
BUSINESS

OVERVIEW

Who we are

Founded in 2013, we are a biopharmaceutical company focused on oncology, autoimmune diseases and metabolic disorders. We have eight product candidates, including two self-developed Core Products D-2570 and taragarestrant (D-0502). D-2570 is intended for the treatment of autoimmune diseases (including psoriasis, ulcerative colitis (“UC”), systemic lupus erythematosus (“SLE”), psoriatic arthritis “PsA”), and vitiligo), and taragarestrant (D-0502) is intended for the treatment of ER+/HER2- breast cancer. Both Core Products are currently under Phase III clinical trials.

The A Shares of our Company have been listed on the Shanghai Stock Exchange STAR Market (stock code: 688382) since July 2022.

We have built a product pipeline spanning multiple disease areas, including breast cancer, colorectal cancer (“CRC”), non-small cell lung cancer (“NSCLC”), psoriasis, UC, SLE, PsA, vitiligo and gout. Within our clinical-stage pipeline, our Core Products tyrosine kinase 2 (“TYK2”) inhibitor D-2570 and oral estrogen receptor degrader (“SERD”) taragarestrant (D-0502) are both advancing through Phase III registration trials, while our urate transporter 1 (“URAT1”) inhibitor darbinurad (D-0120) has completed a Phase IIb clinical trial. In addition, we maintain a robust pipeline of preclinical candidates, including the Werner syndrome protein (“WRN”) inhibitor YF087, the kinesin family member 18A (“KIF18A”) inhibitor YF550, and the oral signal transducer and activator of transcription 6 (“STAT6”) degrader YF057, demonstrating our sustained capacity for innovation.

Our pipeline is clearly structured and supported by growth momentum. Two of our key assets — befortertinib (BPI-D0316), a third-generation EGFR inhibitor, and garsorasib (D-1553), a KRAS G12C inhibitor — have already been approved for marketing in China and included in China’s National Reimbursement Drug List (“NRDL”), marking our transition into a stage of commercial value realization.

Our product pipeline

All of our products are protected by global intellectual property rights, and we have established collaborations with leading biotech and pharmaceutical companies, including Betta Pharmaceuticals Co., Ltd. (“Betta”), Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (“CTTQ”) and InxMed Co. Ltd. (“InxMed”). As of the Latest Practicable Date, our product pipeline comprises two commercialized products, three clinical-stage drug candidates, and a portfolio of preclinical programs, covering the full spectrum from early-stage research to commercial execution. The chart below summarizes the development status of our clinical-stage pipeline products, all of which are self-developed, as of the Latest Practicable Date.

BUSINESS

Candidate	Target/ MoA	Indication, (Lines of Treatment)	Mono/ Combo	IND	Phase I	Phase II	Phase III	Competent Authority	Current Status/ Upcoming Milestones	Rights
Taragrestant (D-0502) ★	ER	Advanced or metastatic ER+/HER2- breast cancer (2L+)	Mono	China				NMPA	Submit NDA in H1 2028	Global
			Mono/Combo	U.S.				FDA	Phase I trial completed	
			+ TROP2/HER3 ADC	China				NMPA	Complete Phase II trial in H2 2028	
D-2570 ★	TYK2	Moderate-to-severe Plaque Psoriasis	Mono	China, registration trial				NMPA	Submit NDA in H2 2027	Global
			Mono	China, head-to-head trial				NMPA	Complete Phase III trial in H2 2027	
			Mono	U.S.				FDA	Complete Phase II trial in Q1 2028	
		Moderate-to-severe active Ulcerative Colitis	Mono	China				NMPA	Complete Phase II trial in Q1 2027	
			Mono	China				NMPA	Complete Phase II trial in H2 2028	
		Active SLE	Mono	China				NMPA	Complete Phase II trial in H2 2028	
		Active PsA	Mono	China				NMPA	Complete Phase II trial in H2 2028	
		Nonsegmental Vitiligo	Mono	China				NMPA	Complete Phase II trial in H2 2028	
			Mono	China				NMPA	Complete Phase II trial in H2 2028	
Darbinurad (D-0120)	URAT1	Gout	Mono	China				NMPA	Phase II trial completed	Global
			+ Allopurinol	U.S.				FDA	Phase II trial completed	
YF087	WRN	Advanced or metastatic solid tumors (2L+)	Mono	IND approved				NMPA	Initiate Phase I trial in Q4 2026	Global
YF550	KIF18A	Advanced solid tumors with chromosomal instability (later-line)	Mono	IND				NMPA	Obtain IND approval in Q4 2026	Global
YF057	STAT6	Atopic dermatitis and asthma	Mono	Lead optimization				FDA	Submit IND in Q2 2027	Global

★ Core Product

BUSINESS

Notes:

1. Abbreviations: MoA = Mechanism of Action, IND = Investigational New Drug, NDA = New Drug Application, NMPA = the National Medical Products Administration of China, FDA = the Food and Drug Administration of the United States, SERD = Selective Estrogen Receptor Degradable, TYK2 = Tyrosine Kinase 2, URAT1 = Urate Transporter 1, WRN = Werner Syndrome RecQ Like Helicase, KIF18A = Kinesin Family Member 18A, STAT6 = Signal Transducer and Activator of Transcription 6, ER+ = Estrogen Receptor Positive, HER2 = Human Epidermal Growth Factor Receptor 2, SLE = Systemic Lupus Erythematosus, PsA = Psoriatic Arthritis, MSI-high = Microsatellite Instability-high, CIN+ = Chromosomal Instability-positive.
2. For taragarestrant (D-0502), the NMPA exempted the Phase II clinical trial based on the finding that the Phase I clinical trial results as of July 19, 2021, which was considered to have generated sufficient clinical data for the safety and efficacy evaluation of D-0502 monotherapy dosed at 400mg OD. With that, the NMPA approved our application to directly proceed with a Phase III clinical trial designed to evaluate the safety and efficacy of D-0502 monotherapy at 400 mg QD without the need to conduct a Phase II clinical trial. After completing the Phase I clinical trial of D-0502, which took place in China and the U.S., we have not conducted further clinical trials of D-0502 in the U.S. and have no concrete clinical development plan for D-0502 in the U.S.
3. For darbinurad (D-0120), we have completed the Phase II clinical trial for combination therapy in the U.S. in March 2026. We are actively seeking strategic partners to support the continued overseas development of darbinurad (D-0120). In China, after completing the Phase II clinical trial, we are now in discussions with CDE regarding the next steps. We may either launch a Phase III clinical trial for monotherapy, or submit an IND to initiate a Phase II clinical trial for combination therapy in China.

Core Products

Our Core Product D-2570 is a self-developed, orally administered, selective TYK2 allosteric inhibitor for the treatment of psoriasis and other autoimmune diseases. Our Phase II clinical trial in moderate-to-severe psoriasis delivered favorable results, with efficacy significantly higher than both placebo and approved products of the same class (based on published clinical data), while maintaining safety and tolerability. We have agreed with the NMPA on the Phase III clinical trial protocol and have initiated the registrational Phase III clinical trial in September 2025 and a head-to-head Phase III clinical trial in January 2026. In parallel, we have also commenced Phase II clinical trials targeting moderate-to-severe active UC, active SLE, active PsA and nonsegmental vitiligo in China, and a Phase II clinical trial targeting moderate-to-severe plaque psoriasis in the U.S.

Our Core Product Taragarestrant (D-0502) is a self-developed, oral SERD for the treatment of ER positive (“ER+”)/HER2 negative (“HER2-”) breast cancer. It is currently undergoing a registrational Phase III head-to-head clinical trial in China against the standard of care, and a Phase II clinical trial initiated in March 2026 in combination with JSKN016, an ADC drug candidate. Taragarestrant has demonstrated antitumor activity, a favorable safety profile, and good bioavailability.

Other Clinical-Stage Products

Darbinurad (D-0120) is a self-developed URAT1 inhibitor for the treatment of gout. The Phase IIb clinical trial conducted in China was completed in November 2024, with early results showing robust uric acid lowering effects and favorable safety and tolerability. In parallel, the Phase II clinical trial for darbinurad (D-0120) and allopurinol combination therapy in the U.S. was completed in March 2026.

Commercialized Products

Befotertinib (賽美納®, 貝福替尼, BPI-D0316)

Befotertinib (BPI-D0316) is a third-generation EGFR tyrosine kinase inhibitor (“TKI”) for the treatment of EGFR-mutated NSCLC. Following receiving the IND approval from the CDE to initiate a Phase II clinical trial, we entered into a collaboration with Betta covering development and commercialization within the designated territories (Chinese Mainland, Hong Kong, and Taiwan). Under this partnership, Betta is responsible for development and commercial sales within the designated territories. Both first-line and second-line treatment indications were approved in

BUSINESS

Chinese Mainland in 2023, and befotertinib (BPI-D0316) was firstly included in the NRDL in the same year. We are currently working with Betta to advance additional late-stage clinical studies in China, including postoperative adjuvant therapy.

Garsorasib (安方寧®, 格索雷塞, D-1553)

Garsorasib (D-1553) is a KRAS G12C inhibitor and the first domestically developed drug targeting this mutation to enter clinical development in China. In August 2023, we entered into a License and Collaboration Agreement with CTTQ (the “CTTQ Agreement”), granting it exclusive rights during the agreement term to develop, register, manufacture, and commercialize garsorasib (D-1553) in Chinese Mainland. The product received marketing approval in Chinese Mainland in November 2024 for the treatment of previously treated KRAS G12C-mutated advanced NSCLC and received a Grade I recommendation in the 2025 CSCO Guidelines for the Diagnosis and Treatment of NSCLC. Garsorasib (D-1553) has been included in the NRDL in December 2025. Recent clinical results show that garsorasib (D-1553), whether used as monotherapy or in combination therapy, achieves robust efficacy and maintains a favorable safety profile in both NSCLC and CRC. Notably, the results from garsorasib (D-1553) and ifebemtinib combination therapy suggest promising potential for use in earlier-line treatment settings.

Preclinical Pipeline

We have built a rich and differentiated preclinical pipeline adopting potentially breakthrough therapeutic targets and modalities. In oncology, our preclinical candidates YF087 and YF550 are representative programs in the field of synthetic lethality, with target selection and antitumor activity validated in multiple preclinical studies. Other than the commercialized poly (ADP-ribose) polymerase (“PARP”) inhibitors, no synthetic-lethality therapies have been successfully launched worldwide, and we are among the few companies globally advancing multiple pipelines in this emerging area. In autoimmune disease, our STAT6 degrader YF057 is designed as a potential oral alternative to IL-4R α antibody therapies, with a focus on developing transformative treatments for atopic dermatitis (“AD”) and asthma.

Leveraging our deep understanding in small-molecule drug design and discovery, we are also prioritizing the optimization of ADC linker and payload designs to build a next-generation ADC platform with an expanded therapeutic window for better efficacy and safety than current approved therapies. We plan to develop drug candidates based on this next-generation ADC platform in the future.

Our Collaborations

We have established extensive and close clinical collaborations with major medical centers and leading clinical experts worldwide, laying a solid foundation for high-quality, globally oriented clinical development. In addition, we have partnered with a number of prominent biotech and pharmaceutical companies, including Betta, CTTQ and InxMed, to advance multiple clinical assets. These collaborations provide strategic synergy and meaningful support for both the development and future commercialization of our pipeline.

Our Management

Our core management team has over 20 years of experience overseeing new drug R&D and managing scientific teams at major global pharmaceutical companies. The management team possesses a well-balanced expertise mix that spans the entire drug development lifecycle, including target identification and validation, medicinal chemistry optimization, CMC, as well as clinical development and regulatory affairs. This combination of deep industry experience and global perspective forms the core engine of our R&D organization, enabling us to rapidly initiate new programs, efficiently advance critical development activities, and continuously generate globally competitive innovations.

BUSINESS

Our Path Forward

Our comprehensive and high-performing R&D capabilities serve as the driving force for our long-term sustainable innovation. Led by Dr. Yaolin Wang and a seasoned management team with technical expertise and global experience, we have built a research and clinical development team with scientific insight and execution capability. Leveraging our fully integrated, end-to-end R&D platform, we aim to continue delivering globally competitive candidates.

OUR COMPETITIVE STRENGTHS

A Pharmaceutical Translation Engine Powered by an Experienced R&D Team and an Established R&D Platform

Scientific Insight and Execution Enabled by Validated In-House R&D Capabilities

Strong scientific capabilities and execution underpin our innovation and core competitive advantage. Every asset in our pipeline has been internally discovered and independently developed, with global intellectual property protection. All core activities, from target selection, molecule design, pharmacology evaluation and CMC development to clinical development and regulatory submissions, are completed by our in-house teams. Since Dr. Yaolin Wang returned to China to lead our development in 2015, we have, in less than a decade, successfully commercialized two small-molecule new drugs, advanced two candidates into Phase III registration trials, one into Phase II clinical development, and built a robust preclinical pipeline.

A Potential Best-in-Class Oral TYK2 Inhibitor in Phase III Stage: D-2570, our selective oral TYK2 inhibitor, is being developed for psoriasis and other autoimmune diseases. Phase II results in moderate-to-severe psoriasis demonstrated efficacy substantially higher than approved oral TYK2 inhibitors (based on published article comparisons), while maintaining favorable safety and tolerability.

An Oral SERD in Phase III Stage: Taragarestrant (“D-0502”) is an oral SERD for ER+/HER2-breast cancer. Its registrational Phase III head-to-head study against fulvestrant is progressing, positioning it to become the first domestically developed oral SERD.

A Competitive URAT1 Inhibitor for the Treatment of Gout: Darbinurad (D-0120) inhibits URAT1, which blocks renal uric acid reabsorption and lowers serum uric acid. Its Phase IIb clinical trial conducted in China was completed in November 2024. In parallel, the Phase II combination therapy study in the U.S. was completed in March 2026.

A Rich and Differentiated Preclinical Pipeline: In March 2025, preclinical data from our candidates YF087, a selective and potent inhibitor of the synthetic-lethality target WRN, and YF550, a small-molecule candidate targeting KIF18A, were selected for the Breakthrough Research poster sessions at the 2025 American Association for Cancer Research (“AACR”) Annual Meeting. Both candidates demonstrated robust antitumor activity across multiple tumor models, providing support for their subsequent clinical development.

Two Commercialized New Drugs: Befotertinib (賽美納®, 貝福替尼, BPI-D0316) is a third-generation EGFR-TKI for EGFR-mutated NSCLC. Both first-line and second-line indications were approved in China in 2023, and the drug was firstly included in the NRDL in the same year. Garsorasib (安方寧®, 格索雷塞, D-1553) is a KRAS G12C inhibitor and the first domestic program targeting this mutation to reach clinical development. It received marketing approval in China in November 2024 for previously treated KRAS G12C-mutated advanced NSCLC and received a Grade I recommendation in the 2025 Chinese Society of Clinical Oncology (“CSCO”) NSCLC Guidelines. Garsorasib (D-1553) was also included in the NRDL in December 2025.

Systematic Global Clinical Development Capabilities as a Core Competitive Advantage and Strategic Pillar

Experienced R&D Leaders and a Scientifically Rigorous Clinical Development Framework

Our global clinical R&D team is headed by Chief Medical Officer Dr. Ling Zhang, a veteran with over two decades of experience in multinational pharmaceutical companies and a track record that includes major contributions to the development of Keytruda®, Temodal®, and Turalio®. Our

BUSINESS

team includes members with extensive multinational pharmaceutical company backgrounds and proven capabilities in executing global programs. As of the Latest Practicable Date, our clinical development team consisted of 68 members, over 41% of whom have obtained post-graduate degrees. By combining deep understanding of MOA, disease epidemiology, standards of care, and unmet medical needs, our R&D team develops rigorous and scientifically grounded clinical development strategies.

Clinical Execution and Development Efficiency

We have developed a three-pillar clinical acceleration model: (i) deep mechanistic understanding of target biology to define the most appropriate regulatory pathway; (ii) prioritization of indications that enable rapid proof-of-concept based on molecule-specific attributes (such as blood — brain barrier penetration); and (iii) the clinical team’s extensive experience in guiding optimal trial design and pathway selection. Collectively, these pillars form a distinct efficiency advantage that drives rapid progression toward pivotal development.

A Global Clinical Collaboration Ecosystem

To support the global advancement of our clinical programs, we have built collaborations with top Class III Grade A Hospitals in China, renowned international medical centers, and leading experts in the field. Our clinical operation model integrates the strengths of both markets: an in-house CRA team in China for faster enrollment and late-stage quality control, and established CRO partnerships and local in-house project managers in the U.S. for efficient clinical strategy execution. Our clinical operational management follows bilingual standards, which better prepare us for global trial executions.

Proven Track Record of Achievements

We have a track record of advancing programs through clinical registration pathways. Garsorasib (D-1553) received CDE Breakthrough Therapy Designation (“BTD”) and approval to conduct a single-arm Phase II trial as a registrational study, enabling the program to progress from IND clearance to pivotal development in less than two years. Based on encouraging Phase I results, taragarestrant (D-0502) was permitted to proceed directly to a registrational Phase III trial. Befotertinib likewise obtained CDE approval to initiate a single-arm Phase II registrational study.

We have achieved a number of significant regulatory and academic milestones. Multiple indications of garsorasib (D-1553) have been included by the CDE in the breakthrough therapy product list. In addition, the research of befotertinib (BPI-D0316) has been published in leading international journals such as *The Oncologist*, *Journal of Thoracic Oncology*, *The Lancet Respiratory Medicine*, and *The Lung Cancer*. Preclinical and clinical research on garsorasib (D-1553) — spanning lung, colorectal, and pancreatic cancers — has likewise been published in leading academic journals including *Cancer Science*, *Journal of Thoracic Oncology*, *The Lancet Respiratory Medicine*, *Signal Transduction and Targeted Therapy*, and *the British Journal of Cancer*. In September 2025, the results of a randomized, double-blind, placebo-controlled Phase II clinical trial evaluating D-2570 for the treatment of moderate-to-severe plaque psoriasis were published in the *Journal of the American Academy of Dermatology*, the official scientific publication of the American Academy of Dermatology. Furthermore, results for darbinurad (D-0120) and taragarestrant (D-0502) have been presented as oral presentations at major industry conferences.

