registered capital	Products/service purchased	Credit term	Year of commencement of business relationship	Payment method	Revenue contribution (RMB'000)	% of total revenue
Customer H	A wholly-owned trading subsidiary of a company dually listed in NASDAQ and HKEX, primarily engaged in the wholesale and retail of pharmaceuticals and medical devices, as well as health food, special medical-purpose formula food, single-use medical supplies and cosmetics.	USD1398 million	Daily-care product distributor	Payment to be made within 7 days from the payment date set forth in the settlement statement	2025	Bank transfer	48	2.2
Customer B	A Guangdong company primarily engaged in the pharmaceutical retail chain business, covering the sale of pharmaceutical products, medical devices, and health supplements, as well as the provision of related healthcare services.	RMB1139 million	Daily-care product distributor	Payment to be made within 45 days after reconciliation and settlement based on actual sales volume	2018	Bank transfer	41	1.9
							442	20.2
For the year ended December 31, 2025								
Customer F	A Hunan company primarily engaged in the pharmaceutical wholesale business, specializing in the procurement, distribution and supply chain management services of pharmaceutical products and medical devices.	RMB150 million	Daily-care product distributor	Payment to be made within 90 days after reconciliation and settlement	2018	Bank transfer	449	13.5
Hunan Mingyulongxing Pharmaceutical Sales Co., Ltd. (湖南名裕龍行醫藥銷售有限公司). . . .	A Hunan company primarily engaged in the wholesale and retail of pharmaceutical products and medical devices, and also in the provision of professional pharmaceutical distribution, marketing, and supply chain services.	RMB30 million	Daily-care product distributor	Payment to be made within 45 days after reconciliation and settlement	2019	Bank transfer, banker's acceptance	230	6.9
Customer B	A Guangdong company primarily engaged in the pharmaceutical retail chain business, covering the sale of pharmaceutical products, medical devices, and health supplements, as well as the provision of related healthcare services.	RMB1139 million	Daily-care product distributor	Payment to be made within 45 days after reconciliation and settlement based on actual sales volume	2018	Bank transfer, banker's acceptance	226	6.8
Customer E	A SSE-listed pharmaceutical retail chain located in Yunnan and primarily engaged in the sale of pharmaceutical and healthcare products and the provision of related services with professional pharmacies at its core, integrating diversified business patterns such as convenience stores and community health services.	RMB155 million	Daily-care product distributor	Payment to be made within 30 days after quarterly reconciliation	2017	Bank transfer	103	3.1
Nanjing Cixi Technology Co., Ltd. (南京賜禧科技有限責任公司). . . .	A company primarily engaged in the sale of daily necessities, disinfection products and hygiene products.	RMB1 million	Daily-care product distributor	Shipment to be made upon full payment	2024	Bank transfer	88	2.6
							1,096	32.9

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Customer	Customer background	Registered capital	Products/service purchased	Credit term	Year of commencement of business relationship	Payment method	Revenue contribution (RMB'000)	% of total revenue
For the year ended December 31, 2024								
Hunan Mingyulongxing Pharmaceutical Sales Co., Ltd. (湖南名裕龍行醫藥銷售有限公司)	A Hunan company primarily engaged in the wholesale and retail of pharmaceutical products and medical devices, and also in the provision of professional pharmaceutical distribution, marketing, and supply chain services.	RMB30 million	Daily-care products distributor	Payment to be made within 45 days after reconciliation and settlement	2019	Bank transfer, banker's acceptance	597	11.5
Customer B	A Guangdong company primarily engaged in the pharmaceutical retail chain business, covering the sale of pharmaceutical products, medical devices, and health supplements, as well as the provision of related healthcare services.	RMB1139 million	Daily-care products distributor	Payment to be made within 45 days after reconciliation and settlement based on actual sales volume	2018	Bank transfer, banker's acceptance	588	11.3
Customer C	A Guangdong company primarily engaged in the R&D, production, and sale of pharmaceutical products, with a core focus on the manufacture of chemical drugs and the marketing of related pharmaceutical products.	RMB5 million	Daily-care products distributor	Shipment to be made upon full payment	2024	Bank transfer	261	5.0
Customer D	A Guangdong new retail company centered around its online platform to engage in B2C pharmaceutical retail, O2O instant delivery, and health management services	RMB500 million	Daily-care products distributor	Payment to be made within 30 days after reconciliation in the following month based on actual sales volume	2018	Bank transfer	244	4.7
Customer E	A SSE-listed pharmaceutical retail chain located in Yunnan and primarily engaged in the sale of pharmaceutical and healthcare products and the provision of related services with professional pharmacies at its core, integrating diversified business patterns such as convenience stores and community health services.	RMB155 million	Daily-care products distributor	Payment to be made within 30 days after quarterly reconciliation	2017	Bank transfer	228	4.4
							<u>1,918</u>	<u>36.9</u>

To the best of our knowledge, the top five largest customers in each year during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates or any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of the five customers during the Track Record Period.