In addition, we possess extensive global clinical development experience. We have independently completed the global multi-center Phase I/II trial of garsorasib (D-1553), the U.S. Phase Ib clinical trial of taragarestrant (D-0502), the U.S. Phase I and II trials of darbinurad (D-0120), and the U.S. Phase I clinical trial of D-2570. This breadth of experience further validates our capability to execute high-quality clinical programs globally.

BUSINESS

Established Target Discovery and Molecular Design Capabilities Driving Higher R&D Productivity

While small-molecule innovation remains our core focus, we are also expanding into ADCs utilizing our expertise in medicinal chemistry to identify next generation linker and payloads, and other emerging therapeutic modalities. Our strategy begins with diseases with unmet medical needs and also with large patient population. Currently, we mainly focus on therapeutic indications in oncology, autoimmune diseases and metabolic disorders.

Our R&D capability is built around two core principles that enable scalable and replicable innovation. The first is to improve upon the limitations of existing therapies through rational structure guided design in medicinal chemistry and performance enhancement, thereby strengthening the clinical value and differentiation of our drug candidates. The second is to expand our therapeutic scope while applying proven design, screening, and evaluation methodologies to lower uncertainty and increase the efficiency and consistency of our R&D output.

Differentiated Advantages of Our Drug Discovery and Development Capability

We have built a robust hardware infrastructure and accumulated extensive experience in developing software and algorithms for computational chemistry and protein structure prediction, driven by rich datasets curated over many years. Leveraging this foundation, we have integrated key technologies, including computer-aided drug design (“CADD”), AI-enabled drug design (“AIDD”), virtual screening, and early PK/toxicology assessment, into a unified, intelligent molecular design platform. Leveraging our integrated computational design capabilities, we designed and developed a number of product candidates including garsorasib (D-1553), taragarestrant (D-0502) and D-2570. For more details, please refer to “Business — Our Technology Platform.”

Combined Translational Medicine and Robust CMC Capabilities Driving Efficient Bench-to-Clinic Progression

Enabled by our deeply integrated translational medicine capability and well-established CMC development framework, we have created a seamless bridge from basic research to clinical application, supporting efficient and high-quality transformation from preclinical candidates into clinical-ready drug products. Through preclinical pharmacology, pharmacodynamics, and biomarker research, we generate key scientific insights to guide clinical design. In turn, clinical observations and trial results are fed back to refine preclinical models and research strategies.

A Streamlined and Efficiency-Driven CMC Development Capability Ensuring Timely Progress and Consistent Quality

Our chemical process and formulation development capabilities are critical to advancing our pipeline efficiently. To that end, we have built a seasoned CMC team with extensive experience in multinational pharmaceutical companies. With a deep understanding of global quality and regulatory standards, the team designs optimal synthetic routes that reduce cost, shorten development timelines, and ensure scalability. On the formulation side, the team focuses on developing dosage forms that deliver adequate drug exposure to ensure efficacy in clinical trials.

Demonstrated Successes of Our Translational Medicine and CMC Platforms

Our translational medicine and CMC platforms operate as two tightly coordinated engines powering our innovation. Insights generated from translational research guide our CMC teams to design dosage forms that directly address clinical needs, while robust CMC execution delivers high-quality drug products that in turn enable more rigorous and informative translational studies. This synergy creates a distinct competitive advantage across our R&D pipeline.

BUSINESS

Our translational medicine platform centers on well-developed biomarker strategies and precision-driven clinical approaches, enabling us to mitigate development risk and cost, identify the most responsive patient populations, refine dosing strategies, and meaningfully improve the efficiency and success rate of clinical development.

Our CMC platform has demonstrated capability in translating complex molecules into high-quality, clinically viable drug products. Leveraging both in-house expertise and partnerships with experienced CDMOs, we advance process development and cGMP manufacturing to ensure process stability, reproducibility, and scalability. A comprehensive quality management system further ensures that every batch — from first-in-human supplies to future commercial production — meets stringent and consistent quality standards.

Our translational medicine and CMC platforms have successfully delivered several product transitions, including D-2570, taragarestrant (D-0502) and darbinurad (D-0120). For more details, please refer to “Business — Chemistry, Manufacturing & Controls (“CMC”).”

A Competitive and Differentiated Pipeline with Multi-Layered Value Drivers

We focus on major disease areas with substantial unmet medical needs, including oncology, autoimmune diseases and metabolic disorders. Our pipeline is competitive and has evolved into a balanced, three-tier structure comprising (i) cash-generating assets, (ii) near-term value catalysts, and (iii) long-term growth drivers.

Stable Cash Engines Empowered by Our Approved Assets

Befotertinib (賽美納[®], 貝福替尼, third-generation EGFR-TKI, BPI-D0316)

As one of the leading third-generation EGFR-TKIs in China, befotertinib (BPI-D0316) has received regulatory approval for both first-line and second-line NSCLC indications and has been included in the NRDL. Its clinical performance — 16.6 months median progression-free survival (“PFS”) and 31.5 months median overall survival (“OS”) in the second-line setting, and 22.1 months median PFS in the first-line setting — has established a clear competitive advantage. Through our strategic collaboration with Betta, whose commercialization capabilities in lung cancer are well recognized, sales are ramping up and generating a stable source of cash flow.

Garsorasib (安方寧[®], 格索雷塞, KRAS G12C inhibitor, D-1553)

As the second KRAS G12C inhibitor approved in China, garsorasib (D-1553) has demonstrated efficacy in its registrational study, with 52.0% overall response rate (“ORR”), and 9.1 months median PFS. Our strategic collaboration with CTTQ enables rapid market penetration through its extensive commercial network. In parallel, we collaborated with InxMed to pursue combination therapy development of garsorasib (D-1553) with a focal adhesion kinase (“FAK”) inhibitor as a first-line treatment for NSCLC. The combination therapy has delivered a clinically meaningful survival benefit, positioning it as a competitive breakthrough therapy globally.

Near-Term Value Catalysts Approaching Commercialization

D-2570 (selective TYK2 allosteric inhibitor)

As a next-generation TYK2 allosteric inhibitor, D-2570 incorporates targeted structural innovation at the TYK2 binding pocket, resulting in breakthrough improvements in selectivity. Building on deep insights into the clinical limitations of first-generation TYK2 inhibitors, we systematically redesigned the molecule to overcome dose-escalation constraints. The optimized candidate achieved favorable exposure levels, showed a favorable safety profile in animal toxicology studies, and successfully escalated to high doses in the Phase I clinical trial without safety concern.

BUSINESS

In the Phase II clinical trial for moderate-to-severe plaque psoriasis, D-2570 delivered exceptional efficacy, achieving a PASI 75 response rate of 90% and a PASI 100 response rate of 50% — markedly higher than existing standard therapies. Clinical benefit emerged as early as Week 4.

We have initiated the registrational and head-to-head Phase III clinical trials of D-2570 for moderate-to-severe plaque psoriasis in China and are actively expanding into additional indications. In addition, we have initiated a Phase II trial of D-2570 in the U.S.

Taragarestrant (D-0502, oral SERD)

For ER+/HER2- breast cancer, taragarestrant (D-0502) is one of the most advanced oral SERDs under clinical development in China. Our registrational Phase III head-to-head trial against fulvestrant is progressing as planned.

We are positioning taragarestrant (D-0502) strategically within the rapidly evolving first-line and combination therapy landscape in breast cancer: In China, we are accelerating development with the goal of making taragarestrant (D-0502) the first approved therapy for ESR1-mutated patients. We are also refining our partnership strategy to develop combination therapies by collaborating with developers of next-generation ADCs.

Long-Term Growth Drivers Addressing Large Unmet Needs

Darbinurad (D-0120, URAT1 inhibitor)

Darbinurad (D-0120) is a selective inhibitor of the renal urate transporter URAT1 and has demonstrated rapid onset of action in both Phase I and Phase II clinical trials, with meaningful reductions in serum uric acid observed within 24 hours in both healthy volunteers and patients, suggesting the potential of darbinurad (D-0120) to become a promising therapy in this large and underserved market.

To mitigate the risks associated with overly aggressive uric acid excretion — such as urate crystal mobilization triggering inflammatory flares, or high urinary uric acid concentrations leading to stone formation or mild renal impairment — we intentionally adopted a “moderate urate-lowering” dosing strategy for darbinurad (D-0120).

A Robust and Growing Preclinical Pipeline

Beyond our clinical-stage assets, we maintain a broad portfolio of preclinical programs targeting next-generation therapeutic modalities.

YF087 (WRN inhibitor — synthetic lethality)

YF087 is one of our lead programs in the field of synthetic lethality. The antitumor activity of YF087 has been validated across multiple preclinical studies, with data presented at the AACR Annual Meeting in 2025. Compared to the competing WRN inhibitors, YF087 achieves meaningfully higher systemic exposure at lower doses and demonstrates greater potency in relevant tumor models.

YF550 (KIF18A inhibitor — synthetic lethality)

By inhibiting KIF18A, YF550 effectively suppresses the growth of chromosomally unstable (“CIN+”) tumor cells while sparing normal cells, suggesting a more targeted and potentially safer approach compared with existing anti-mitotic therapies. Data presented at AACR Annual Meeting 2025 show that YF550 outperforms KIF18A inhibitor AMG 650 in ovarian cancer animal models and induces tumor regression in both ovarian cancer and HER2-positive breast cancer models.

BUSINESS

YF057 (oral STAT6 degrader)

We have established our oral STAT6 degrader YF057 as a strategically prioritized initiative, aiming to offer a differentiated oral alternative to IL-4R α and IL-13 antibody injections and to develop transformative treatments for AD and asthma. We see significant market potential in STAT6-related indications, supported by target validation and clear druggability, and we expect this field to become increasingly competitive globally.

Next-generation ADC platform

Leveraging our core strengths in medicinal chemistry design and chemical synthesis we are developing the next-generation ADC platform. Our research prioritizes ADC linker and payload designs, with a focus on creating more effective and stable linkers and new payloads to expand the therapeutic window. Through iterative structural optimization and mechanistic studies, we have established a proprietary linker technology system and an optimized ADC molecular architecture. We have also developed new payloads designed to address resistance observed with agents such as DS-8201. These advances have already led to significant improvements in both *in vivo* efficacy and safety profiles exhibited in animal studies.

Extensive Global Collaboration Network and Commercial Execution Capabilities

We have established broad and deep collaborations with leading medical centers and expert physicians worldwide. In parallel, we have formed research and development partnerships with major biotech and pharmaceutical companies, bringing strategic synergy to both our pipeline development and future commercialization. We continuously evaluate the commercial potential of each pipeline asset throughout its development lifecycle. We have adopted a hybrid commercialization model that combines strategic licensing partnerships with independent commercialization.

In China, we have entered into licensing agreements with Betta and CTTQ for the development and commercialization of befotertinib (BPI-D0316) and garsorasib (D-1553), respectively. This partnership-driven model helps us optimize R&D and commercialization costs, provides upfront and milestone-based cash inflow prior to product launch, and lowers operational risk — ultimately ensuring efficient and successful market entry for our products.

A R&D Team with Global Experience, Strengthening Financial Fundamentals, and Long-Term Support from Leading Global Investors

Our core management team, led by Drs. Yaolin Wang, Yueheng Jiang, Xing Dai, and Ling Zhang, brings extensive experience from leading multinational pharmaceutical companies, with an average of more than 20 years in global drug discovery, development, and team leader roles. Their expertise spans the full continuum of drug R&D, including target identification and validation, medicinal chemistry optimization, CMC, clinical development and regulatory affairs.

Dr. Yaolin Wang, our chairman of the Board, executive Director and general manager, oversees the Company’s overall strategy and operations and leads major R&D decisions, including target selection and new-drug discovery. Dr. Wang holds a Ph.D. in Pharmacology from SUNY Stony Brook and previously spent nearly 20 years at Schering-Plough and Merck & Co., Inc. During his tenure, he participated in the preclinical pharmacology R&D of multiple oncology small molecules and antibody therapeutics and was responsible for external research and collaborations in *in vivo* oncology pharmacology at Merck & Co., Inc.

Dr. Yueheng Jiang, our executive Director and deputy general manager and secretary of the Board, draws on nearly 15 years of small-molecule drug discovery experience at Schering-Plough and Merck & Co., Inc. He leads our business development and CMC functions, manages key partnerships — including license-in/out deals and co-development projects — and oversees process development, manufacturing, and supply chain activities for drug substances and finished products.

BUSINESS

Dr. Xing Dai is our executive Director and deputy general manager. He brings more than 17 years of experience managing drug discovery programs and R&D teams at multinational pharmaceutical companies, including roles as Senior Scientist at Schering-Plough and project lead at Merck & Co., Inc.

Dr. Ling Zhang, our deputy general manager and chief medical officer, oversees the full spectrum of clinical development, leading clinical design and execution, coordinating cross-functional activities including biostatistics, data management, pharmacokinetics, compliance, and risk management, and steering with the regulatory team to drive submissions. Dr. Zhang brings over 20 years of clinical research experience and has worked at major global pharmaceutical companies including GSK, Sanofi, Merck & Co., Inc., Celgene Corporation, and Daiichi Sankyo.

We emphasize on practical, cost-disciplined team management. Even after our A-share listing, senior management continues to take on multiple operational roles. For example, Dr. Jiang remains both deputy general manager and secretary of the Board, demonstrating our commitment to an efficient, hands-on operating approach.

With two major products approved and scaling commercially, we have entered a phase of rapid revenue growth, with financial performance continuing to improve and net losses narrowing steadily. We have sufficient cash reserve to provide ample funding to support operations and advance our core pipeline over the next several years. Our financial position remains resilient. Our long-standing support from leading global life sciences investors, including Lilly Asia Ventures and OrbiMed, demonstrates deep confidence in our strategic direction, R&D pipeline, operational execution, and long-term value creation.

OUR GROWTH STRATEGIES

Accelerate Clinical Development of Our Core Products

For D-2570, we plan to advance the registrational and head-to-head (against deucravacitinib) Phase III trials and subsequent NDA submission targeting psoriasis in China. In the U.S., we initiated a Phase II clinical trial of for psoriasis in July 2026. Meanwhile, we will continue with the China Phase II clinical trials targeting moderate-to-severe active UC, active SLE, active PsA and nonsegmental vitiligo.

For taragarestrant (D-0502), our goal is to position it as the first domestically developed oral SERD. We also plan to pursue combination strategies with high-potential ADC candidates to reinforce its competitiveness in multi-line treatment settings. We initiated a Phase II clinical trial of taragarestrant in combination with JSKN016, a bispecific ADC targeting trophoblast cell surface antigen 2 (“TROP2”) and human epidermal growth factor receptor 3 (“HER3”), in March 2026. We expect to initiate a Phase III clinical trial for this combination therapy in 2028.

Accelerate the Expansion of Our Pipeline Across Oncology, Autoimmune Diseases, and Metabolic Disorders Through Precision Target Discovery

We have a robust portfolio of preclinical assets and plan to advance more than three programs into clinical development and achieve first-in-human milestones over the next three years. Leveraging our precision target identification capabilities, we will continue to discover and assess cutting-edge biological targets and further expand our pipeline across major therapeutic areas, including oncology, metabolic diseases and autoimmune disorders.

In our small-molecule portfolio, we are progressing multiple programs centered on next-generation mechanisms, including synthetic lethality assets such as YF087 and YF550. We are also dedicating significant resources to the discovery and optimization of STAT6 degraders — a frontier in immunology. With an early-mover advantage in this field, our STAT6 degrader candidate YF057 has already demonstrated competitive preclinical profile and continues to advance to IND-enabling studies. In August 2026, we entered into a collaboration agreement with MSD R&D (China) Co. Ltd. to jointly advance the clinical development of small-molecule drugs in the field of oncology.

BUSINESS

In the ADC field, we focus on next-generation design, prioritizing core technologies that drive therapeutic performance, including enhanced linker stability, payload optimization, and targeted therapeutic efficacy, to achieve a broader safety window. Through continuous structural optimization and mechanistic innovation, we have established a proprietary linker technology and an integrated ADC molecular-optimization framework. We have also developed new payloads designed to overcome resistance mechanisms observed with agents such as trastuzumab deruxtecan. These innovations lay a solid technological foundation for improving the therapeutic window and balancing efficacy and safety in future ADC programs.

Strategic Global Advancement of Garsorasib (D-1553), D-2570, and Darbinurad (D-0120) Through Partnerships with Trusted Collaborators

We intend to advance the global development of our late-stage assets, garsorasib (D-1553), D-2570, and darbinurad (D-0120), through strategic collaborations with reputable international partners. Our global strategy is built on a partnership-driven model, under which we collaborate with organizations that possess strong late-stage clinical development capabilities and established commercialization infrastructures. We are actively identifying and engaging potential partners in major developed markets, including the U.S., the European Union and Japan, to support the international clinical advancement and future commercial deployment of our near-to-late-stage programs. We have a dedicated business development team that oversees these initiatives and leads all ongoing partnering discussions. Leveraging favorable clinical trial results, we intend to prioritize global expansion and international collaboration for three lead programs:

Garsorasib (D-1553, KRAS G12C inhibitor): Phase I and II clinical trials have been completed in China and overseas (including the U.S., Australia and Korea), and garsorasib (D-1553) has shown encouraging efficacy in first-line NSCLC treatment.

D-2570 (TYK2 inhibitor): The U.S. Phase II clinical trial targeting moderate-to-severe plaque psoriasis has been initiated, with completion expected in the first quarter of 2028.

Darbinurad (D-0120, URAT1 inhibitor): The U.S. Phase II clinical trial of darbinurad (D-0120) in combination with allopurinol was completed in March 2026.