During the Track Record Period and up to the Latest Practicable Date, we have no overlapping customers and suppliers, who was also our five largest customers or suppliers in each year/period during the Track Record Period.

COMPETITION

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, according to Frost & Sullivan. 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. As of the Latest Practicable Date, there were six clinical-stage peptide-based anti-infective drug candidates under development overseas and seven clinical-stage peptide-based anti-infective drug candidates in China. Any drug candidates successfully developed and commercialized by us will compete with existing drugs or any new drugs that may become available in the future. For more information on the competitive landscape of our drug candidates, please see “Industry Overview — Peptide-based Anti-infective Drug Market.”

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EMPLOYEES

As of the Latest Practicable Date, we had 111 employees and all of them are in China. The following table sets forth the number of our employees categorized by functions as of the Latest Practicable Date:

Function	Number of employees	As a percentage of our total number of employees
R&D	36	32.4%
CMC and Regulatory Affairs	43	38.7%
General and Administration	21	18.9%
Sales personnel	11	9.9%
Total	111	100.0%

Employee Agreement

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

Employee Training

To maintain our workforce’s quality, knowledge, and skill levels, we also provide trainings based on the needs of our employees in different departments. We regularly organize training sessions conducted by senior employees or third-party consultants covering various aspects of our business operations including overall management, project execution and technical know-how. We also set up an annual training budget, which will be used to attend external training upon application of our employees.

Employee Benefits

Our employees’ remuneration comprises salaries, bonuses, house provident funds, social insurance premium, and other welfare payments. Furthermore, we provide various incentives and benefits, including bonuses and share-based compensation, to our employees, particularly our key employees.

We strive to create an equitable, inclusive, and diverse workplace while fostering positive working relationships with our employees. We believe that we maintain a good working relationship with our employees. During the Track Record Period, we did not have any strikes, protests or other material labor conflicts that may materially affect our business and image.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover AEs in clinical trials and we also maintain social insurance for our employees in accordance with relevant PRC laws and regulations. We have also taken out employers’ liability insurance for employees to specifically cover various accidental incidents. Although our production processes are simple and the risk of work-related injuries is relatively low, this insurance can effectively cover accidental scenarios that may occur during employees’ commutes, further improving our risk protection system.

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

Environmental, Social and Governance Matters

We recognize the importance of Environmental, Social and Governance (ESG) management to our sustainable development and core operations. Upon [REDACTED], we will comply with Appendix C2 to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and publish an annual ESG report.

ESG Governance

We plan to gradually establish a sound ESG governance structure upon [REDACTED]. The Board of Directors will bear ultimate responsibility for ESG matters, including identifying and supervising ESG risks, reviewing ESG targets and progress, approving the ESG report, and integrating ESG into business strategy.

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We intend to establish an ESG Working Group to support the Board. The ESG Working Group will assess ESG risks and material issues, formulate and monitor ESG targets, policies and initiatives. We will maintain continuous communication with stakeholders and allocate resources to high-impact ESG areas.

Environmental Matters

We strictly adhere to environmental protection laws and regulations in the jurisdictions where we operate, including the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), the Atmospheric Pollution Prevention and Control Law of the PRC (《中華人民共和國大氣污染防治法》), the Water Pollution Prevention and Control Law of the PRC (《中華人民共和國水污染防治法》), and the Law of PRC on the Prevention and Control of Environmental Pollution by Solid Wastes (《中華人民共和國固體廢物污染環境防治法》). Concurrently, we have established internal policies such as the Environmental Protection Responsibility System (《環境保護責任制》) and the Hazardous Waste Environmental Management System (《危險廢物環境管理制度》).

Emissions Management

We adhere to an air emissions control strategy that emphasizes both source reduction and end-of-pipe treatment. At source, we reduce the generation of volatile organic compounds (VOCs) by using benzalkonium compounds to decrease the use of anhydrous ethanol as a disinfectant. For end-of-pipe treatment, we employ activated carbon adsorption to further treat organic emissions. These measures effectively help ensure that our air emissions concentrations comply with applicable national and local standards.

We implement full life cycle management of waste. At source, we reduce waste generation through the reuse of certain packaging materials. For disposal, we implement strict segregation, labeling, collection, and temporary storage management. Hazardous waste is transferred to qualified third-party service providers for compliant treatment and disposal, while general non-hazardous waste is handled by the local sanitation authority, ensuring the entire process from generation to disposal is compliant with the applicable laws and regulations.

The following table sets out the waste produced during the indicated periods:

	Unit	Year Ended December 31,			Six Months Ended June 30,
		2023	2024	2025	2026
Non-hazardous waste	Tonnes	14.50	15.80	16.80	7.80
Non-hazardous waste intensity	Tonnes/RMB10,000 of revenue	0.02	0.03	0.05	0.04
Hazardous waste.	Tonnes	10.95	6.58	2.60	2.89
Hazardous waste intensity	Tonnes/RMB10,000 of revenue	0.02	0.01	0.01	0.01

Resources Management

We integrate energy conservation into daily operations and have formulated the Energy Saving and Consumption Reduction Management System (《節能降耗管理制度》). In production, we promote energy-saving upgrades and have implemented electricity-saving renovations for air compressors and screw chillers to reduce industrial energy consumption. In operations, we adopt intelligent management methods such as sensor-controlled lighting in offices and public areas to enhance energy efficiency. We also promote energy-saving practices among employees through communications and awareness initiatives.

We promote the recycling and conservation of water resources. Technically, we reuse purified water concentrate generated from production processes in cooling towers and implement water-saving measures such as anti-overflow technical modifications for the cooling tower, effectively improving the recycling rate of water resources. Managerially, we establish monthly and quarterly water-use targets, and adopt a metrics-based management approach to drive continuous improvements in water efficiency.

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The following table sets out the energy consumption during the indicated periods:

	Unit	Year Ended December 31,			Six Months Ended June 30,
		2023	2024	2025	2026
Natural Gas	Cubic meters	—	1,373.38	2,784.50	1,406.15
Liquefied Petroleum Gas	kg	1,915.00	1,300.00	—	—
Total Purchased Electricity . . .	kWh	1,295,641.70	1,249,585.80	1,211,200.30	481,567.70
Total Purchased Steam	kg	282,000.00	336,000.00	355,000.00	69,000.00
Direct energy consumption . . .	kWh	26,711.83	30,425.62	24,922.29	12,585.56
Indirect energy consumption . .	kWh	1,590,720.61	1,601,169.16	1,582,664.87	553,767.86
Total energy consumption . . .	kWh	1,617,432.44	1,631,594.78	1,607,587.16	566,353.42
Total energy consumption intensity	kWh/RMB10,000 of revenue	2,732.15	3,141.31	4,827.59	2,583.73

The following table sets out the water consumption during the indicated periods:

	Unit	Year Ended December 31,			Six Months Ended June 30,
		2023	2024	2025	2026
Water consumption	Cubic meters	13,562.00	13,973.00	14,851.00	4,486.00
Water consumption intensity . .	Cubic meters/RMB10,000 of revenue	22.91	26.90	44.60	20.47

Climate Change Response

In terms of greenhouse gas emission management, we seek to control energy consumption at the source. Through energy-saving upgrades and refined management, we reduce the intensity of greenhouse gas emissions arising from our production and operations. We also monitor potential climate-related risks, including physical risks such as extreme heat and typhoons, and transition risks such as the tightening of climate-related laws, regulations and policies. To address physical risks, we adopt preventive measures to minimize potential operational disruptions caused by them. For transition risks, we closely track developments in laws, regulations, and industry standards, adjusting our operational strategies in a timely manner to maintain compliance.

The following table sets out the greenhouse gas emissions during the indicated periods:

	Unit	Year Ended December 31,			Six Months Ended June 30,
		2023	2024	2025	2026
Total greenhouse gas emissions (Scope 1 and Scope 2)	tCO2 equivalent	786.20	778.98	763.34	282.32
Greenhouse gas emission intensity (Scope 1 and Scope 2)	tCO2 equivalent/RMB10,000 of revenue	1.33	1.50	2.29	1.29
Scope 1 emissions	tCO2 equivalent	5.65	6.81	6.02	3.04
Scope 2 emissions	tCO2 equivalent	780.55	772.17	757.32	279.28
Scope 3 emissions ¹	tCO2 equivalent	98.70	98.43	62.63	36.27

¹ For scope 3 greenhouse gas emissions, we have compiled and calculated the emission data corresponding to Category 3 (Fuel- and Energy-Related Activities). In the future, we will progressively improve the data collection and calculation for other categories of Scope 3 greenhouse gas emissions, and enhance the completeness and transparency of Scope 3 greenhouse gas emission disclosures.

Packaging Materials Management

In the management of packaging materials, we adhere to the principles of “reduction and reuse.” While ensuring product safety and compliance, we integrate green and low-carbon development throughout the entire operational process. By implementing source reduction and the reuse of certain

BUSINESS

packaging materials, we reduce raw material consumption and solid waste emissions. The following table sets out the consumption of packaging materials during the indicated periods:

	Unit	Year Ended December 31,			Six Months Ended June 30,
		2023	2024	2025	2026
Plastics	Tonnes	32.10	22.90	11.23	6.81
Paper	Tonnes	21.30	30.50	8.06	3.01
Packaging material consumption	Tonnes	53.40	53.40	19.29	9.82
Packaging material consumption intensity	Tonnes/RMB10,000 of revenue	0.09	0.10	0.06	0.04

Commercialization of our products will lead to an expansion of our production scale, which in turn will result in an increase in the absolute consumption and emission levels of the environmental subject areas disclosed above. We intend to continue to adopt source reduction and appropriate treatment measures for emissions, implement full life cycle management of waste, promote energy conservation and water recycling in our operations, and uphold the principles of reduction and reuse in packaging materials management where practicable. These measures are intended to support our ongoing management of energy and resource consumption and emission intensities throughout the product life cycle. We will also continue to collect annual emissions data and, once our production capacity becomes stable and comparable, formulate product-related intensity targets in respect of energy and resource consumption and emission levels.