Advancing an AI-Enabled Drug Design Platform Through Integrated Internal Development and Strategic External Collaboration

We intend to enhance our strategic focus on artificial intelligence (“AI”)-driven capability to bolster our drug discovery engine and improve R&D productivity. Leveraging over a decade of proprietary data, extensive computational chemistry infrastructure, and a suite of multimodal deep learning algorithms, we have developed approximately 100 AI-driven property prediction models. These models encompass multi-task ADMET (absorption, distribution, metabolism, excretion, and toxicity) prediction, cytochrome P450 metabolic site prediction, and volume of distribution prediction models. Collectively, they enable a multidimensional assessment of molecular structure, physicochemical characteristics, and pharmacokinetic properties. Concurrently, we have established an in-house molecular generation platform that integrates multiple proprietary generative models covering stochastic molecular generation, pocket-shape-guided generation, ligand conformation-based 3D generation, PK property-driven generation, and scaffold hopping. Such capabilities allow rapid exploration of millions of chemical structures and the swift identification of promising drug candidates.

To augment design diversity and precision, we have curated high-quality internal compounds and fragment libraries. These libraries feature synthesizability and drug-likeness, serving as optimized starting points for molecular generation and virtual screening. They can be customized for specific discovery scenarios and integrated with our predictive models to guide exploration of targeted chemical spaces. Our internal AI platform unifies these capabilities through a flexible technical architecture that incorporates Expert-in-the-Loop validation. The platform supports multiple molecular representations (e.g., SMILES, graph structures) and diverse modeling approaches, ranging from conventional machine learning to deep learning algorithms. By utilizing

BUSINESS

various learning paradigms, including pretraining, transfer learning, reinforcement learning, and active learning, we can tailor the optimal AI model configuration for each project. This adaptability facilitates more accurate predictions and faster design cycles, ultimately enhancing overall R&D efficiency. We are also implementing a protein structure prediction and *de novo* antibody design platform to support our basic research and biologic development.

Looking forward, we intend to sustain investment and advance our AI-driven discovery capabilities through both internal development and selective external collaborations. By further scaling algorithmic power, improving predictive accuracy, and deepening integration with our experimental workflows, we aim to accelerate hit-to-lead and lead-to-candidate progression. These advancements will help mitigate development risk and support the systematic expansion of our pipeline across oncology, autoimmune, and metabolic diseases. Collectively, these efforts will reinforce AI as a central pillar of our long-term innovation strategy and a sustainable driver of R&D efficiency and pipeline growth.

Continue to Recruit, Develop, and Retain Talent Across All Business Functions to Support Our Long-term Growth

As a R&D-driven biopharmaceutical company, our people are central to our ability to discover, develop, and commercialize new products. We will continue to recruit, train, promote and retain talent with relevant experience in the pharmaceutical and biotechnology industries, and we are committed to building a workforce with the scientific, clinical, operational, and managerial capabilities required to advance our strategic objectives. To support our continued expansion, we will further invest in talent development and incentive programs designed to attract and retain top global professionals across all aspects of our business.

We currently prioritize the advancement of clinical programs on two fronts. One is the relatively late stage clinical trials of Core Products targeting key indications, which are expected to generate commercialized products with significant market value in the near-term future. This includes: (1) the ongoing registrational and head-to-head Phase III clinical trials of D-2570 targeting moderate-to-severe psoriasis; (2) the Phase II clinical trial of D-2570 targeting moderate-to-severe active UC, active SLE, active PsA and nonsegmental vitiligo; (3) the registrational Phase III clinical trial of taragarestrant (D-0502) targeting ER+/HER2- breast cancer; and (4) the Phase II clinical trial of taragarestrant (D-0502) in combination with JSKN016 targeting ER+/HER2- breast cancer. The other front is expansion of our pipeline products, particularly YF087, YF550 and YF057, for which we expect to initiate Phase I clinical trials in the fourth quarter of 2026, obtain IND approval in fourth quarter of 2026 and submit IND application in second quarter of 2027, respectively.

OUR PRODUCT PIPELINE

We are a biopharmaceutical company focused on oncology, autoimmune diseases, and metabolic disorders. As of the Latest Practicable Date, our product pipeline comprised two commercialized products, three clinical-stage drug candidates, and a portfolio of preclinical programs, covering the full spectrum from early-stage research to commercial execution.

BUSINESS

Core Product D-2570: Selective Oral TYK2 Inhibitor Designed for Autoimmune Disease Treatment

Overview

D-2570 is an oral selective allosteric inhibitor of TYK2 under clinical development for the treatment of autoimmune diseases, including psoriasis, UC, SLE, PsA, and vitiligo. By selectively targeting TYK2, D-2570 modulates key cytokine signaling pathways involved in autoimmune inflammation. D-2570 offers broad therapeutic value in autoimmune diseases and a potential alternative to biologic therapies.

In a completed Phase II clinical trial targeting moderate-to-severe plaque psoriasis, D-2570 demonstrated robust efficacy and a favorable safety and tolerability profile. In particular, PASI 75 reached 90.0% at week 12 in patients that received D-2570 18 mg once a day (“QD”).

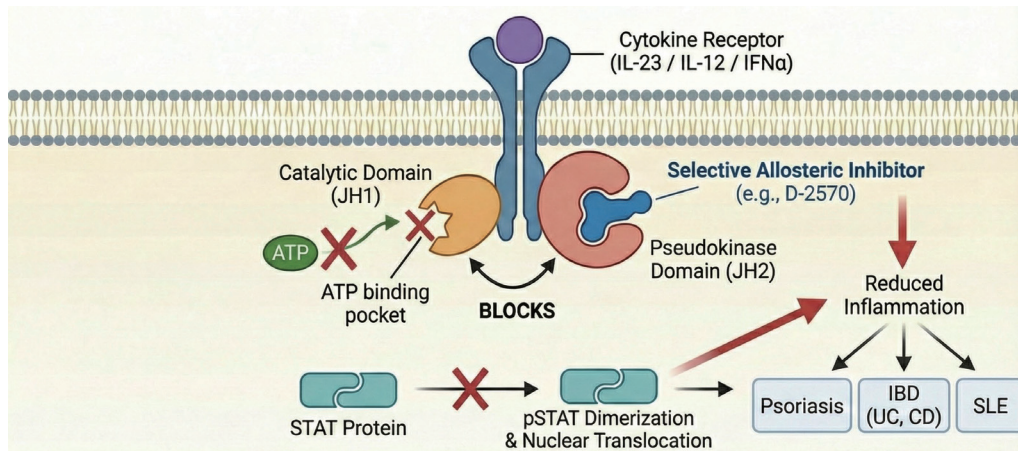
Currently, a registrational Phase III clinical trial and a head-to-head Phase III clinical trial of D-2570 targeting moderate-to-severe plaque psoriasis are ongoing. We expect to complete the trials in the second half of 2027 and thereafter submit to the NMPA an NDA for D-2570.

Meanwhile, we are exploring the potential of D-2570 as an induction therapy for moderate-to-severe active UC. A Phase II clinical trial is ongoing for that purpose in China, and we expect to complete the trial in the first quarter of 2027. We are also conducting Phase II clinical trials targeting active SLE, active PsA and nonsegmental vitiligo in China, and a Phase II clinical trial targeting moderate-to-severe plaque psoriasis in the U.S.

We developed D-2570 internally and hold the global rights for its use, manufacture, and commercialization.

Mechanism of Action

TYK2 is a member of the JAK family of intracellular enzymes, which play a crucial role in immune signaling and inflammatory responses. D-2570 achieves allosteric inhibition of TYK2 by targeting its JH2 pseudokinase domain. With that, D-2570 can precisely block the signaling pathways of pro-inflammatory cytokines such as IL-23 and IL-12, while avoiding interference with other JAK family members (such as JAK1-3), thereby reducing the common side effects of traditional JAK inhibitors, such as bone marrow suppression, tumorigenesis and infection risks. Below is a diagram illustrating the MOA of D-2570.



BUSINESS

Market Opportunity and Competitive Landscape

As of the Latest Practicable Date, globally and in China there was one approved TYK2 inhibitor drug and six TYK2 inhibitor drug candidates in the Phase III clinical stage. For more details, including a comparison of approved TYK2 inhibitor drug with available biologics, please refer to “Industry Overview — Overview of Autoimmune Disease Drug Market — Tyrosine Kinase 2 (“TYK2”) Inhibitors.”

Competitive Advantages

High Subtype Selectivity

By optimizing the structure of TYK2 inhibitors, we successfully identified D-2570, which exhibited enhanced binding selectivity for TYK2 by 800–1,000-fold over other JAK family members, as validated by *in vitro* assays.

Robust Clinical Efficacy

Phase II results in moderate-to-severe psoriasis demonstrated efficacy substantially higher than placebo and approved oral TYK2 inhibitors (based on comparison of published clinical data), while maintaining favorable safety and tolerability profiles. Significant efficacy of D-2570 was shown from week 4, with PASI 75 response rate is 45.0% in patients that received 18 mg D-2570 QD, compared to 5.0% in the placebo group. At week 12, D-2570 achieved skin clearance with PASI 75 response rate is 90.0% in patients that received D-2570 at 18 mg QD, compared to 12.5% in the placebo group, and PASI 100 reaching 50.0% in patients that received D-2570 at 36 mg QD, compared to 2.5% in the placebo group.

Favorable Safety Profile

D-2570 has demonstrated favorable safety and tolerability profiles. In a completed Phase I clinical trial, no SAE or Grade 3 or above AE was observed in subjects that received a single administration of D-2570 at 3 to 48 mg, or QD administration of D-2570 at 6 to 36 mg for 10 consecutive days. In a completed Phase II trial, no SAE was reported, and the incidences of Grade 3 or above TEAE and Grade 3 or above treatment related TEAE were 3.3% and 1.7%, respectively.

Potential Broad Applicability

Activation of TYK2 is implicated in the cellular processes that contribute to the development of multiple autoimmune diseases. D-2570, as a selective inhibitor of TYK2, can be developed as a therapy for multiple autoimmune diseases. We are currently investigating TYK2 in clinical trials targeting moderate-to-severe plaque psoriasis, moderate-to-severe active UC, active SLE, active PsA and nonsegmental vitiligo.

Summary of Clinical Trials

The following sets forth an overview of the key clinical trials of D-2570.

Phase	Study design	Sites	Subjects	Status	Subject enrollment
I . . .	Evaluate the safety, tolerability, PK and food effects on PK of D-2570 tablets under single ascending dose and multiple ascending dose schedules	China	Healthy subjects	Completed	122 (Actual)

BUSINESS

Phase	Study design	Sites	Subjects	Status	Subject enrollment
II . . .	Evaluate the efficacy and safety of D-2570	China	Patients with moderate-to-severe plaque psoriasis	Completed	161 (Actual)
III . . .	Evaluate the efficacy and safety of D-2570	China	Patients with moderate-to-severe plaque psoriasis	Ongoing	390 (Expected)
III . . .	Evaluate the efficacy and safety of D-2570	China	Patients with moderate-to-severe plaque psoriasis	Ongoing	477 (Expected)
II . . .	Evaluate the safety and efficacy of D-2570 as induction therapy	China	Patients with moderate-to-severe active UC	Ongoing	120 (Expected)
II . . .	Evaluate the efficacy and safety of D-2570	China	Patients with active SLE	Ongoing	120 (Expected)
II . . .	Evaluate the efficacy and safety of D-2570	China	Patients with active PsA	Ongoing	222 (Expected)
II . . .	Evaluate the efficacy and safety of D-2570	China	Patient with nonsegmental vitiligo	Ongoing	160 (Expected)
I . . .	Evaluate the safety, tolerability and PK of D-2570	U.S.	Healthy subjects	Completed	51 (Actual)
II . . .	Evaluate the efficacy and safety of D-2570	U.S.	Patients with moderate-to-severe plaque psoriasis	Ongoing	75 (Expected)

Clinical development of D-2570 in China:

A Phase I clinical trial to evaluate the safety, tolerability, PK and food effects of D-2570 tablets in healthy subjects in China sponsored by us

Overview. This was a randomized, double-blind, placebo-controlled Phase I clinical trial. The objective was to evaluate the safety, tolerability, PK and food effects on PK of D-2570 tablets under single ascending dose (“SAD”) and multiple ascending dose (“MAD”) schedules in healthy subjects.

Trial design. The trial enrolled 122 subjects and consisted of three studies, as described below.

SAD study

The SAD study involved 48 subjects randomized into 6 arms. The subjects included 43 males and 5 females aged 19 to 40 years, with a mean weight of 66.0 kg and a mean height of 170.2 cm. Within each arm of 8 subjects, 6 received D-2570 and 2 received placebo. Subjects in Arm 1, Arm 2, Arm 3, Arm 4, Arm 5 and Arm 6 received an oral administration of D-2570 or placebo at 6 mg, 12 mg, 24 mg, 3 mg, 36 mg and 48 mg, respectively, on day 1 on an empty stomach. Subjects were under an observation period until day 7.

Food effect study

The food effect study involved 14 subjects in Arm 7, who were randomly assigned in 1:1 ratio to two treatment sequences. The subjects included 10 males and 4 females aged 19 to 41 years, with a mean weight of 61.7 kg and a mean height of 165.7 cm. In Sequence A, subjects received an oral administration of D-2570 9 mg on day 1 on an empty stomach in the first 7-day treatment and observation cycle and an oral administration of D-2570 9 mg on day 1 after meal in the second 7-day treatment and observation cycle. In Sequence B, subjects received an oral administration of

BUSINESS

D-2570 9 mg on day 1 after meal in the first 7-day treatment and observation cycle and an oral administration of D-2570 9 mg on day 1 on an empty stomach in the second 7-day treatment and observation cycle. For each subject, there was an washout period of at least 10 days between the two treatment cycles.

MAD study

The MAD study involved 60 subjects randomized into 5 arms. The subjects included 50 males and 10 females aged 20 to 42 years, with a mean weight of 64.1 kg and a mean height of 167.5 cm. Within each arm of 12 subjects, 9 received D-2570 and 3 received placebo. Subjects in Arm 8, Arm 9, Arm 10, Arm 11 and Arm 12 received an oral administration of D-2570 or placebo at 6 mg, 12 mg, 18 mg, 27 mg and 36 mg, respectively, QD after meal from day 1 for 10 consecutive days and were under observation until day 16. The trial endpoints included PK profile and safety endpoints, including AE, vital signs, physical examination, blood test and ECG.

Key inclusion criteria included: (i) male and female subjects aged 18 to 45 years (inclusive); (ii) male weight ≥ 50 kg, and female weight ≥ 45 kg; (iii) body mass index (“BMI”) ranging from 19 to 26 kg/m² (inclusive). Key exclusion criteria included: (i) more than 5 cigarettes per day on average within 3 months before screening; (ii) subjects with a clinically significant history of drug allergy or specific allergic diseases (asthma, urticaria) or known allergy to the investigational medicinal product or its excipients; (iii) history of alcohol abuse; (iv) blood donation or massive blood loss (>450 mL) within 3 months before screening.

Trial status. We initiated the trial in August 2022 and completed the trial in June 2023. All trial endpoints were reached in June 2023, as marked by the last observation of subjects.

Safety data. D-2570 demonstrated good safety and tolerability. No SAE or Grade 3 or above AE was observed in subjects that received a single administration of D-2570 at 3 to 48 mg or QD administration of D-2570 at 6 to 36 mg for 10 consecutive days. One subject experienced AE that led to withdrawal from the trial.

The recorded incidences of AEs are summarized below.

	TEAE	TRAE
SAD study	25.0% (12/48)	22.9% (11/48)
MAD study placebo	53.3% (8/15)	46.7% (7/15)
MAD study D-2570 6 mg	66.7% (6/9)	66.7% (6/9)
MAD study D-2570 12 mg	66.7% (6/9)	66.7% (6/9)
MAD study D-2570 18 mg	55.6% (5/9)	55.6% (5/9)
MAD study D-2570 27 mg	100.0% (9/9)	88.9% (8/9)
MAD study D-2570 36 mg	66.7% (6/9)	66.7% (6/9)
MAD study D-2570 total	71.1% (32/45)	68.9% (31/45)
MAD study total	66.7% (40/60)	63.3% (38/60)

Food effect data. Administration after meal was found to increase D-2570 exposure in plasma to some extent (approximately 15% and 30% for C_{max} and AUC, respectively), but had no significant effect on the time to peak concentration.

A Phase II clinical trial to evaluate the efficacy and safety of D-2570 in patients with moderate-to-severe plaque psoriasis in China sponsored by us

Overview. This was a randomized, double-blind, placebo-controlled, multicenter Phase II clinical trial in patients with moderate-to-severe plaque psoriasis. The primary objective was to conduct a preliminary evaluation of the efficacy of different doses of D-2570 in the treatment of

BUSINESS

moderate-to-severe plaque psoriasis. The secondary objective was to conduct a preliminary evaluation of the safety of different doses of D-2570 in the treatment of moderate-to-severe plaque psoriasis and an evaluation of the PK and PD of D-2570 in the patients with moderate-to-severe plaque psoriasis.

Trial design. The trial enrolled 161 patients and consisted of two parts. In Part A, 40 patients were randomized 1:1:1:1 to receive 18/27/36 mg D-2570 or placebo in 3 mg tablets according to the following schedule.

	Day 1	Days 2-4	12 weeks from Day 5
Experimental group 1 (N=10)	6 D-2570 tablets + 6 placebo tablets	Washout period	6 D-2570 tablets QD + 6 placebo tablets QD
Experimental group 2 (N=10)	9 D-2570 tablets + 3 placebo tablets	Washout period	9 D-2570 tablets QD + 3 placebo tablets QD
Experimental group 3 (N=10)	12 D-2570 tablets	Washout period	12 D-2570 tablets QD
Control group (N=10) . .	12 placebo tablets	Washout period	12 placebo tablets QD

In Part B, 121 patients were randomized 1:1:1:1 to receive 18/27/36 mg D-2570 or placebo in 3 mg tablets according to the following schedule.

	12 weeks
Experimental group 1 (N=30)	6 D-2570 tablets QD + 6 placebo tablets QD
Experimental group 2 (N=31)	9 D-2570 tablets QD + 3 placebo tablets QD
Experimental group 3 (N=30)	12 D-2570 tablets QD
Control group (N=30)	12 placebo tablets QD

The mean age of the enrolled subjects was 43.2 years, and 83.2% were men. The median (SD) psoriasis duration was 8.9 (9.6) years. After the above 12-week treatment period, subjects in both Part A and Part B went through a 2-week follow-up period. The primary difference between Part A and Part B was that Part A included a single-dose PK study period.

The primary endpoint was the proportion of patients achieving improvement of psoriasis area severity index (“PASI”) by at least 75% (“PASI 75”) at week 12. Secondary endpoints included PASI 75 at weeks 4 and 8, PASI 90/100 at weeks 4, 8 and 12, percentage improvement of PASI at weeks 4, 8 and 12, the proportion of patients achieving static Physician Global Assessment (“sPGA”) score of 0/1 at weeks 4, 8 and 12, safety, and PK/PD characteristics.

Key inclusion criteria included: (i) aged 18 to 70 years (inclusive); (ii) plaque psoriasis assessed by the investigator as suitable for systemic treatment and stable for at least 6 months prior to signing informed consent; (iii) during the screening period and before taking the investigational drug for the first time, psoriatic surface area $\geq 10\%$, PGA score ≥ 3 , PASI score ≥ 12 . Key exclusion criteria included: (i) erythrodermic psoriasis, pustular psoriasis, guttate psoriasis, reverse psoriasis, drug-induced psoriasis; (ii) prior use of TYK2 inhibitor; (iii) having serious malignant diseases, such as tumors, cardiovascular and cerebrovascular diseases, or severe infections.

Trial status. We initiated the Phase II clinical trial in January 2024 and completed the trial in April 2025. All trial secondary endpoints were reached in November 2024, as marked by the last observation of subjects. In March 2025, we reported the Phase II clinical trial results in an oral presentation at the 2025 American Academy of Dermatology annual meeting.

BUSINESS

Efficacy data. D-2570 achieved significant efficacy in improving skin clearance. At week 12, significantly higher response rates for PASI 75, PASI 90, PASI 100 and sPGA 0/1 were achieved in patients receiving D-2570 at 18/27/36 mg versus placebo ($P < 0.001$ for all the endpoints), as shown in the below table.

	18 mg D-2570 (N=40)	27 mg D-2570 (N=41)	36 mg D-2570 (N=40)	Placebo (N=40)
PASI 75	90.0%	85.4%	85.0%	12.5%
PASI 90	75.0%	70.7%	77.5%	5.0%
PASI 100	40.0%	39.0%	50.0%	2.5%
sPGA 0/1	82.5%	80.5%	87.5%	20.0%

Also, D-2570 exhibited significant efficacy from week 4. The below table shows the significantly higher response rates for PASI 75 in patients receiving D-2570 at 18/27/36 mg versus placebo ($P < 0.01$ for all the time points).

	18 mg D-2570 (N=40)	27 mg D-2570 (N=41)	36 mg D-2570 (N=40)	Placebo (N=40)
Week 4	45.0%	29.3%	32.5%	5.0%
Week 8	80.0%	85.4%	72.5%	15.0%
Week 12	90.0%	85.4%	85.0%	12.5%

Safety data. D-2570 was well-tolerated, with no SAE reported. The majority of AEs were mild to moderate (Grade 1 or 2), and no new safety signals were identified. The recorded incidences of AEs in the experimental groups are summarized below.

TEAE	TAE	Grade 3 or above TEAE	Grade 3 or above TAE	TEAE leading to study discontinuation
70.2% (85/121)	53.7% (65/121)	3.3% (4/121)	1.7% (2/121)	0.8% (1/121)

A registrational Phase III clinical trial to evaluate the efficacy and safety of D-2570 in patients with moderate-to-severe plaque psoriasis in China sponsored by us

Overview. This is a randomized, double-blind, placebo-controlled, multicenter Phase III clinical trial in patients with moderate-to-severe plaque psoriasis. The primary objective is to evaluate whether different doses of D-2570 were superior to placebo at week 16 in treating patients with moderate-to-severe plaque psoriasis. The secondary objective is to evaluate the long-term effects, safety and PK/PD of D-2570 in treating patients with moderate-to-severe plaque psoriasis.

Trial design. The trial expects to enroll 390 patients. The patients will be randomized 1:1:1 to receive 9/18 mg D-2570 or placebo in 9 mg tablets according to the following schedule.

	16 weeks	36 weeks
Experimental group 1	1 D-2570 tablet QD + 1 placebo tablets QD	1 D-2570 tablet QD + 1 placebo tablets QD
Experimental group 2	2 D-2570 tablets QD	2 D-2570 tablets QD
Control group	2 placebo tablets QD	1 D-2570 tablet QD + 1 placebo tablet QD or 2 D-2570 tablets QD

BUSINESS

The patients will be under a 4-week follow-up period after the above 52-week treatment period. The primary endpoint was PASI 90 at week 16. The key secondary endpoint was the proportion of patients achieving PGA score of 0/1 and reduction from baseline by at least 2 in PGA score at week 16.

Key inclusion criteria included: (i) aged between 18 and 70 years old (inclusive) at the time of signing the informed consent form, regardless of gender; (ii) the investigator assesses that the subject has plaque psoriasis suitable for systemic therapy, and the condition has been stable for ≥ 6 months before signing the informed consent form; (iii) at the screening stage and Day 1 of the treatment period, BSA is $\geq 10\%$, PGA score is ≥ 3 points, and PASI score is ≥ 12 points. Key exclusion criteria included: (i) suffering from any type of psoriasis including erythrodermic psoriasis, pustular psoriasis, guttate psoriasis, inverse psoriasis, or drug-induced psoriasis; (ii) having other skin lesions that may interfere with the assessment of treatment outcomes, such as eczema; (iii) a history of severe herpes zoster/simplex infection.

Trial status. We initiated the trial in September 2025 and expect to complete the trial in the second half of 2027.

A head-to-head Phase III clinical trial to evaluate the efficacy and safety of D-2570 in patients with moderate-to-severe plaque psoriasis in China sponsored by us

Overview. This is a multicenter, randomized, double-blind, placebo- and active-controlled Phase III clinical trial in patients with moderate-to-severe plaque psoriasis. The primary objective is to evaluate the efficacy of different doses of D-2570 compared with placebo in patients with moderate-to-severe plaque psoriasis. The secondary objective is to evaluate: (i) the efficacy of different doses of D-2570 compared with deucravacitinib in patients with moderate-to-severe plaque psoriasis; (ii) the safety of different doses of D-2570 in the treatment of moderate-to-severe plaque psoriasis; and (iii) the PK and PD profiles of D-2570 in patients with moderate-to-severe plaque psoriasis.

Trial design. The trial expects to enroll 477 patients. The subjects will be randomized in a 3:3:2:1 ratio to the D-2570 9 mg group (experimental group A), D-2570 18 mg group (experimental group B), deucravacitinib group (active control group), and placebo group (placebo control group), and will receive the corresponding investigational product QD for 16 consecutive weeks. After the 16-week controlled treatment period, the subjects in experimental group A and experimental group B will directly enter the extension treatment period and continue their dosing schedule unchanged through week 28; and the subjects in active control group and placebo group will undergo re-randomization in a 1:1 ratio under blinded conditions to receive either D-2570 9 mg QD or D-2570 18 mg QD, and will continue treatment through week 28. Subjects will be under a 4-week follow-up period after end of treatment.

The primary endpoint is PASI 90 at week 16. The secondary endpoints include: percentage of subjects with a PGA score of 0/1 at week 16 and a decrease of ≥ 2 points from baseline; PASI 75, PASI 90 and PASI 100 at each study visit; percentage improvement from baseline in PASI at each study visit; percentage of subjects with a PGA score of 0/1 and a decrease of ≥ 2 points from baseline at each study visit. Safety endpoints include: AE, vital signs, physical examination and ECG.

Key inclusion criteria include: (i) aged 18 to 70 years (inclusive); (ii) plaque psoriasis assessed by the investigator as suitable for systemic treatment and stable for at least 6 months prior to signing informed consent; (iii) during the screening period and before taking the investigational drug for the first time, psoriatic surface area $\geq 10\%$, PGA score ≥ 3 , PASI score ≥ 12 . Key exclusion criteria include: (i) suffering from any type of psoriasis including erythrodermic psoriasis, pustular psoriasis, guttate psoriasis, inverse psoriasis, or drug-induced psoriasis; (ii) having other skin lesions that may interfere with the assessment of treatment outcomes, such as eczema; (iii) a history of severe herpes zoster/simplex infection; (iv) a history of tuberculosis, active tuberculosis, latent tuberculosis, or clinical manifestations suggestive of tuberculosis infection.

Trial status. We initiated this head-to-head Phase III clinical trial in January 2026 and expect to complete it in the second half of 2027.

BUSINESS

A Phase II clinical trial to evaluate the safety and efficacy of D-2570 as induction therapy in subjects with moderate-to-severe active UC in China sponsored by us

Overview. This is a multicenter, randomized, double-blind, placebo-controlled Phase II clinical trial. The target population is the patients with moderate-to-severe active UC. The primary objective is to conduct a preliminary evaluation of the efficacy of different doses of D-2570 in the treatment of moderate-to-severe active UC. The secondary objective is to conduct a preliminary evaluation of the safety of different doses of D-2570 in the treatment of moderate-to-severe active UC and an evaluation of the PK and PD of D-2570 in the patients with moderate-to-severe active UC.

Trial design. A total of 120 subjects are planned to be included. The treatment is divided into two phases: the induction treatment phase and the extended treatment phase. The induction treatment phase will be divided into two parts. Part A (induction treatment phase) will include 30 subjects, and Part B (extended treatment phase) will include 90 subjects. The primary difference between Part A and Part B is that Part A includes a single-dose PK study period. In both Part A and Part B, subjects will be randomized in a 1:1:1 ratio to receive D-2570 or placebo in 9 mg tablets. The following schedule will apply to Part A:

	Day 1	Days 2-4	12 weeks from Day 5
Experimental group 1 (N=10)	2 D-2570 tablets + 1 placebo tablet	Washout period	2 D-2570 tablets QD + 1 placebo tablet QD
Experimental group 2 (N=10)	3 D-2570 tablets	Washout period	3 D-2570 tablets QD
Control group (N=10)	3 placebo tablets	Washout period	3 placebo tablets QD

The following schedule will apply to Part B:

	12 weeks
Experimental group 1 (N=30)	2 D-2570 tablets QD + 1 placebo tablet QD
Experimental group 2 (N=30)	3 D-2570 tablets QD
Control group (N=30)	3 placebo tablets QD

After completing the 12-week induction treatment phase, the subjects in Part A and Part B can choose to enter the extended treatment phase, during which the subjects will receive 2 D-2570 tablets (18 mg) QD for up to 12 weeks. After completing the extended treatment phase, the subjects will have a 2-week follow-up period.

The primary endpoint is the percentage of subjects achieving clinical remission at 12 weeks of treatment. The secondary endpoints included the percentage of subjects achieving clinical response at 12 weeks of treatment, the percentage of subjects achieving symptom remission at weeks 4, 8, and 12 of treatment and at every 4-week interval during the extended treatment phase, AE and PK.

Key inclusion criteria included: (i) males and females, 18 to 70 years of age, inclusive at the time of signing of informed consent form; (ii) having an established diagnosis of UC of ≥ 3 months in duration prior to signing of informed consent form (supported by endoscopy reports, histopathology reports and clinical manifestations consistent with UC, as determined by investigators); (iii) involved intestinal segment extending ≥ 15 cm from the anal verge as confirmed by a screening endoscopy; (iv) active moderate to severe UC, defined by a modified Mayo score of 5 to 9 points at screening, which includes a stool frequency subscore of ≥ 2 , a rectal bleeding subscore ≥ 1 and an endoscopic subscore of ≥ 2 (based on a screening endoscopy, confirmed by

BUSINESS

central reading). Key exclusion criteria included: (i) diagnosed or suspected CD, indeterminate colitis, fulminant colitis, toxic megacolon, microscopic colitis, ischemic colitis, radiation colitis, or colitis associated with diverticula; (ii) history of colonic resection, subtotal or total colectomy, or surgical intervention for UC, or anticipated need for, as assessed by the investigator, surgical intervention for UC during the study, or with other gastrointestinal diseases or surgical histories that may affect the absorption of study treatment.

Trial status. We initiated the Phase II clinical trial in May 2025 and expect to complete the trial in the first quarter of 2027.

A Phase II clinical trial to evaluate the safety and efficacy of D-2570 in patients with active SLE in China sponsored by us

Overview. This is a multicenter, randomized, double-blind, placebo-controlled Phase II clinical trial in patients with active SLE. The primary objective is to evaluate the efficacy of different doses of D-2570 in the treatment of active SLE. The secondary objective is to (i) evaluate the safety of different doses of D-2570 in the treatment of active SLE and (ii) characterize the PK and PD profiles of D-2570 in patients with active SLE.

Trial design. The trial expects to enroll 120 patients. The subjects will be randomized in a 1:1:1:1 ratio to the D-2570 3 mg QD group, D-2570 6 mg QD group, D-2570 12 mg QD group, or placebo group, and will enter the study treatment period, during which they will receive the corresponding investigational product QD for 48 consecutive weeks. Subjects will be under a 4-week follow-up period after end of treatment.

The primary endpoint is the proportion of subjects that reach SRI-4 at week 32. The secondary endpoints include: proportion of subjects achieving SRI-4 at weeks 4, 12, 24, and 48; proportion of subjects achieving SRI-6 at weeks 4, 12, 24, 32, and 48; improvement from baseline in Systemic Lupus Erythematosus Disease Activity Index 2000 (“SLEDAI-2K”) score at weeks 4, 12, 24, 32, and 48; proportion of subjects with a baseline Cutaneous Lupus Erythematosus Disease Area and Severity Index (“CLASI”) activity score ≥ 10 who achieve a $\geq 50\%$ reduction from baseline at weeks 4, 12, 24, 32, and 48. Safety endpoints include: AE, vital signs, physical examination and ECG.

The SLE Responder Index (“SRI”) is a composite responder definition that is a common primary efficacy end point used in SLE Phase II and III randomized controlled trials. An SRI-4 response is defined as a reduction in the SLE Disease Activity Index (“SLEDAI”) by ≥ 4 points, with no worsening of the British Isles Lupus Assessment Group index (new grade 1A or 2B score) or deterioration from baseline ≥ 0.3 points in the physician global assessment. SRI-6 is the same instrument with reduction defined as 6 points respectively versus 4 points for SRI-4.

Key inclusion criteria include: (i) aged 18 to 70 years (inclusive); (ii) diagnosed with SLE for at least 24 weeks prior to screening, in accordance with the 2019 European League Against Rheumatism/American College of Rheumatology (“EULAR/ACR”) classification criteria for SLE; (iii) presence of at least one of the following: antinuclear antibody titer $\geq 1:80$; positive anti-dsDNA antibody; positive anti-Smith antibody; (iv) total SLEDAI-2K score ≥ 6 at screening; and a clinical SLEDAI-2K score ≥ 4 at both screening and on the day of randomization, with joint involvement and/or rash and/or cutaneous vasculitis (the clinical SLEDAI-2K includes the following clinical items: vasculitis, arthritis, myositis, rash, pleurisy, and pericarditis). Key exclusion criteria include: (i) diagnosed with an autoimmune or rheumatic disease other than SLE (with the exception of secondary Sjögren’s syndrome or autoimmune thyroiditis), or drug-induced lupus; (ii) active neuropsychiatric SLE, including: seizure, new-onset or worsening altered consciousness, psychosis, delirium or confusional state, aseptic meningitis, ascending or transverse myelitis, chorea, cerebellar ataxia, mononeuritis multiplex, or demyelinating syndrome; (iii) lupus nephritis that required induction therapy within 6 months prior to screening, or unstable renal disease.

Trial status. We initiated this Phase II clinical trial in February 2026 and expect to complete it in the second half of 2028.

BUSINESS

A Phase II clinical trial to evaluate the safety and efficacy of D-2570 in patients with active PsA in China sponsored by us

Overview. This is a multicenter, randomized, double-blind, placebo-controlled Phase II clinical trial in patients with active PsA. The primary objective is to evaluate the efficacy of different doses of D-2570 compared with placebo in patients with active PsA. The secondary objective is to (i) evaluate the safety and tolerability of different doses of D-2570 in the treatment of active PsA and (ii) characterize the PK and PD profiles of D-2570 in patients with active PsA.

Trial design. The trial expects to enroll 222 patients. The subjects will be randomized in a 1:1:1 ratio into the D-2570 9 mg group (experimental group 1), D-2570 18 mg group (experimental group 2), and placebo group (control group), and will enter the double-blind controlled treatment period, during which they will receive the corresponding investigational product QD for 12 consecutive weeks. After completion of the 12-week controlled treatment period, subjects will enter the extension treatment period through week 24. Subjects in experimental group 1 and experimental group 2 will directly enter the extension treatment period and continue to receive the investigational product QD at the same dose administered during the controlled treatment period through week 24. Subjects in control group, after completing the 12-week controlled treatment period, will be re-randomized under blinded conditions in a 1:1 ratio to receive either D-2570 9 mg QD or D-2570 18 mg QD through week 24. Subjects will be under a 4-week follow-up period after end of treatment.