Social Matters

We believe that our employees are an important asset of the Company, and we seek to provide a working environment that is fair, safe, healthy and efficient. We strictly comply with relevant laws and regulations in the jurisdictions where we operate, integrate social responsibility into our corporate development strategy, and actively seek synergistic and sustainable development among employee growth, corporate benefits, and social value.

Labor Standards

We implement internal policies such as the Recruitment Management System (《招聘管理制度》) and the Personnel Management System (《人事管理制度》).

We adhere to the principles of fair and equal employment, strictly prohibiting any form of discrimination in recruitment, promotion, compensation, and termination on the basis of gender, age, race, religion, disability, or other factors. We prohibit child labor and forced labor. Recruitment procedures include identity verification and pre-employment health checks to ensure employees meet the legal working age and are employed voluntarily. Any non-compliance with labor standards will be addressed immediately in accordance with applicable laws and regulations.

We respect employees’ right to rest by establishing working hours and paid leave policies that meet regulatory requirements. We also provide a range of non-monetary benefits to enhance employees’ sense of belonging and satisfaction. We encourage continuous learning and long-term career development, and have established clear multi-dimensional job grades and promotion pathways based on the principles of “openness, fairness, and selection on merit,” to help ensure that employees have access to appropriate promotion opportunities.

Occupational Health and Safety

We attach great importance to employees’ occupational health and safety (OHS), adhering to the policy of “safety first, prevention paramount.” We comply with relevant laws and regulations, including the Work Safety Law of the PRC (《中華人民共和國安全生產法》) and the Regulations on the Safety Management of Hazardous Chemicals (《危險化學品安全管理條例》). We have established an OHS system including the Full Participation in the Responsibility System for Safety Production (《全員安全生產責任制》), the Hazardous Chemicals Safety Management System (《危險化學品安全管理制度》), the Management System for Easy-to-produce Toxic and Explosive Chemicals (《易制毒、易製爆化學品安全管理制度》) and the Workplace Occupational Hazard Factors Monitoring System (《作業場所職業

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危害因素監控制度》), which standardize the management requirements for the procurement, storage and issuance of hazardous chemicals and implementation of hazardous chemicals. We have designated safety management roles responsible for supervising and implementing safety measures, with an aim to achieve “zero major” workplace accidents.

We manage and monitor potential occupational health risks, strictly implement the Employee Health Management Procedures (《員工健康管理規程》), conduct regular monitoring of occupational hazard factors in workplaces, and organize periodic health check-ups for employees. Employees engaged in special operations are required to hold the necessary certifications. We also conduct regular meetings and inspections to identify and address hazards promptly. In addition, we maintain work safety liability insurance coverage for employees to provide protection.

We have equipped comprehensive hazardous chemical protection facilities and emergency response devices, and continuously optimize the working environment through engineering and technical measures. To enhance employees’ safety awareness and emergency response capabilities, we regularly organize safety education and training as well as emergency drills for scenarios such as hazardous chemical leaks, and have established an accident reporting mechanism to handle any incidents timely. For third-party partners, we conduct qualification reviews of service providers engaged in raw material production services and perform relevant compliance audits during the project quality audit process.

Employee Development and Training

We provide employees with multi-level and multi-dimensional training and development opportunities. We have formulated the Employee Training and Education Management System (《員工培訓教育管理制度》) to support employees’ professional development and alignment of skills with job responsibilities.

We operate a two-tier training system and formulate an annual training plan covering quality-related training, management training, professional technical training, and general basic training. All new employees are required to complete induction training covering corporate culture, internal rules and procedures, and work safety knowledge. We also encourage self-directed learning through various methods, including internal training, external training, job rotation, and support for employees to participate in relevant professional qualification and academic examinations.

Product Responsibility and Trial Ethics

We adhere to the Regulation on the Administration of Laboratory Animals (《實驗動物管理條例》) and internationally accepted standards, and implement the “3R²” principles and the “Five Freedoms³” standards to ensure that animal experiments are conducted in full compliance. To demonstrate humane care, we have established a humane endpoint system to prevent animals from suffering severe pain. We require all personnel involved in animal experiments to complete professional ethics training and assessment, and have put in place an anonymous reporting mechanism to ensure that operations are standardized and that personnel possess the necessary professional competence in animal experimentation. In addition, we exercise comprehensive supervision over CROs engaged by us, which includes qualification review, on-site audits, process monitoring and handling of non-compliance.