The primary endpoint is the percentage of subjects that reach ACR20 at week 12. The secondary endpoints include: percentage of subjects achieving minimal disease activity at week 12; percentage of subjects achieving very low disease activity at week 12; change from baseline in disease activity index for psoriatic arthritis score at week 12; percentage of subjects achieving ACR50 at week 12; percentage of subjects achieving ACR70 at week 12; percentage of subjects achieving ACR20, ACR50, and ACR70 at each study visit. Safety endpoints include: AE, vital signs, physical examination and ECG. Safety endpoints include: AE, vital signs, physical examination and ECG.

ACR20 is a composite measure of how much a person with rheumatoid arthritis improves since taking a medication. It is defined as an improvement of 20% in the number of tender and swollen joints and a 20% improvement in three of the following five criteria: patient global assessment, physician global assessment, functional ability measure, visual analog pain scale, and erythrocyte sedimentation rate or C-reactive protein. ACR50 and ACR70 are the same instruments with improvement levels defined as 50% and 70% respectively versus 20% for ACR20.

Key inclusion criteria include: (i) aged 18 to 70 years (inclusive); (ii) having an psoriatic arthritis of ≥ 3 months in duration prior to signing informed consent; (iii) having active arthritis, characterized by at least ≥ 3 tender joints (68 joint tenderness counts) and ≥ 3 swollen joints (66 joint swelling counts). Key exclusion criteria include: (i) presence of autoimmune/inflammatory diseases other than psoriatic arthritis, including rheumatoid arthritis, axial spondyloarthritis (excluding spondylitis as part of the primary diagnosis of psoriatic arthritis), SLE, gout, or fibromyalgia; (ii) presence of forms of psoriasis other than plaque psoriasis, such as erythrodermic psoriasis, pustular psoriasis, guttate psoriasis, inverse psoriasis, or drug-induced psoriasis; (iii) presence of other skin lesions that may interfere with the evaluation of treatment response of psoriatic skin lesions, such as eczema; (iv) history of severe herpes zoster/herpes simplex infection; (v) history of tuberculosis, active tuberculosis, latent tuberculosis, or clinical manifestations suggestive of tuberculosis infection.

Trial status. We initiated this Phase II clinical trial in January 2026 and expect to complete it in the second half of 2028.

BUSINESS

A Phase II clinical trial to evaluate the safety and efficacy of D-2570 in patients with nonsegmental vitiligo in China sponsored by us

Overview. This is a multicenter, randomized, parallel, double-blind, placebo-controlled Phase II clinical trial in patients with nonsegmental vitiligo. The primary objective is to evaluate the efficacy of different doses of D-2570 in the treatment of nonsegmental vitiligo. The secondary objective is to (i) evaluate the safety of different doses of D-2570 in the treatment of nonsegmental vitiligo and (ii) characterize the PK and PD profiles of D-2570 in patients with nonsegmental vitiligo.

Trial design. The trial expects to enroll 160 patients. The subjects will be randomized in a 1:1:1:1 ratio to the D-2570 9 mg QD group (experimental group A), D-2570 18 mg QD group (experimental group B), D-2570 27 mg QD group (experimental group C), or placebo group (placebo control group), and will enter the double-blind controlled treatment period, during which they will receive the corresponding investigational product QD for 24 consecutive weeks. After completion of the week 24 visit, subjects in experimental group A and experimental group B will continue into the 24-week extension treatment period at their original dose; and subjects in experimental group C and placebo control group will, under blinded conditions, be re-randomized in a 1:1 ratio to receive either D-2570 9 mg QD or D-2570 18 mg QD in the 24-week extension treatment period. Subjects will be under a 4-week follow-up period after end of treatment.

The primary endpoint is the change rate of facial vitiligo area, measured by Facial Vitiligo Area Scoring Index (“F-VASI”) score, relative to baseline. The secondary endpoints include: change from baseline in F-VASI at weeks 4, 8, 12, 16, 20, 24, 32, 40, and 48; change rate from baseline in F-VASI at weeks 4, 8, 12, 16, 20, 32, 40, and 48; proportion of subjects achieving a $\geq 50\%$, $\geq 75\%$, and $\geq 90\%$ reduction from baseline in F-VASI at weeks 4, 8, 12, 16, 20, 24, 32, 40, and 48; change from baseline and change rate from baseline in Total Vitiligo Area Scoring Index (“T-VASI”) at weeks 4, 8, 12, 16, 20, 24, 32, 40, and 48; proportion of subjects achieving a $\geq 50\%$, $\geq 75\%$, and $\geq 90\%$ reduction from baseline in T-VASI at weeks 4, 8, 12, 16, 20, 24, 32, 40, and 48. Safety endpoints include: AE, vital signs, physical examination and ECG.

Key inclusion criteria include: (i) aged 18 to 65 years (inclusive); (ii) clinical diagnosis of nonsegmental vitiligo at screening; (iii) F-VASI ≥ 0.25 and T-VASI ≥ 5 at screening and baseline, with either active or stable vitiligo. Key exclusion criteria include: (i) segmental, mixed vitiligo or other concurrent pigmentary/active skin disorders interfering with study assessment; (ii) over 33% facial or total vitiligo lesions with leukotrichia; (iii) active, latent or inadequately treated tuberculosis infection; (iv) positive HIV, active HBV/HCV infection, or untreated syphilis.

Trial status. We initiated this Phase II clinical trial in July 2026 and expect to complete it in the second half of 2028.

Clinical development of D-2570 in the U.S.:

A Phase I clinical trial to evaluate the safety, tolerability, PK and food effect of D-2570 in healthy subjects in the U.S. sponsored by us

Overview. This was a randomized, double-blind, placebo-controlled Phase I clinical trial. Its objective is to evaluate the safety, tolerability, PK of SAD and MAD, and food effect of D-2570 tablets in healthy subjects.

Trial design. The trial recruited 51 healthy subjects. The trial included two parts: (i) the double-blind, placebo-controlled SAD and MAD study; (ii) the open-label food effect study. The SAD and MAD study comprised three dose cohorts: 9 mg, 18 mg and 27 mg. Each cohort included 12 subjects: 9 received D-2570 tablets (9 mg each), and 3 received placebo (except for the 9 mg cohort that had 9 subjects receiving D-2570 and 4 subjects receiving placebo). Subjects first underwent a single-dose period. On Day 1, a single dose was administered in the morning after fasting overnight for at least 10 hours. After completing the safety and tolerability evaluation on Day 7, subjects proceeded to the multiple-dose period. In the multiple-dose period, subjects

BUSINESS

received study medication QD, under the same fasting conditions as in single-dose period, from Day 8 for 7 consecutive days. The food effect study included 14 subjects, randomized into two sequences, A and B (7 subjects each), to undergo two-period crossover dosing. Each period lasted 7 days. For Sequence A, subjects took 18 mg of D-2570 tablets under fasting conditions in the first period and 18 mg of D-2570 tablets after a high-fat meal in the second period. For Sequence B, subjects took 18 mg of D-2570 tablets after a high-fat meal in the first period and 18 mg of D-2570 tablets under fasting conditions in the second period. There was a 3-day washout period between the two periods. Safety endpoints included AEs, laboratory tests, vital signs, physical examination, and ECG.

Key inclusion criteria included: (i) male or female subjects aged 18-55 years (inclusive); (ii) male subjects weight at least 50 kg, and female subjects weight at least 45 kg; (iii) BMI is within the range of 19-32 kg/m² (inclusive). Key exclusion criteria included: (i) subjects who have smoked an average of more than 5 cigarettes per day within 3 months prior to screening; (ii) subjects with a history of clinically significant drug allergy or hypersensitivity diseases (*e.g.*, asthma, urticaria), or known allergies to the study medication or its excipients; (iii) subjects with a history of alcohol abuse (with an average weekly alcohol intake of more than 14 units within 3 months prior to screening; 1 unit = 285 mL beer, 25 mL spirits, or 100 mL wine); (iv) subjects with a history of drug or substance abuse within the last year or a positive urine drug abuse screening test.

Trial status. We initiated the trial in December 2025 and completed it in June 2026.

Safety data. D-2570 was generally safe and well tolerated. In the SAD and MAD study, all TEAEs were mild to moderate (Grade 1 or 2). No Grade 3 or above TEAEs, Grade 3 or above TRAEs, SAEs, or TEAEs leading to study discontinuation were reported. The recorded incidences of AEs are summarized below.

	TEAE	TRAE
Placebo	20.0% (2/10)	10.0% (1/10)
D-2570 9 mg	44.4% (4/9)	22.2% (2/9)
D-2570 18 mg	44.4% (4/9)	22.2% (2/9)
D-2570 27 mg	55.6% (5/9)	44.4% (4/9)
D-2570 total	48.1% (13/27)	29.6% (8/27)

Food effect data. Administration with food did not meaningfully affect the systemic exposure of D-2570. Administration after meals resulted in essentially unchanged C_{max} and a slight increase in AUC, with changes of approximately -2% and 6 ~ 7% for C_{max} and AUC, respectively, and had no significant effect on the time to peak concentration.

A Phase II clinical trial to evaluate the efficacy and safety of D-2570 in patients with moderate-to-severe plaque psoriasis in the U.S. sponsored by us

Overview. This is a randomized, double-blind, placebo-controlled, multicenter Phase II clinical trial in patients with moderate-to-severe plaque psoriasis. The primary objective is to evaluate the efficacy of different doses of D-2570 in participants with moderate-to-severe plaque psoriasis. The secondary objective is to evaluate (i) the safety of different doses of D-2570 in patients with moderate-to-severe plaque psoriasis and (ii) the plasma concentration of D-2570 and its metabolite in patients with moderate-to-severe plaque psoriasis.

Trial design. The trial expects to enroll 75 patients. The subjects will be randomized in a 1:1:1 ratio to receive D-2570 9 mg QD, D-2570 18 mg QD and placebo, for 12 weeks. Subjects who complete 12-week treatment period or discontinue study treatment early are expected to be followed for safety for 4 additional weeks after the last dose of D-2570 or placebo.

BUSINESS

The primary endpoint is the proportion of subjects achieving PASI-90 at week 12. The secondary endpoints include: proportion of subjects achieving a PGA of 0/1 at week 12; proportion of subjects achieving PASI-75 at week 12; proportion of participants achieving PASI-100 at week 12; proportion of subjects achieving a PGA 0/1, PASI-75, PASI-90 and PASI-100 at week 4 and week 8; plasma concentrations of D-2570 and its metabolite. Safety endpoints include: AE, laboratory tests, vital signs, physical examination, ECG.

Key inclusion criteria include: (i) aged 18 to 65 years (inclusive); (ii) diagnosed with plaque psoriasis which has no significant flares of disease activity in the opinion of the investigator for at least 6 months before signing the informed consent; (iii) with moderate-to-severe plaque psoriasis as defined by a total body surface area $\geq 10\%$, a PASI score ≥ 12 and a PGA score ≥ 3 at screening and day 1. Key exclusion criteria include: (i) evidence of erythrodermic psoriasis, pustular psoriasis, guttate psoriasis, inverse psoriasis, or drug-induced psoriasis; (ii) a history of skin disease or presence of skin condition that, in the opinion of the investigator, would interfere with the study assessments, such as eczema; (iii) presence of herpes zoster lesions at screening or day 1; or with a history of serious herpes zoster or serious herpes simplex infection; (iv) a history of tuberculosis, or has active tuberculosis, latent tuberculosis, or clinical manifestations suspicious of tuberculosis infection.

Trial status. We initiated this Phase II clinical trial in July 2026 and expect to complete it in the first quarter of 2028.

Clinical Development Plan

We expect to complete: The registrational Phase III clinical trial of D-2570 and the head-to-head Phase III clinical trial of D-2570 (comparing it with deucravacitinib) targeting moderate-to-severe plaque psoriasis in China in the second half of 2027; the Phase II clinical trial of D-2570 as induction therapy targeting moderate-to-severe active UC in China in the first quarter of 2027; the Phase II clinical trials of D-2570 targeting active SLE, active PsA and nonsegmental vitiligo in China in the second half of 2028; the Phase II clinical trial for moderate-to-severe plaque psoriasis in the U.S. in the first quarter of 2028. We expect to submit an NDA for D-2570 to the NMPA in the second half of 2027. In addition, we expect to initiate: a Phase III clinical trial for UC in China in 2027; a Phase III clinical trial for PsA in China in 2028; and a Phase III clinical trial for SLE in China in 2029.

Material Communications with Competent Authorities

In June 2022, the CDE granted the umbrella IND approval to conduct the clinical trial of D-2570 targeting plaque psoriasis. After completion of the Phase I clinical trial in healthy subjects and Phase II clinical trial in plaque psoriasis patients, in January 2025, we had an end-of-Phase II meeting with the CDE and received CDE’s approval to conduct the registrational Phase III clinical trial of D-2570 for moderate-to-severe plaque psoriasis.

In March 2025, the CDE granted the IND approval to conduct the Phase II clinical trial of D-2570 as induction therapy in subjects with moderate-to-severe active UC. In August 2025, the CDE granted the IND approval to conduct a head-to-head Phase III clinical trial of D-2570 for moderate-to-severe plaque psoriasis. The CDE granted IND approvals for the Phase II clinical trials targeting active SLE, active PsA and nonsegmental vitiligo in October 2025, November 2025 and April 2026, respectively. In November 2025, the FDA issued the IND clearance to conduct a Phase I clinical trial of D-2570 in healthy subjects. In February 2026, the FDA received our protocol for the Phase II clinical trial of D-2570 in patients with moderate-to-severe plaque psoriasis. The FDA did not raise any objections to the application during the 30-day period following the date of receipt.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET D-2570 SUCCESSFULLY.

BUSINESS

Core Product Taragarestrant (D-0502): An Oral SERD for Breast Cancer Treatment

Overview

Taragarestrant (D-0502) is a potent, orally active and selective SERD. It is designed to treat ER+/HER2- breast cancer. Taragarestrant (D-0502) is the first oral SERD developed by a Chinese company that has entered clinical development in the U.S.

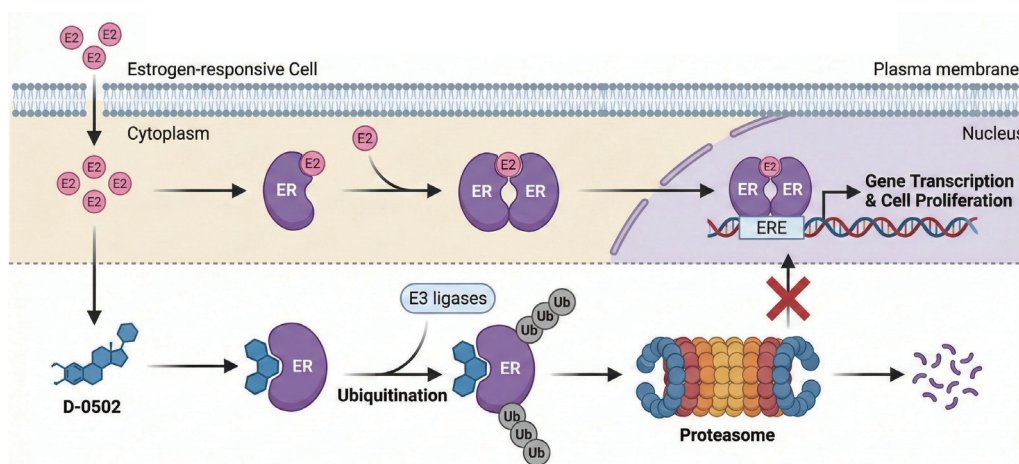
We are investigating taragarestrant (D-0502) a monotherapy for the treatment of ER+/HER2- breast cancer and its use in combination with ADCs. We have completed the Phase I clinical trial of taragarestrant (D-0502) — as a monotherapy or in combination with palbociclib — in both China and the U.S. In the clinical trials, taragarestrant (D-0502) demonstrated a favorable safety profile and promising anti-tumor activities.

In October 2021, we received the NMPA’s approval to conduct a registrational head-to-head Phase III clinical trial of taragarestrant (D-0502), with fulvestrant injection as the control. The NMPA exempted the requirement to conduct the Phase II clinical trial for taragarestrant (D-0502) as monotherapy, based on the finding that the Phase I clinical trial results as of the Data Cutoff Date, which was considered to have generated sufficient clinical data for the safety and efficacy evaluation of D-0502 monotherapy dosed at 400mg OD. With that, the NMPA approved our application to directly proceed with a registrational Phase III clinical trial designed to evaluate the safety and efficacy of D-0502 monotherapy at 400 mg QD without the need to conduct a Phase II clinical trial. The approval by the NMPA was not subject to any additional work/conditions that had to be completed prior to progression to the registrational Phase III clinical trial. The Phase III clinical trial of taragarestrant (D-0502) is currently ongoing, and we expect to complete it in the first half of 2028 and thereafter submit to the NMPA an NDA for taragarestrant (D-0502).

We developed taragarestrant (D-0502) internally and hold the global rights for its use, manufacture, and commercialization.

Mechanism of Action

After estrogen binds to the estrogen receptor (“ER”), ER will undergo a structural change and form a dimer (a chemical structure formed from two similar sub-units). The dimer can enter the cell nucleus and bind to the estrogen response element (“ERE”) in the promoter (a specific DNA sequence upstream of a gene for initiation of gene transcription) of target genes, thereby initiating gene transcription and promoting cell proliferation. SERDs can compete with estrogen in binding to ER. On the one hand, SERDs can prevent ER dimerization and thereby block the ER binding to the target genes. On the other hand, SERDs can bind to ER to form the SERD-ER complex, which can be recognized by the ubiquitin enzymes in the cell’s internal protein degradation system. The ubiquitin enzymes will then accelerate ER degradation and reduce the intracellular ER concentration. Below is a diagram illustrating the MOA of D-0502.



BUSINESS

Market Opportunity and Competitive Landscape

The efficacy of SERD drugs as monotherapy is generally low (with PFS lower than six months), and SERD drugs are therefore usually used in combination therapies. Globally, there were four approved oral SERD drugs (including one in China) and one approved non-oral SERD drug (approved in China), as well as five SERD drug candidates under clinical development in the Phase III stage or beyond, as of the Latest Practicable Date. For more details, please refer to “Industry Overview — Overview Oncology Drug Market — Selective Estrogen Receptor Degraders (“SERDs”).”

Competitive Advantages

Clinical Leadership

Taragarestrant (D-0502) is the first oral SERD developed by a Chinese company that has entered clinical development in the U.S. In China, there is currently no approved oral SERD drug. We are currently conducting a registrational Phase III clinical trial of taragarestrant (D-0502), which we expect to complete in 2027.

Promising Anti-tumor Efficacy

Taragarestrant (D-0502) was discovered via high throughput screening of active molecules in MCF7 cells (a human breast cancer cell line). We established three different animal models of breast cancer to conduct a comprehensive evaluation of taragarestrant (D-0502) before its clinical development. In these animal models, we validated the preliminary efficacy of taragarestrant (D-0502) and its potential synergy with CDK4/6 inhibitors.

Convenience of use

Taragarestrant (D-0502) is orally administered. As of the Latest Practicable Date, only one SERD drug was approved in China, and it must be administered by injection. The oral administration of taragarestrant (D-0502) is expected to improve the acceptance by physicians and patients, as well as patient compliance.

Summary of Clinical Trials

The following sets forth an overview of the key clinical trials of taragarestrant (D-0502).

Phase	Study design	Sites	Subjects	Status	Subject enrollment
I . . .	Assess the safety and tolerability, identify the maximum tolerated dose and/or RP2D, evaluate the PK properties and evaluate preliminary anti-tumor activities of taragarestrant (D-0502) single agent and taragarestrant (D-0502) in combination with standard dose of palbociclib	China, U.S.	Women with advanced or metastatic ER+/HER2- breast cancer	Completed	197 (Actual)
III . .	Compare the efficacy and safety of taragarestrant (D-0502) with fulvestrant	China	Patients with ER+/HER2- locally advanced or metastatic breast cancer	Ongoing	640 (Expected)
Ib/II .	Evaluate the safety, tolerability, DLTs, and preliminary antitumor activity of JSKN016 in combination with D-0502	China	Patients with hormone receptor-positive (“HR+”) /HER2- locally advanced or metastatic breast cancer	Ongoing	60 (Expected)

BUSINESS

Clinical development of taragarestrant (D-0502) in China and the U.S.:

A Phase I clinical trial of taragarestrant (D-0502) single agent and taragarestrant (D-0502) in combination with palbociclib in women with advanced or metastatic ER+/HER2- breast cancer in China and the U.S. sponsored by us

Overview. This was an open-label, Phase I MRCT of taragarestrant (D-0502) single agent and taragarestrant (D-0502) in combination with standard dose of palbociclib to assess the safety and tolerability, identify the maximum tolerated dose (“MTD”), and/or recommended Phase II dose (“RP2D”), evaluate the PK properties and evaluate preliminary anti-tumor activities in women with advanced or metastatic ER+/HER2- breast cancer. The primary objective was to characterize the safety and tolerability of taragarestrant (D-0502) and taragarestrant (D-0502) in combination with palbociclib, to identify an MTD and/or RP2D. The secondary objectives were to evaluate the PK properties and the preliminary anti-tumor activities.

Trial design. The trial had 3 parts: Dose Escalation (Phase Ia), Dose Expansion and Combination (Phase Ib), and Evaluation of twice a day (“BID”) dosing schedule (Phase Ic).

The Phase Ia part enrolled 16 patients. Patients received taragarestrant (D-0502) orally once daily in 28-day cycles and were evaluated using conventional 3+3 dose-escalation to identify the MTD of taragarestrant (D-0502) as a single agent. Up to 4 sequential cohorts were evaluated: Cohort 1 (50 mg QD), Cohort 2 (100 mg QD), Cohort 3 (200 mg QD), and Cohort 4 (400 mg QD). The treatment period in Phase Ia part lasted around three years.

The Phase Ib part was divided into 2 stages, with 20 patients enrolled in Stage 1 and 118 patients enrolled in Stage 2. In Stage 1, taragarestrant (D-0502) was evaluated with palbociclib at a dose below the MTD first before escalating to the MTD. In China, 4 cohorts were evaluated: 1C (200 mg taragarestrant (D-0502)), 2C (400 mg taragarestrant (D-0502)), 3C (200 mg taragarestrant (D-0502) + 125 mg palbociclib), and 4C (400 mg taragarestrant (D-0502) + 125 mg palbociclib). In the U.S., 2 cohorts were evaluated: Cohort 1U (200 mg taragarestrant (D-0502) + 125 mg palbociclib) and Cohort 2U (400 mg taragarestrant (D-0502) + 125 mg palbociclib). Stage 2 further evaluated the MTD for both single agent and combination of taragarestrant (D-0502) with palbociclib. Two cohorts were evaluated in Stage 2 in China and the U.S.: Cohort 1 (taragarestrant (D-0502) single agent) and Cohort 2 (taragarestrant (D-0502) plus palbociclib). Cohorts 1 and 2 were enrolled by randomization in a 1:1 ratio. The treatment period in Phase Ib part lasted around two years.

The Phase Ic part evaluated the BID dosing schedule of taragarestrant (D-0502). It involved two cohorts: the single agent cohort (with 13 patients enrolled) and the combination cohort (with 30 patients enrolled). In the single agent cohort, each patient received a single dose of taragarestrant (D-0502) on Cycle 1 Day 1, then taragarestrant (D-0502) BID (approximately 12±1 hours apart) from Cycle 1 Day 2 to Day 28. All subsequent cycles had taragarestrant (D-0502) BID dosing every day. Each 28-day period was considered 1 treatment cycle. In the combination cohort, each patient had 2 treatment periods. In the first PK assessment period (Period A, 14 days), patients received an oral dose of palbociclib (125 mg capsule) QD from Day 1 to Day 7. In the second continuous dosing period (Period B), each patient took both taragarestrant (D-0502) and palbociclib with food or within 1 hour after breakfast and taragarestrant (D-0502) in the evening in a 4-week cycle. The treatment period in Phase Ic part lasted around three years.

The primary endpoints of Phase Ia, Ib and Ic parts included AEs, DLT and MTD. The secondary endpoints included PK characteristics, ORR, CBR, disease control rate (“DCR”), PFS, and duration of response (“DOR”). Patients continued to receive treatment until disease progression, intolerable toxicity, withdrawal of informed consent or termination for other reasons. Patients were subject to a follow-up period of about 30 days after end of treatment.

Key inclusion criteria included: (i) female patients age >18 years old with menopausal status and histologically proven, ER+/HER2-, locally advanced, inoperable, and/or metastatic breast cancer; (ii) having received ≤2 lines of prior chemotherapy for metastatic disease (≤1 line of prior

BUSINESS

chemotherapy for Phase Ib patients) and had radiological or objective evidence of disease progression on or after the last systemic therapy (if applicable) before starting current study treatment; (iii) having had measurable disease according to RECIST v1.1 and ECOG score of 0 or 1. Key exclusion criteria included: (i) patients with prior anticancer therapy <14 days before the first dose of study treatment or any investigational drug treatment <28 days or 4 half-lives (whichever was shorter) before the first dose of study treatment; (ii) unstable or progressive central nervous system metastases; (iii) unresolved toxicities from previous anticancer therapy.

Trial status. We initiated the Phase I clinical trial (Ia and Ib parts in China and the U.S.) in May 2018 and completed the trial in January 2024. The prolonged period of the Phase I clinical trial was due to its complex trial design and the addition of Ic part while the trial was ongoing. Phase Ia and Ib parts were completed in July 2021, evidenced by the safety review committee’s conclusion that all primary endpoints of Phase Ia and Ib had been reached and recommendation of proceeding to the advanced phase of clinical trial RP2D at 400mg QD. We voluntarily (without any request or recommendation from the NMPA) added Phase Ic part in July 2020, enrolled the first patient in August 2020 and completed it in October 2023, evidenced by the reach of all trial endpoints. Thereafter, in January 2024, the clinical study report for entire Phase I clinical trial (including Phase Ia, Ib and Ic) was finalized, which marked the completion of the entire Phase I clinical trial. It is in line with the industry norm for a Phase I trial to have an extended timeframe, especially when the trial design includes different treatment parts with varying dosing schedules that assess both monotherapy and combination therapies in multiple regions, as confirmed by Frost & Sullivan.

Safety data. The MTD was not reached and RP2D was determined to be 400 mg for taragarestrant (D-0502). Taragarestrant (D-0502) was generally well tolerated. The most commonly reported TEAEs were nausea, diarrhoea, and vomiting. In Phase Ia, Phase Ib Stage 2 Cohort 1, and Phase Ic single agent cohorts, TEAEs were mainly Grade 1 or 2. The incidences of Grade 3 or above TEAEs were 55.0%, 58.6% and 46.7% in Phase Ib Stage 1, Phase Ib Stage 2 and Phase Ic combination cohort treatment cohort, respectively. No patients in Phase Ia and Phase Ic single agent cohort experienced SAEs. In the other phases and cohorts, the incidence of SAEs was below 20%, and most SAEs were not treatment related.

The recorded incidences of AEs are summarized below.

	TEAE	TAE	Grade 3 or above TAE	TEAE leading to study discontinuation
Phase Ia	87.5%	62.5%	12.5%	0.0%
Phase Ib Stage 1	100.0%	90.0%	40.0%	0.0%
Phase Ib Stage 2 Cohort 1 . .	96.7%	95.0%	31.7%	6.7%
Phase Ib Stage 2 Cohort 2 . .	100.0%	93.1%	36.2%	6.9%
Phase Ic single agent cohorts	100.0%	84.6%	15.4%	0.0%
Phase Ic combination cohorts	100.0%	90.0%	33.3%	12.5%

Clinical development of taragarestrant (D-0502) in China only:

A Phase III clinical trial to compare the efficacy and safety of taragarestrant (D-0502) with fulvestrant in patients with previously treated ER+/HER2- locally advanced or metastatic breast cancer in China sponsored by us

Overview. This is a randomized, parallel-controlled, open-label, multicenter registrational Phase III clinical trial to assess the efficacy and safety of taragarestrant (D-0502) in the treatment of subjects with ER+/HER2- locally advanced or metastatic breast cancer, with fulvestrant injection as a control drug. The primary objective is to compare the efficacy of taragarestrant (D-0502) with

BUSINESS

fulvestrant in treating ER+/HER2- locally advanced or metastatic breast cancer. The secondary objective is to evaluate the safety and population PK of taragarestrant (D-0502) in the treatment of ER-positive, HER2-negative locally advanced or metastatic breast cancer.

Trial design. The trial expects to enroll 640 patients, to be randomized in a 1:1 ratio into two groups. The experimental group will be orally administered with taragarestrant (D-0502) tablet at 200 mg QD in the first two weeks and at 400 mg QD thereafter. The control group will receive intramuscular injection of fulvestrant 500 mg QD on Day 1 and Day 15 of the first 28-day treatment cycle and on Day 1 only in the next 28-day treatment cycles. Patients will continue to receive treatment until disease progression, intolerable toxicity, withdrawal of informed consent or termination for other reasons. Patients will be subject to a follow-up period of about 30 days after end of treatment. The primary endpoint was the PFS assessed by Independent Review Committee (“IRC”). The secondary endpoints included the PFS assessed by the investigator, ORR, CBR, DCR, DOR and OS.

Key inclusion criteria included: (i) female subjects aged between 18 and 75 years (inclusive); (ii) pathologically confirmed with ER+/HER2- breast cancer; (iii) subjects with locally advanced (unresectable) or metastatic breast cancer who have disease recurrence during or after adjuvant endocrine therapy, or whose disease has progressed after 1-2 lines of systemic endocrine therapy. Key exclusion criteria included: (i) subjects with unstable or symptomatic or progressive central nervous system metastases; (ii) subjects with locally advanced or metastatic breast cancer who have previously received more than 2 prior systemic chemotherapy; (iii) subjects who are unsuitable for endocrine therapy judged by the investigator, including uncontrolled pleural effusion, ascites or pericardial effusion.

Trial status. After an end-of-Phase I communication meeting in October 2021, the CDE granted the approval to conduct a registrational Phase III clinical trial of taragarestrant (D-0502). The CDE confirmed that we did not need to wait until the completion of Ic part of the Phase I clinical trial before progressing to the Phase III clinical trial for D-0502 as monotherapy, based on the fact that the endpoints under Ia and Ib parts of the Phase I clinical trial were met. We initiated the Phase III clinical trial in September 2022 and expect to complete the trial in the first half of 2028.

A Phase Ib/II clinical trial to evaluate the safety, tolerability, DLTs, and preliminary antitumor activity of JSKN016 in combination with D-0502 in patients with HR+/HER2- locally advanced or metastatic breast cancer in China sponsored by us

Overview. This is a multicenter, open-label, Phase Ib/II randomized study designed to evaluate the safety, tolerability, DLTs, and preliminary antitumor activity of JSKN016 in combination with D-0502 in patients with locally advanced or metastatic HR+/HER2- breast cancer who have previously progressed on CDK4/6 inhibitor-based endocrine therapy. The primary objective is to evaluate the safety, tolerability, DLTs, and preliminary antitumor activity of JSKN016 in combination with D-0502 in patients with locally advanced or metastatic HR+/HER2- breast cancer. The secondary objective is to evaluate the overall safety and tolerability of JSKN016 in combination with D-0502, PK profile of JSKN016 and D-0502, and immunogenicity of JSKN016.

Trial design. Approximately 60 patients will be randomized in a 1:1 ratio to receive JSKN016 administered intravenously at 4 mg/kg every 2 weeks or every 3 weeks, in combination with daily oral D-0502 at 200 mg. Each dosing cohort will include a safety lead-in phase to assess DLTs prior to cohort expansion. Tumor response will be assessed according to RECIST v1.1. Patients will continue to receive treatment until disease progression, intolerable toxicity, withdrawal of informed consent, death or termination for other reasons assessed by the investigator. Patients will be subject to a follow-up period of about 30 days after end of treatment. Primary endpoints include DLTs, ORR, safety and tolerability. Secondary endpoints include DCR, DOR, CBR, PFS, OS, PK profile and anti-drug antibody.

BUSINESS

Key inclusion criteria include: (i) female subjects aged 18 or above; (ii) histologically or cytologically confirmed locally advanced or metastatic HR+/HER2- breast cancer (HR+ defined as ER and/or PR $\geq 1\%$ in nuclear staining by immunohistochemistry); (iii) prior progression on CDK4/6 inhibitor plus endocrine therapy. Key exclusion criteria include: (i) active or untreated metastases in the central nervous system; (ii) prior treatment with ADCs containing topoisomerase I inhibitor payloads; (iii) active interstitial lung disease or pneumonitis.

Trial status. We initiated the Phase II clinical trial in March 2026 and expect to complete it in 2028.

Clinical Development Plan

We expect to complete the registrational Phase III clinical trial of taragarestrant (D-0502) in China in the first half of 2028 and thereafter submit to the NMPA an NDA for taragarestrant (D-0502) in the first half of 2028. We expect to complete the Phase II clinical trial of taragarestrant (D-0502) in combination with JSKN016 in 2028. Also, we expect to initiate a Phase III clinical trial of taragarestrant (D-0502) in combination with JSKN016 in 2028.

Material Communications with Competent Authorities

In February 2018, the FDA granted the IND approval to conduct a Phase I clinical trial of taragarestrant (D-0502). In July 2018, the NMPA granted the IND approval to conduct Phase I clinical trials of taragarestrant (D-0502) in 10 mg and 50 mg tablets.

The Phase I clinical trial of taragarestrant (D-0502) in China and the U.S. was completed in January 2024 (marked by finalization of the clinical study report). The initiation and completion time of different parts of the trial are summarized below.

	Initiation (marked by enrollment of first subject)	Completion (marked by reaching all trial endpoints)
Phase Ia	May 2018	July 2021
Phase Ib	July 2019	July 2021
Phase Ic	August 2020	October 2023

The trial design of Phase Ia and Phase Ib parts were included in the IND application package for the purpose of securing IND approval of D-0502, which was received in July 2018. The Phase Ic part was subsequently included in the overall Phase I clinical trial in July 2020. Accordingly, the clinical results of Phase Ic part is not required for the progression to the Phase III trial, which is designed to evaluate the efficacy and safety of D-0502 as monotherapy dosed at 400 mg QD. We included the Phase Ic part in the EOP1 meeting package submitted to the CDE in August 2021. The CDE raised no objection to the amended Phase I trial protocol containing the Phase Ic part.

As of July 19, 2021 (the “Data Cutoff Date”), the subjects in the Phase I clinical trial that received D-0502 monotherapy QD dosing schedule (the “Mono Subjects”), as required by the Phase I trial protocol, had all completed their treatment and follow-up assessments for the purpose of reaching primary endpoints. As of the Data Cutoff Date, the Phase Ic part was still ongoing and patient enrolment was in progress; as such, no summary of the Phase Ic clinical results was generated at the time. Phase Ic part was subsequently completed in October 2023. Based on the Phase I clinical trial results (without the Phase Ic results) as of the Data Cutoff Date (the “Phase I Clinical Trial Results”), the safety review committee (i) concluded that we had completed the safety and efficacy evaluations of the Mono Subjects, with all the primary endpoints met and (ii) recommended proceeding to the advanced phase of clinical trial to evaluate the safety and efficacy of D-0502 as monotherapy at 400 mg QD. Subsequently, we requested an EOP1 meeting with the CDE, the purpose of which was to (i) seek CDE’s approval to directly proceed to a Phase III clinical trial of D-0502 monotherapy based on the Phase I Clinical Trial Results and (ii) agree with the CDE on the clinical trial design of the Phase III clinical trial.