We attach great importance to the rights and interests of trial subjects and data security in clinical trials. Through stringent ethical review, execution of informed consent forms, purchase of insurance for trial subjects, and the operation of a standardized adverse event monitoring and pharmacovigilance system, we strive to establish a multi-layered risk defense mechanism to safeguard patient safety in clinical trials. To protect patient data privacy, we adopt measures such as double-blinding and the use of coded records to prevent the leakage of sensitive information.

We are concerned about the social risks that may arise from the inappropriate use of our products. Our internal control measures include the establishment of an effective adverse reaction collection mechanism, monitoring of drug-resistant bacteria, and surveys on medication behavior. In the clinical safety summary report for Pecienganan (PL-5), we have provided detailed elaboration on the safety profile for special populations and special situations in accordance with the requirements of the

² Replacement, Reduction and Refinement

³ Freedom from hunger and thirst, Freedom from discomfort, Freedom from pain, injury and disease, Freedom from fear and distress, Freedom to express normal behavior

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application materials, covering intrinsic factors, extrinsic factors, drug interactions, use during lactation and pregnancy, and drug overdose, among others. Clinical studies have confirmed that systemic exposure of the Peceleganan (PL-5) spray following topical administration is negligible, and the expected incidence of adverse reactions from overdose is low.

Supply Chain Management

Our supply chain management is guided by the principles of “quality first, risk control, and selection on merit.” We have established supplier management systems including the Procurement Management System (《採購管理制度》) and the Management Procedure for Preliminary Screening of Material Suppliers (《物料供貨商的初步篩選管理規程》), which cover procurement activities relating to materials, equipment, and instruments, third-party services and engineering construction.

We adopt a supplier assessment approach that incorporates ESG-related considerations, including suppliers’ compliance with applicable requirements on environmental protection, labor standards and business ethics, with a view to promoting responsible procurement and helping ensure that our supply chain operates in a sustainable and compliant manner. For suppliers involved in serious breaches of trust or material non-compliance, we may initiate an exit mechanism in accordance with our internal provisions and, upon approval, place them on a blacklist, with a view to safeguarding the integrity and safety of the supply chain.

Business Ethics

We maintain a zero-tolerance approach to bribery, extortion, fraud, and money laundering and comply with applicable laws and regulations. We have formulated the Anti-Corruption and Whistleblowing Management System (《反腐敗及舉報管理制度》) to regulate the professional ethics of our directors, senior management, and employees.

Our stakeholders can report any potential breaches or misconduct through designated channels. We maintain confidentiality and whistleblower protection measures and prohibit retaliation. We investigate reports and, where appropriate, take disciplinary actions based on the findings, which may include termination of employment and, where applicable, referral to the relevant authorities and/or pursuit of legal liabilities. We also incorporate anti-corruption and integrity as mandatory components of our employee training and regularly provide training with a focus on new hires and employees in higher-risk roles, to help ensure understanding of applicable laws, internal policies, expected standards of conduct and consequences for breaches.

Community Investment

Our community contributions focus on healthcare, public service support and education. Leveraging our expertise and product strengths, we donate in-house developed antibacterial products to healthcare professionals and frontline personnel, including firefighters, police officers and sanitation workers to support public health and public services. We also work with local organizations to conduct outreach programs and provide material support to children in need, welfare homes and elderly care centers, demonstrating care for vulnerable groups.

PROPERTIES

We are headquartered in Jiangyin, Jiangsu Province. As of June 30, 2026, we owned (i) one property, which serves as our office, R&D center and manufacturing plant, with an aggregate GFA of over 27,000 sq.m. in Jiangyin, Wuxi City, Jiangsu Province; and (ii) one parcel of land of over 30,000 sq.m. in Taizhou City, Zhejiang Province. As of the Latest Practicable Date, we leased three properties with an aggregate GFA of approximately 2,012.8 sq.m. from Independent Third Parties in Nanjing and Changchun, which were primarily used as our office premises and R&D center in the PRC.

The following table sets forth the details of our leased properties as of the Latest Practicable Date:

Location	Type of Property	Gross Floor Area (sq.m)	Lease Term	Expiry Dates
The first floor, Office Building, No. 928, Guanggu Street, High-tech Zone, Changchun City	Building	75.0	One year	September 19, 2026

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Location	Type of Property	Gross Floor Area (sq.m)	Lease Term	Expiry Dates
The 3rd Floor, Building 5, North District, Nanjing Life Science and Technology Town, No. 568, Longmian Avenue, Jiangning District, Nanjing City.	Building/R&D center	905.8	Three years	September 30, 2028
The 7th Floor, Building 5, North District, Nanjing Life Science and Technology Town, No. 568, Longmian Avenue, Jiangning District, Nanjing City.	Building/R&D center	1,032.0	Three years	September 30, 2028

AWARDS AND RECOGNITION

The table below sets forth the major awards and recognition we received as of June 30, 2026:

Year of Grant	Award/Recognition	Issuing Authority
2019.	Potential Unicorn Enterprise in Sunan National Innovation Demonstration Zone (蘇南國家自主創新示範區潛在獨角獸企業)	Construction Promotion Service Center of Sunan National Innovation Demonstration Zone (江蘇省蘇南國家自主創新示範區建設促進服務中心)
2019.	National Science and Technology Major Project for “Significant New Drugs Development” under the 13th Five-Year Plan (Pre-clinical Research on Class I New Antifungal Peptide PL-18 and Anti-drug-resistant Peptide Cbf-14) (國家「十三五」重大新藥創製重大科技專項(I類新藥抗真菌多肽PL-18和抗耐藥菌多肽Cbf-14臨床前研究))	Ministry of Science and Technology of the People’s Republic of China
2019.	Potential Unicorn Enterprise in Wuxi (無錫市准獨角獸企業)	Wuxi Municipal Science and Technology Bureau (無錫市科學技術局)
2020, 2023	National High-Tech Enterprise (國家高新技術企業)	Jiangsu Provincial Department of Science and Technology, Department of Finance of Jiangsu Province, Jiangsu Provincial Tax Service, State Taxation Administration
2022, 2023	Top 100 China Pharmaceutical Innovation Seed Enterprises (中國醫藥創新種子企業100強)	Healthcare Executive (E藥經理人)
2023.	Special Fund for Transformation of Scientific and Technological Achievements (Pecceleganan Spray)(省科技成果轉化專項 (培來加南噴霧劑))	Jiangsu Provincial Department of Science and Technology, Department of Finance of Jiangsu Province
2024.	Jiangsu Provincial Engineering Research Center for Innovative Peptide-based Drugs (江蘇省多肽創新藥物工程研究中心)	Jiangsu Provincial Development and Reform Commission (江蘇省發展和改革委員會)

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LICENSES, PERMITS AND APPROVALS

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

The following table sets forth details of selected material licenses and permits obtained by our Group as of the Latest Practicable Date:

License/permit	Holder	Issuing Authority	Date of Grant	Expiry Date
Drug Registration Certificate (藥品註冊證書)	ProteLight Pharmaceuticals (Jiangsu)	National Medical Products Administration	June 17, 2026	June 16, 2031
Drug Manufacturing License (藥品生產許可證)	ProteLight Pharmaceuticals (Jiangsu)	Jiangsu Medical Products Administration	February 9, 2026	August 23, 2030
Certificate of High&New Technological Enterprise (高新技術企業證書)	ProteLight Pharmaceuticals (Jiangsu)	Jiangsu Provincial Department of Science and Technology, Department of Finance of Jiangsu Province and Jiangsu Provincial Tax Service, State Taxation administration	November 6, 2023	November 5, 2026 ⁽¹⁾
Hygiene License for Disinfection Product Manufacturing Enterprises (消毒產品生產企業衛生許可證)	Jiangsu Putai	Jiangsu Commission of Health	November 11, 2024	November 10, 2028
Record-keeping Certificate for the Operation of Class II Medical Devices (第二類醫療器械經營備案憑證)	Jiangsu Putai	Wuxi Municipal Bureau of Administrative Approval (無錫市行政審批局)	January 18, 2021	No expiration unless we are dissolved, liquidated, declared bankrupt, deregistered, have our business license revoked, annulled, or are ordered to shut down in accordance with the PRC law or the provisions of articles of association
Record-keeping Certificate for the Operation of Class II Medical Devices (第二類醫療器械經營備案憑證)	Wuxi Ruiyi	Wuxi Municipal Bureau of Administrative Approval (無錫市行政審批局)	January 18, 2021	No expiration unless we are dissolved, liquidated, declared bankrupt, deregistered, have our business license revoked, annulled, or are ordered to shut down in accordance with the PRC law or the provisions of articles of association

Note:

- (1) We plan to renew our High and New Tech Enterprise Certificate in 2027, for which we have completed relevant preparatory work in advance and our Directors are of the view that there is no legal impediments for such renewal.

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As of the Latest Practicable Date, our Core Product PL-5 and key products PL-3301 and PL-18 all received notice for approval of clinical trials (臨床試驗通知書) issued by the NMPA. The following table sets forth details of the clinical trial approvals obtained by our Group as of the Latest Practicable Date:

Approval Authority	Acceptance number	Product Name	Licensed Content	Approval Date
NMPA	CXHL1400688 Ji	Antimicrobial Peptide PL-5	Clinical trials related to Antimicrobial Peptide PL-5	May 4, 2016
NMPA	CXHL1400689 Ji	Antimicrobial Peptide PL-5 Spray	Clinical trials related to Antimicrobial Peptide PL-5 Spray	May 4, 2016
NMPA	CXHL2200882	Antimicrobial Peptide PL-18 Suppository	Clinical trials related to Antimicrobial Peptide PL-18 Suppository	January 13, 2023
NMPA	CXHL2200883	Antimicrobial Peptide PL-18 Suppository	Clinical trials related to Antimicrobial Peptide PL-18 Suppository	January 13, 2023
NMPA	CXHL2200884	Antimicrobial Peptide PL-18 Suppository	Clinical trials related to Antimicrobial Peptide PL-18 Suppository	January 13, 2023
NMPA	CXHL2200885	Antimicrobial Peptide PL-18 Suppository	Clinical trials related to Antimicrobial Peptide PL-18 Suppository	January 13, 2023
NMPA	CXHL2200886	Antimicrobial Peptide PL-18 Suppository	Clinical trials related to Antimicrobial Peptide PL-18 Suppository	January 13, 2023
NMPA	CXHL2500380	Antimicrobial Peptide PL-3301 Oral Gel	Clinical trials related to Antimicrobial Peptide PL-3301 Oral Gel	July 3, 2025
NMPA	CXHL2500381	Antimicrobial Peptide PL-3301 Oral Gel	Clinical trials related to Antimicrobial Peptide PL-3301 Oral Gel	July 3, 2025

LEGAL PROCEEDING AND COMPLIANCE

As of the Latest Practicable Date, there was no litigation, arbitration or administrative proceedings pending or threatened against the Company or any of our Directors which could have a material and adverse effect on the research and development of our product candidates, our financial condition or results of operations. Potential future litigation or any other legal or administrative proceeding, regardless of the merit or outcome, is likely to result in substantial costs, diversion of our resources, and have a negative impact on our reputation and brand image, which in turn, would have a negative impact on our business, financial condition, and results of operations. For the potential impact of legal or administrative proceedings on us, please see “Risk Factors — Risks Relating to Our General Operations — If we face litigation, legal disputes, government investigations, or administrative actions, our management’s focus could be shifted, leading to significant costs and liabilities for us.”

During the Track Record Period, we did not make full contributions to social insurance and housing provident funds for certain employees of us in accordance with applicable PRC laws and regulations. Such non-compliance was mainly because certain employees were unwilling to bear the employee portion of the relevant contributions strictly in proportion to their salaries, as doing so would reduce their disposable income.

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Since the full payment of social insurance and housing provident fund contributions requires co-contributions from both the employer and the employees, immediate full rectification prior to the [REDACTED] would require us to make proportional statutory deductions from the relevant employees’ salaries. In order to maintain stable employer-employee relationships and avoid any disruption to our operations, we require sufficient time to communicate with our employees, explain the relevant regulatory requirements and gradually seek their understanding and cooperation. We have been actively taking steps to prepare for rectification, including (i) continuously communicating with our employees to seek their understanding and cooperation; and (ii) keeping our employees informed of the latest regulatory requirements issued by the relevant authorities. We expect to commence gradual rectification of our social insurance and housing provident fund contributions within one year from the [REDACTED]. If the relevant authorities require us to make full contributions or rectify such non-compliance within a specified period, we undertake to do so promptly within such period. Given that we will make timely payments for the outstanding amount and overdue charges as soon as requested by relevant authorities, our Directors are of the view that we are less likely to be subject to administrative penalties as a result of such non-compliance.

As advised by our PRC Legal Advisor, as we had not made full social insurance contributions for certain employees in accordance with applicable PRC laws and regulations, the relevant social insurance collection agency may order us to pay the outstanding amounts within a prescribed time limit. We may also be subject to a late payment charge at a daily rate of 0.05% of the outstanding amounts from the date on which such amounts became due and unpaid. If we fail to make such payment within the prescribed period, the competent authorities may further impose a fine ranging from one to three times the amount of the overdue payment. In addition, if the relevant housing provident fund authorities determine that we have failed to make full housing provident fund contributions for certain employees in accordance with applicable PRC laws and regulations, they may order us to make the outstanding contributions within a prescribed time limit. If we fail to do so within such time limit, the relevant authorities may apply to the PRC courts for compulsory enforcement.

As of the Latest Practicable Date, we had not received any order of correction, fine or penalty from the competent authorities in relation to the above non-compliance. We have either consulted the relevant competent social insurance and housing provident fund authorities or obtained special credit reports (certifying no records of illegal or non-compliant activities), which confirmed that there was no record of any employing entity within our Group having been subject to administrative penalties by the competent authorities for violation of the applicable laws and regulations. As advised by our PRC Legal Advisor, provided that there are no material adverse changes in the current regulatory policies and environment and no employee complaints occur, the likelihood that we will be required to settle all historical shortfalls in social insurance premiums and housing provident fund contributions or be subject to material administrative penalties as a result of such non-compliance is remote. Accordingly, our Directors and our PRC Legal Advisor are of the view that such non-compliance would not have any material adverse impact on our business, financial condition or results of operations. Consequently, we did not make any provision in respect of such non-compliance during the Track Record Period.