BUSINESS

In the EOP1 meeting package submitted in August 2021, we presented to the CDE (a) synopsis of the Phase I Clinical Trial Results and (b) the status of the Phase I clinical trial of D-0502, including the fact that Phase Ic is still ongoing. Based on these data and having considered the on-going status of the Phase Ic, the CDE agreed with us to proceed directly with a registrational Phase III clinical trial of D-0502 monotherapy and approved the proposed design of the Phase III clinical trial (with the dosing schedule of 200 mg QD in the first two weeks and at 400 mg QD thereafter). As confirmed by the Frost & Sullivan, it is not uncommon in the industry for a study drug to proceed from a Phase I trial directly to a Phase III trial.

Accordingly, in October 2021, the CDE in the EOP1 Meeting agreed with our assessment that the relevant patient size and the Phase I Clinical Trial Results were sufficient to adequately support the evaluation of the safety and efficacy of D-0502 monotherapy at a dose of 400 mg QD in a registrational Phase III trial, such that we were considered to have completed a conventional Phase I clinical trial of D-0502 as monotherapy. In addition, the CDE in the same EOP1 Meeting agreed with us to directly proceed with a registrational Phase III clinical trial of D-0502 as monotherapy, and did not impose any additional work/conditions that had to be completed prior to the completion of the Phase Ic clinical trial and progression to the registrational Phase III clinical trial.

In January 2024, the entire Phase I clinical trial, including the Phase Ic part, was completed — all patients had completed treatment and follow-up period, all primary endpoints had been reached, and the clinical study report was finalized. In September 2025, we submitted to the NMPA an IND application to conduct a Phase II clinical trial for D-0502 in combination with JSKN016, an ADC drug candidate (the “Combo IND Application”), which included the synopsis of the results of the entire Phase I clinical trial of D-0502, including the Phase Ic part. Based on such results of D-0502, in December 2025, the NMPA had no objection for us to proceed with Phase II clinical trial by granting the IND application to conduct a Phase II clinical trial of D-0502 in combination with JSKN016 in patients advanced or metastatic ER+/HER2- breast cancer (the “D-0502 Phase II Combo Trial”).

We have not received any additional communication with the NMPA/CDE regarding the Phase I clinical trial after the approval of the Combo IND Application.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TARAGARESTRANT (D-0502) SUCCESSFULLY.

Darbinurad (D-0120): An Oral Selective URAT1 Inhibitor with First-in-class Potential for the Treatment of Gout

Overview

Darbinurad (D-0120) is an oral selective URAT1 inhibitor under clinical development for the treatment of gout. Darbinurad (D-0120) functions by blocking the reabsorption of uric acid in the kidney via URAT1, thereby reducing the serum uric acid concentrations.

Gout occurs as a result of the high levels of uric acid in the blood (hyperuricemia) and its subsequent deposition in the form of monosodium urate in the joints causing inflammation. There is a large patient base for gout and hyperuricemia globally and in China. The prevalence of gout among adults in China is approximately 0.86%-2.20%.

Darbinurad (D-0120) is the first URAT1 inhibitor developed by a Chinese company to enter clinical trials in the U.S. As a URAT1 inhibitor, darbinurad (D-0120) is anticipated to have a potent serum uric acid reducing effect, but with less toxicity and wider therapeutic window. In the human URAT1-expressed CHO cell model, darbinurad (D-0120)’s inhibitory activity toward URAT1 was shown to be 150-fold more potent than lesinurad and slightly more potent than verinurad.

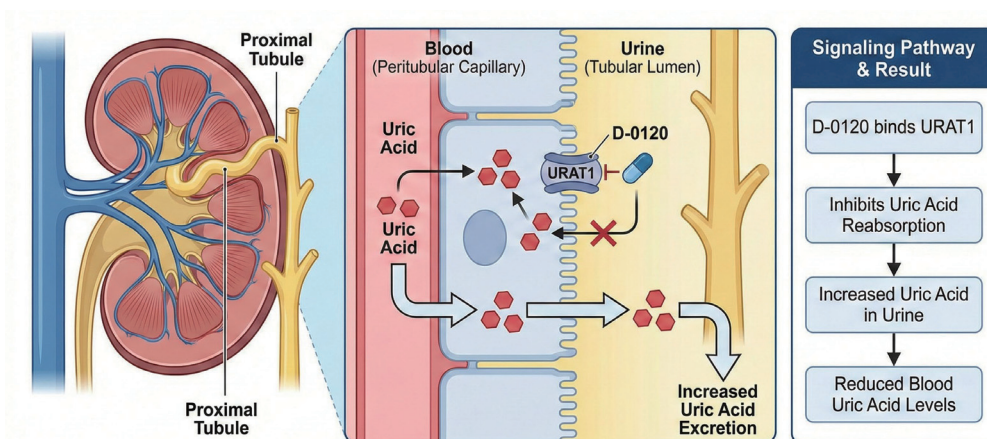
BUSINESS

In a completed Phase IIb clinical trial, darbinurad (D-0120) demonstrated a favorable safety profile and significant efficacy in lowering serum uric acid levels in gout patients, regardless of the presence or absence of gout. Meanwhile, we are exploring the potential of darbinurad (D-0120) in combination with allopurinol as a treatment for gout. A Phase II clinical trial for that purpose was completed in March 2026.

We developed darbinurad (D-0120) internally and hold the global rights for its development, manufacture and commercialization.

Mechanism of Action

Uric acid is a product of purine metabolism. Elevated levels of uric acid can lead to hyperuricemia. Renal uric acid reabsorption transporters, including URAT1, are involved in the uric acid metabolism in the human body. URAT1 is located on the luminal membrane of the proximal convoluted tubule in the kidney. It is responsible for reabsorbing uric acid from the tubular fluid (urine) into the proximal tubular cells. URAT1 inhibitors can inhibit urate reabsorption, thereby promoting uric acid excretion from the body and lowering the blood uric acid level. Below is a diagram illustrating the MOA of darbinurad (D-0120).



Market Opportunity and Competitive Landscape

As of the Latest Practicable Date, globally there were three approved URAT1 inhibitor drugs and three URAT1 inhibitor drug candidates under clinical development in both China and the U.S. For more details, please refer to “Industry Overview — Overview of Metabolic Disease Drug Market — Urate Transporter 1 (“URAT1”) Inhibitors.”

Competitive Advantages

Potent Serum Uric Acid Reducing Effect

In a completed Phase IIb clinical trial, darbinurad (D-0120) demonstrated significant efficacy in lowering serum uric acid levels in gout patients, regardless of the presence or absence of gout. Besides, darbinurad (D-0120) exhibited a rapid onset of action after oral administration. In a completed Phase Ib/IIa clinical trial, darbinurad (D-0120) was shown to significantly reduce blood uric acid levels within 24 hours in both healthy subjects and gout patients. Notably, for the arm that received darbinurad (D-0120) at 1 mg BID for 14 consecutive days followed by 2 mg BID for 28 consecutive days, the proportion of hyperuricemia patients achieving the target serum uric acid level (below 360 $\mu\text{mol/L}$) reached 80%.

BUSINESS

Favorable Safety Profile

Darbinurad (D-0120) demonstrated favorable safety and tolerability in both healthy volunteers and gout patients in the completed Phase Ib/IIa and Phase IIb clinical trials. No SAE or death was recorded. The majority of TEAEs were Grade 1 (mild) in severity.

Summary of Clinical Trials

The following sets forth an overview of the key clinical trials of darbinurad (D-0120).

Phase	Study design	Sites	Subjects	Status	Subject enrollment
I . . .	Evaluate the safety, tolerability, PK, PD and food effect on PD of darbinurad (D-0120) under SAD	U.S.	Healthy subjects	Completed	39 (Actual)
I . . .	Evaluate the safety, tolerability, PK, and PD of darbinurad (D-0120) under MAD	U.S.	Healthy subjects	Completed	40 (Actual)
Ib/IIa.	Evaluate the safety, tolerability, PK and PD characteristics of darbinurad (D-0120) after multiple doses	China	Healthy subjects and gout patients	Completed	52 (Actual)
IIb . .	Evaluate the efficacy and safety of darbinurad (D-0120) tablets	China	Primary gout patients	Completed	121 (Actual)
I . . .	Evaluate the PK interactions between darbinurad (D-0120) and allopurinol	U.S.	Healthy subjects	Completed	20 (Actual)
II . . .	Evaluate efficacy and safety of darbinurad (D-0120) in combination with allopurinol	U.S.	Gout patients	Completed	80 (Actual)

A Phase I Clinical Trial to Evaluate the Safety, Tolerability, PK, and PD of darbinurad (D-0120) in Healthy Volunteers in the U.S. sponsored by us

Overview. This is a Phase I, randomized, double-blind, placebo-controlled, single-dose, and dose-escalation study to evaluate the safety, tolerability, PK, and PD of darbinurad (D-0120); including an open-label cohort to determine the effect of food on the PD of darbinurad (D-0120) tablet in healthy volunteers in the U.S. The primary objective was to evaluate the safety and tolerability of darbinurad (D-0120) in single ascending doses in healthy volunteers. The secondary objectives were to characterize the PK of darbinurad (D-0120) and possibly assess any PD effects and to determine the effect of food on the single dose PK of 10 mg darbinurad (D-0120) tablets in healthy volunteers.

Trial design. Overall, 39 subjects entered and completed the trial, with 8 subjects in each of Cohorts 1, 2, 4, and 5, and 7 subjects in Cohort 3. Single oral doses were administered in each of Cohorts 1 to 4, and 2 single doses separated by 3 days were administered in Cohort 5. In Cohorts 1, 2 and 4, 8 subjects were randomized to receive a single oral dose of darbinurad (D-0120) (6 subjects per cohort) or placebo (2 subjects per cohort). In Cohort 3, 7 subjects were randomized to receive a single oral dose of darbinurad (D-0120) (5 subjects) or placebo (2 subjects). In Cohorts 1 to 4, the subjects receiving darbinurad (D-0120) were studied at respective daily doses of 5 mg, 10 mg, 20 mg, and 40 mg in the fasted state from Day 1 to Day 3. All subjects in Cohorts 1 to 4 returned for follow-up visits on Day 7 and Day 14. In Cohort 5, 8 subjects received 2 doses of 10 mg darbinurad (D-0120) in an open-label manner, once in the fasted state (Day 1) and once in the fed state (Day 4). All subjects in Cohort 5 returned for a follow-up visit on Day 11, and an

BUSINESS

additional safety assessment was performed on Day 18 via telephone call. The primary endpoints included AEs, clinical laboratory evaluations, vital signs, 12-lead ECG, and physical examinations. The secondary endpoints included PK and PD characteristics.

Key inclusion criteria included: (i) healthy male or female subjects aged between 18 and 60 years (inclusive); (ii) BMI between 18.0 and 30.0 kg/m² (inclusive); (iii) body weight of 50 kg or higher; (iv) serum uric acid level ≥ 4.5 mg/dL. Key exclusion criteria included: (i) any history or clinical manifestations of significant metabolic, hematological, pulmonary, cardiovascular, gastrointestinal, neurologic, hepatic, renal, urological, or psychiatric disorders; (ii) any history or suspicion of kidney stones; (iii) positive for HIV, Hepatitis B, and/or Hepatitis C.

Trial status. We initiated the trial in September 2017 and completed the trial in February 2018. All trial endpoints were reached in February 2018, as marked by last observation of subjects.

Safety data. Darbinurad (D-0120) was safe and well-tolerated when administered as single oral doses between 5 mg and 40 mg in the fasted state, and as a single oral dose of 10 mg in the fed state. There were no deaths, SAEs, or Grade 3 or above TEAEs/TRAEs reported during the trial. No subjects discontinued from the trial due to a TEAE. Overall, 11 (28.2%) of the 39 subjects reported 25 TEAEs. The incidence of TEAEs was similar between subjects receiving placebo and subjects receiving darbinurad (D-0120) in the fasted state reported a total of 9 TEAEs. The majority of all TEAEs were mild. Overall, 18 (72.0%) TEAEs in 10 subjects were considered to be not related or unlikely related, 6 TEAEs in 2 subjects were considered to have a possible relationship, and 1 TEAE in 1 subject was considered to have a probable relationship.

A Phase I clinical trial to evaluate the safety and tolerability of darbinurad (D-0120) in multiple ascending doses in healthy volunteers in the U.S. sponsored by us

Overview. This is a Phase I, randomized, double-blind, placebo-controlled, multiple-dose, and dose-escalation trial to evaluate the safety, tolerability, PK, and PD of darbinurad (D-0120) in healthy volunteers. The primary objective was to evaluate the safety and tolerability of darbinurad (D-0120) in multiple ascending doses ("MAD") in healthy volunteers. The secondary objectives included characterizing the PK of darbinurad (D-0120) and possibly assessing any PD effects, and determining the effect of drug-drug interaction ("DDI") of febuxostat and darbinurad (D-0120) in healthy volunteers.

Trial design. The trial enrolled 40 healthy volunteers. 32 of them were dosed with darbinurad (D-0120) within 4 different single agent cohorts for a period of 7 days (Day 1 to Day 7) at the daily dosage level of 2.5 mg, 5 mg, 10 mg and 20 mg, respectively. Each cohort had 8 subjects randomized at 3:1 ratio for darbinurad (D-0120):placebo. The safety assessment was performed on Day 8. These subjects were followed-up on telephone call on Day 14. A fifth cohort of 8 healthy volunteers were enrolled and dosed with darbinurad (D-0120) in combination with febuxostat over a period of 9 days. The subjects received darbinurad (D-0120) at 5 mg once daily on Day 1, Day 3 to Day 9, as well as febuxostat at 40 mg once daily on Day 2 to Day 9. The safety assessment was performed on Day 10. Subjects were followed-up on telephone call on Day 16. The primary endpoints included TEAEs, SAEs, vital signs, 12-lead ECG, physical examination, and laboratory parameters. The secondary endpoints included PK and PD characteristics.

Key inclusion criteria included: (i) healthy male or female subjects aged between 18 and 60 years (inclusive); (ii) BMI between 18.0 and 30.0 kg/m²; (iii) body weight ≥ 50.0 kg for males and ≥ 45.0 kg for females. Key exclusion criteria included: (i) history of significant allergic reactions to any drug; (ii) any history or suspicion of kidney stones; (iii) positive for HIV, Hepatitis B, and/or Hepatitis C.

Trial status. We initiated the trial in September 2019 and completed the trial in November 2020. All trial endpoints were reached in April 2020, as marked by last observation of subjects.

BUSINESS

Safety data. Overall, the administration of multiple doses of darbinurad (D-0120) ranging from 2.5 to 20 mg or darbinurad (D-0120) 5 mg + febuxostat 40 mg was generally safe and well tolerated in healthy subjects. There were no deaths nor SAEs during this trial. A total of 17 TEAEs were reported by 7 (21.9%) subjects who received multiple doses of darbinurad (D-0120). The majority of TEAEs reported were Grade 1 in severity and all were transient during the study. The majority of TEAEs were resolved by the end of the study spontaneously.

A Phase Ib/IIa trial to evaluate the safety, tolerability, PK and pharmacodynamic (“PD”) characteristics of darbinurad (D-0120) after multiple doses in healthy volunteers and gout patients in China sponsored by us

Overview. This is a randomized, double-blind, placebo-controlled, multiple ascending dose Phase Ib/IIa clinical trial to evaluate the safety, tolerability, PK and PD characteristics of darbinurad (D-0120) after multiple doses in healthy volunteers and gout patients. The primary objective was to evaluate the safety and tolerability of multiple escalating doses of darbinurad (D-0120) tablets in healthy subjects and gout patients. The secondary objective was to evaluate the PK and PD of darbinurad (D-0120) tablets in gout patients. The trial consisted of two parts: the Phase Ib part and the Phase IIa part.

Trial design. The Phase Ib part enrolled 16 health subjects, randomized into two arms. Within each arm of 8 subjects, 6 received darbinurad (D-0120) and 2 received placebo. Subjects in the two arms received an oral administration of darbinurad (D-0120) or placebo at 2.5 mg QD and 5 mg QD, respectively, for 7 consecutive days. The follow-up period was 7 days after the oral administration.

The Phase IIa part enrolled 36 gout patients, randomized into three arms. Within each arm of 12 subjects, 10 received darbinurad (D-0120) and 2 received placebo. Subjects in the three arms received an oral administration of darbinurad (D-0120) or placebo at 2.5 mg QD for 28 consecutive days, 1 mg BID for 28 consecutive days, 1 mg BID for 14 consecutive days followed by 2 mg BID for 28 consecutive days, respectively. The follow-up period was 14 days after the oral administration.

The primary endpoint was AE. The secondary endpoint was PK profile.

Key inclusion criteria included: (i) Aged between 18 and 65 years (inclusive); (ii) BMI between 18.0 and 30.0 kg/m² (inclusive). Additional inclusion criteria for Phase Ib part: fasting serum uric acid (“sUA”) in the morning of screening period (fasted after 8 pm on the previous day) of healthy subjects meets the following requirement: 270 µmol/l (4.5 mg/dL) ≤ sUA <420 µmol/l (7 mg/dL). Additional inclusion criteria for Phase IIa part: patients with hyperuricemia must meet one of the following criteria: (i) having a history of gout and, during the screening period, have a fasting sUA level of ≥420 µmol/L (7 mg/dL) in the morning (fasting from 8 pm the previous day); and (ii) having a history of hyperuricemia, fasting sUA was ≥540 µmol/L (9 mg/dL) during the screening period (fasting from 8 pm the previous day), and deemed by the investigators to require uric acid-lowering treatment. Key exclusion criteria included: (i) history of significant metabolic, hematological, pulmonary, cardiovascular, gastrointestinal, nervous, hepatic, renal, urinary, gastrointestinal, immune, endocrine, psychiatric diseases, or clinical abnormalities that may pose excessive risks to the subjects or affect outcome or study interpretation at the discretion of the investigators; (ii) allergic constitution, or allergy to any drug used in the study or any ingredient of study drug; (iii) history of malignant tumors.