During the Track Record Period and up to the Latest Practicable Date, we had complied, in all material respects, with all relevant laws and regulations and did not have any systemic non-compliance in the jurisdictions we operate in. We had not been and were not involved in any non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our Group’s business operations.

RISK MANAGEMENT AND INTERNAL CONTROL

We are committed to developing and maintaining risk management and internal control systems comprised of policies and procedures tailored to our business operations. Our dedication lies in the continual enhancement of these systems to ensure their effectiveness.

Risk Management

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the Chinese and global biologics markets, our ability to develop, manufacture and commercialize our product candidates, and our ability to compete with other peer companies. See “Risk

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Factors” for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to credit and liquidity risks that arise in the normal course of our business. See “Financial Information — Market Risks” for a discussion of these market risks.

We have implemented a comprehensive set of risk management policies that establish a framework for identifying, assessing, evaluating, and continuously monitoring key risks aligned with our strategic objectives. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors. Our audit committee supervise the implementation of our risk management policies.

The following key principles outline our Group’s approach to risk management and internal control that we plan to implement:

- Our audit committee will oversee, evaluate, and enhance the internal control system, which includes: (i) reviewing internal control and risk management policies and providing suggestions for improvement; (ii) engaging in discussions with management to evaluate the effectiveness of internal control and risk management policies, ensuring that management fulfills its duties in formulating effective policies; (iii) analyzing material findings related to internal control and assessing the measures taken by management; (iv) supervising potential misconduct by employees regarding internal control and establishing procedures to investigate and address complaints related to internal control within the Company.
- Our Board will be responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) providing guidance on our risk management approach to the relevant teams in our Company; (iii) reviewing the relevant teams’ reporting on key risks and providing feedbacks; and (vi) supervising the implementation of our risk management measures by the relevant teams.
- The relevant departments within our Company bear the responsibility of implementing our risk management policy and executing day-to-day risk management practices. To standardize risk management procedures across our organization and ensure a consistent level of transparency and risk management performance, these teams will: (i) collect information regarding the risks associated with their respective operations or functions; (ii) conduct comprehensive risk assessments, encompassing the identification, prioritization, measurement, and categorization of all key risks that could impact their objectives; (iii) prepare an annual risk management report for review by our chief executive officer; (iv) continuously monitor key risks pertinent to their operations or functions; (v) implement appropriate risk responses when necessary; (vi) develop and maintain a suitable mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an internal control consultant (the “**Internal Control Consultant**”) to perform certain agreed-upon procedures (the “**Internal Control Review**”) in connection with the internal control during the period from September 1, 2024 to August 31, 2025 of our Company and our major operating subsidiaries in certain aspects, including entity-level controls, financial reporting and disclosure controls, human resources and payroll management, general controls of IT system and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review in November and December 2025, identified internal control deficiencies and provided recommendation accordingly. These deficiencies primarily concerned internal control policies with respect to information system control, monitoring of software usage on employees’ computers, monitoring of regulatory filing process, and other deficiencies in relation to the Company’s governance structure and policies required for a listed company according to the Listing Rules, none of which had resulted in any material adverse impact on the Group’s business operation and financial performance. We have been taking steps to rectify these deficiencies and enhance our internal control measures based upon the recommendations given by the Internal Control Consultant. The Internal Control Consultant performed a follow-up review

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with regard to those actions taken by us and there are no further material findings identified in the process of the follow up review. As of the Latest Practicable Date, there were no material outstanding issues relating to our Company’s internal control.

Having considered the report prepared by our Internal Control Consultant, the Directors confirmed that all of the major recommendations provided by the Internal Control Consultant have been followed and corrective actions were taken accordingly to address our internal control deficiencies. Our Internal Control Consultant has reviewed the enhanced internal control measures and confirmed that the enhanced internal control measures adopted are effective to prevent recurrence of similar internal control deficiencies. Our Directors are of the view, and the Sole Sponsor concurs, that the above internal control deficiencies had not resulted in any material adverse impact on the Group’s business operation and financial performance, and our enhanced internal control measures are adequate and effective to ensure compliance with relevant laws and regulations going forward.

During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management, environmental protection and occupational health and safety. For more information, see “— Social, Health, Work Safety and Environmental Matters” in this section. We provide periodic training about these measures and procedures to our employees as part of our employee training program. Our internal audit department conducts audit field work to monitor the implementation of our internal control policies, reports any weaknesses identified to our management and audit committee, and follows up on the rectification actions.
- We provide various training programs to keep our employees updated on relevant laws, regulations, and policies. Our new employees are required to attend compliance training programs soon after on-boarding and must pass tests which examine their understanding of the compliance issues addressed by the training programs. Our employees are also required to regularly attend on-site and online training sessions to keep them informed of recent updates in the relevant laws and regulations.
- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect to financial reporting as well as oversees internal control procedures of our Group.
- We maintain strict anti-corruption policies and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the biopharmaceutical industry.