Trial status. We initiated the Phase Ib/IIa clinical trial in May 2020 and completed the trial in May 2022. All trial endpoints were reached in October 2021, as marked by last observation of subjects.

BUSINESS

Safety data. Darbinurad (D-0120) demonstrated good safety and tolerability in healthy volunteers and gout patients under the tested dosages. In the Phase Ib part, 5 (31.3%), 3 (18.8%) and 1 (6.3%) subjects experienced TEAEs, treatment related TEAEs and Grade 3 or above TEAEs, respectively. In the Phase IIa part, 28 (77.8%), 15 (41.7%) and 3 (8.3%) subjects experienced TEAEs, treatment related TEAEs and Grade 3 or above TEAEs, respectively. No TEAE leading to death occurred in the trial.

Efficacy and PK data. In all arms in the Phase Ib part and the Phase IIa part, an increase in the average total amount of urinary uric acid was observed, and the average urinary uric acid concentration increased with increasing total urine sample volume. The maximum urinary uric acid concentration was reached within the 24 hours. Also, darbinurad (D-0120) caused an increase in fractional excretion of uric acid ("FEUa") from baseline in both healthy volunteers and gout patients, with the maximum FEUa reached within 24 hours. Notably, in the Phase IIa part, for the arm that received darbinurad (D-0120) at 1 mg BID for 14 consecutive days followed by 2 mg BID for 28 consecutive days, the proportion of patients achieving the target serum uric acid level (below 360 µmol/L) reached 80%.

A Phase IIb clinical trial to evaluate the efficacy and safety of darbinurad (D-0120) tablets in patients with gout in China sponsored by us

Overview. This was a randomized, open-label, parallel-controlled, multicenter Phase IIb clinical trial in gout patients. The trial consisted of two parts.

The primary objective of Part A was to conduct a preliminary evaluation of the efficacy of different doses of darbinurad (D-0120) in lowering uric acid in patients with gout. The secondary objective of Part A was to conduct a preliminary evaluation of the safety of darbinurad (D-0120) in patients with gout and an evaluation of population PK of darbinurad (D-0120) in patients with gout.

The primary objective of Part B was to conduct a preliminary evaluation of the safety of darbinurad (D-0120) in patients with gout. The secondary objective of Part B was to conduct a preliminary evaluation of the efficacy of different doses of darbinurad (D-0120) in lowering uric acid in patients with gout and an evaluation of population PK of darbinurad (D-0120) in patients with gout.

Trial design. Part A enrolled 91 patients, who were randomized into D-0120 group 1, D-0120 group 2 or benzbromarone control group. D-0120 group 2 received darbinurad (D-0120) at 1 mg BID in weeks 1 and 2, and at 2 mg BID in weeks 3 to 12. D-0120 group 1 received darbinurad (D-0120) at 1 mg BID in weeks 1 to 12. The benzbromarone control group received benzbromarone at 50 mg QD in weeks 1 to 12. Benzbromarone, a uricosuric agent, served as positive control. Part B enrolled 30 patients (D-0120 group 3), who received darbinurad (D-0120) at 1 mg BID in weeks 1 and 2, at 2 mg BID in weeks 3 and 4, and at 3 mg BID in weeks 5 to 12. After completion of the 12-week treatment period, patients in both Part A and Part B had a 2-week follow-up period. Primary endpoint was the percentage of subjects with serum uric acid ≤ 360 µmol/L at week 12 of treatment. Secondary endpoints included: (i) the percentage of subjects with serum uric acid ≤ 360 µmol/L at weeks 4 and 8 of treatment; (ii) the changes in serum uric acid from baseline at weeks 4, 8 and 12 of treatment; and (iii) the change percentage in serum uric acid from baseline at weeks 4, 8 and 12 of treatment.

Key inclusion criteria included: (i) aged between 18 and 65 years; (ii) BMI between 18.0 and 32.0 kg/m²; (iii) meeting one of the two criteria, (1) a history of gout attacks and fasting sUA ≥ 480 µmol/L at the time of screening, and (2) asymptomatic hyperuricemia but with a previous diagnosis of hyperuricemia, and sUA ≥ 420 µmol/L for at least 3 months, with fasting sUA ≥ 540 µmol/L at screening and no other concurrent metabolic diseases; or fasting UA ≥ 480 µmol/L at screening, with concurrent essential hypertension, essential hyperlipidemia, or type 2 diabetes. Key exclusion criteria included: (i) prior intolerance to benzbromarone or contraindication to medication; (ii) secondary hyperuricemia caused by tumor, chronic kidney disease, blood disease or drugs.

BUSINESS

Trial status. We initiated the Phase IIb trial in September 2022 and completed the trial in November 2024. All trial endpoints were reached in May 2024, as marked by last observation of subjects.

Efficacy data. Darbinurad (D-0120) demonstrated significant efficacy in lowering serum uric acid levels in gout patients, regardless of the presence or absence of gout. The percentages of patients with serum uric acid ≤ 360 $\mu\text{mol/L}$ at week 12 of treatment were 30.0%, 53.6%, 70.4% and 55.2% in D-0120 group 1, D-0120 group 2, D-0120 group 3 and benzbromarone control group, respectively.

Safety data. Darbinurad (D-0120) demonstrated a safety profile comparable to benzbromarone and good tolerability in gout patients. Most reported treatment-related TEAEs were Grade 1 or 2. No deaths or treatment-related SAEs were reported.

Phase I clinical trial to evaluate the interactions between darbinurad (D-0120) and allopurinol in healthy adult subjects in the U.S. sponsored by us

Overview. This was a randomized, open-label, multiple-dose, Phase 1 clinical trial to evaluate the interactions between darbinurad (D-0120) and allopurinol in healthy adult subjects. The primary objective was to evaluate the potential PK interactions between darbinurad (D-0120) and allopurinol. The secondary objective was to assess the safety of darbinurad (D-0120) in single-agent and combination therapy with allopurinol in healthy subjects.

Trial design. A total of 20 subjects were enrolled in the trial and randomly assigned to 1 of 2 treatment sequences (Sequence A or B) in a 1:1 ratio. The following dosing schedule was applied to the subjects.

	Day 1	Days 2-8	Day 9
Sequence A	Darbinurad (D-0120) 2.5 mg single dose	Allopurinol 300 mg QD $\times$ 7 days	Darbinurad (D-0120) 2.5 mg + allopurinol 300 mg
Sequence B	Allopurinol 300 mg single dose	Darbinurad (D-0120) 2.5 mg BID $\times$ 7 days	Allopurinol 300 mg + darbinurad (D-0120) 2.5 mg BID

After completing treatment under Sequence A or B, subjects had a follow-up period until Day 16. The primary endpoints were main PK parameters including AUC_{0-t} , $\text{AUC}_{0-\infty}$ and C_{max} . The secondary endpoints included other PK parameters, AE, clinical laboratory test results, vital sign measurements, 12-lead ECG and physical examination findings.

Key inclusion criteria included: (i) Aged between 18 and 55 years (inclusive); (ii) BMI between 18.0 and 35.0 kg/m^2 (inclusive). Key exclusion criteria included: significant medical history or current comorbidly determined by the Investigator.

Trial status. We initiated the trial in November 2021 and completed the trial in January 2022. All trial endpoints were reached in January 2022, as marked by last observation of subjects.

Safety data. Darbinurad (D-0120) in combination with allopurinol 300 mg was safe and well tolerated by the healthy subjects. Overall, 9 (45.0%) and 4 (20.0%) subjects reported TEAEs and TEAEs possibly/probably related to study drug. All TEAEs were Grade 1 (mild) in severity. There were no moderate or severe TEAEs, serious TEAEs, deaths, or TEAEs that led to study discontinuation. All TEAEs were documented as recovered/resolved by the end of trial.

BUSINESS

Phase II clinical trial to evaluate efficacy and safety of darbinurad (D-0120) in combination with allopurinol in subjects with gout in the U.S. sponsored by us

Overview. This was a randomized, open-label, multiple-dose Phase II clinical trial to evaluate efficacy and safety of darbinurad (D-0120) administered in combination with allopurinol in gout patients with inadequate urate-lowering response to allopurinol single-agent therapy.

Trial design. The subjects were randomized in 1:1 ratio into two cohorts. Each of the cohorts consisted of 40 subjects to receive a 12-week treatment. Subjects in Cohort A received darbinurad (D-0120) 1 mg BID for 7 days followed by 2.5 mg BID until the end of week 12. Subjects in Cohort B received darbinurad (D-0120) 1 mg BID for 7 days, followed by 2.5 mg BID for 7 days, and then 5 mg BID until the end of week 12. Allopurinol was orally taken within 30 minutes after breakfast in combination with darbinurad (D-0120), and the dose of allopurinol should be the same as the dose the patient used before signing informed consent form. After completing the 12-week treatment period, subjects in Cohort A and Cohort B had a 2-week follow-up period. The primary endpoint was percentage of subjects with a sUA level < 6.0 mg/dL at week 12. The secondary endpoints included percentage of subjects with an sUA level < 6.0 mg/dL at week 4 and 8, change in sUA level, AE and PK.

Key inclusion criteria included: (i) aged between 18 and 75 years (inclusive); (ii) BMI between 18.0 and 40.0 kg/m² (inclusive); (iii) having reported at least 2 gout flares in the previous 12 months. Key exclusion criteria included: (i) history of significant allergic reactions to allopurinol, colchicine or excipients of D-0120; (ii) any clinically significant metabolic, hematological, pulmonary, cardiovascular, gastrointestinal, neurologic, hepatic, renal, urological, or psychiatric disorders; (iii) positive for HIV, Hepatitis B, and/or Hepatitis C.

Trial Status. We initiated the Phase II clinical trial in April 2023 and completed it in March 2026.

Clinical Development Plan

In China, we are currently in discussions with CDE regarding next steps for darbinurad (D-0120). We may either launch a Phase III clinical trial for darbinurad (D-0120) monotherapy, or submit an IND to initiate a Phase II clinical trial for a combination therapy of darbinurad (D-0120). In U.S., we are actively seeking strategic partners to support the continued overseas development of darbinurad (D-0120).

Material Communications with Competent Authorities

In July 2017, we received an IND approval from the FDA to conduct a Phase I clinical trial of darbinurad (D-0120) in single ascending doses. In March 2018, we received an IND approval from the CDE to conduct Phase I and Phase II clinical trials of darbinurad (D-0120).

In August 2019, we submitted to the FDA the protocol for a Phase I clinical trial of darbinurad (D-0120) in multiple ascending doses. We have not received any objection from the FDA regarding the protocol.

In October 2021, we submitted to the FDA the protocol for a Phase I clinical trial of darbinurad (D-0120) in combination with allopurinol in subjects with gout. We have not received any objection from the FDA regarding the protocol.

In December 2022, we submitted to the FDA the protocol for a Phase II clinical trial of darbinurad (D-0120) in combination with allopurinol in subjects with gout. We have not received any objection from the FDA regarding the protocol.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET DARBINURAD (D-0120) SUCCESSFULLY.

BUSINESS

Befotertinib (BPI-D0316): A Third-generation EGFR-TKI Approved for the Treatment of NSCLC

Overview

Befotertinib (BPI-D0316) is an orally administered, selective, third-generation EGFR-TKI. It was initially developed by us as a treatment of NSCLC.

In May 2023, befotertinib (BPI-D0316) received marketing approval from the NMPA for the second-line treatment of patients with locally advanced or metastatic NSCLC who have received EGFR-TKI therapy and have disease progression with positive EGFR T790M mutation. The approval was based on a Phase II clinical trial, where befotertinib (BPI-D0316) achieved a medium PFS of 16.6 and a medium OS of 31.5 months in patients. In October 2023, befotertinib (BPI-D0316) received another marketing approval from the NMPA, for first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. The approval was based on a Phase III clinical trial, where befotertinib (BPI-D0316) achieved a medium PFS of 22.1 months in patients. Befotertinib (BPI-D0316) was commercialized in China in June 2023.

In both first-line and second-line treatment settings, befotertinib (BPI-D0316) achieved record-breaking PFS compared with existing treatments under the same scenarios and has been incorporated into authoritative guidelines such as the CSCO guidelines. Also, befotertinib (BPI-D0316) was included in the NRDL in China in 2023. Currently, befotertinib (BPI-D0316) is under a Phase III clinical trial as a postoperative adjuvant therapy. The trial aims to evaluate the efficacy and safety of befotertinib (BPI-D0316) versus icotinib in patients with stage IB-IIIB (T3N2M0) NSCLC harboring EGFR-sensitive mutations.

Befotertinib (BPI-D0316) is currently under two ongoing clinical trials sponsored by Betta in China: (1) a Phase III clinical trial of befotertinib (BPI-D0316) as postoperative adjuvant therapy in stage IB-IIIB (T3N2M0) EGFR-mutant NSCLC; and (2) a Phase I clinical trial of befotertinib (BPI-D0316) in combination with MCLA-129 (a bispecific antibody that targets EGFR and c-MET) in advanced NSCLC patients with EGFR-sensitive mutations.

Mechanism of Action

EGFRs are small proteins that are found on the surface of all cells. EGFR binds proteins circulating in the blood called epidermal growth factors. The binding action between EGFR and epidermal growth factors stimulates the signal transduction in multiple pathways to promote growth of a cell in a strictly controlled manner. However, if EGFR is either abundantly over-expressed or the EGFR biological processes are constantly active, the cancer cell may grow excessively and out of control. Befotertinib (BPI-D0316) specifically binds to and inhibits EGFR mutants, including T790M, a secondarily acquired resistance mutation, which prevents EGFR-mediated signaling and leads to cell death in EGFR T790M-expressing tumor cells. Compared to some other EGFR inhibitors, befotertinib (BPI-D0316) may have therapeutic benefits in tumors with T790M-mediated drug resistance.

Licenses, Rights and Obligations

In December 2018, when we had received a NMPA IND approval to conduct a Phase II clinical trial of befotertinib (BPI-D0316) targeting NSCLC, we entered into agreement with Betta to grant Betta the exclusive rights to develop and commercialize the product in Chinese Mainland, Hong Kong and Taiwan (the “Betta Agreement”). Pursuant to the Betta Agreement, we are entitled to receive from Betta upfront payment and development milestone payment of RMB230 million. The development milestones include the granting of a Chinese patent for befotertinib (BPI-D0316), NMPA regulatory approval of befotertinib (BPI-D0316) for a second-line treatment of NSCLC, and NMPA regulatory approval of befotertinib (BPI-D0316) for a first-line treatment of NSCLC. We are also entitled to receive commercial milestone payments and royalty payments based on the annual net sales of befotertinib (BPI-D0316). For details, please refer to “— Major Collaboration Arrangements.”

BUSINESS

Garsorasib (D-1553): The Second KRAS G12C Inhibitor Drug Approved in China with Significant Anti-tumor Efficacy

Overview

Garsorasib (D-1553) is a selective KRAS G12C inhibitor initially developed by us. It works by irreversibly binding to the KRAS G12C-mutant protein, locking it in an inactive state, which can be used to treat KRAS G12C-mutant non-small cell lung cancer (“NSCLC”), colorectal cancer (“CRC”), and other cancers. Garsorasib (D-1553) is the first KRAS G12C inhibitor independently developed in China and entering the clinical trial stage. It has been investigated in multi-regional clinical trials (“MRCTs”) in many countries and regions including Chinese Mainland, the U.S., Australia, South Korea, and Taiwan.

In November 2024, the NMPA granted conditional marketing approval of garsorasib (D-1553) for the treatment of adult patients with advanced NSCLC harboring the KRAS G12C mutation, who have previously received at least one systemic therapy. The marketing approval was based on the results of a Phase II clinical trial in China, where garsorasib (D-1553) achieved an ORR of 52.0%, a DCR of 88.6%, a median PFS of 9.1 months and a median OS of 14.1 months. In November 2024, we transferred the marketing authorization holder of garsorasib (D-1553) as a second-line treatment of NSCLC to CTTQ in China. Garsorasib (D-1553) was commercialized in China in December 2024.

Prior to that, garsorasib (D-1553) was included in the BTD program by the NMPA in June 2022, being the first domestically developed KRAS G12C inhibitor that was granted BTD. In addition, garsorasib (D-1553) received BTD from the NMPA for two other indications in June 2024: (i) for the treatment of locally advanced or metastatic pancreatic ductal adenocarcinoma (“PDAC”) with KRAS G12C mutation, in patients who have failed first-line therapy; (ii) in combination with cetuximab injection, for the treatment of KRAS G12C-mutant, locally advanced or metastatic CRC that has progressed after second-line standard treatments (including oxaliplatin, irinotecan, 5-fluorouracil, and anti-VEGF monoclonal antibodies) and is not amenable to surgery.

Garsorasib (D-1553) is currently under four ongoing clinical trials in China: (1) a Phase Ib/II clinical trial of ifebemtinib in combination with garsorasib (D-1553) in patients with locally advanced or metastatic solid tumors with KRAS G12C mutation (including NSCLC) sponsored by InxMed; (2) a Phase Ib/II clinical trial of ifebemtinib in combination with garsorasib (D-1553) in patients with CRC sponsored by InxMed; (3) a Phase III clinical trial to compare PPFS of garsorasib (D-1553) with docetaxel injection in patients with locally advanced or metastatic NSCLC with KRAS G12C mutation sponsored by CTTQ; and (4) a Phase III clinical trial of ifebemtinib in combination with garsorasib (D-1553) versus standard therapy, as first-line treatment for non-squamous NSCLC with KRAS G12C mutation sponsored by InxMed. Garsorasib (D-1553) is commercialized only in China, for one indication: adult patients with advanced NSCLC harboring the KRAS G12C mutation, who have previously received at least one systemic therapy.

Mechanism of Action

The KRAS protein is responsible for transmitting extracellular signals to the cell nucleus and promotes cell survival, proliferation, and differentiation. Mutations in KRAS may render the protein persistently active, thereby stimulating the downstream pathways involved in cell proliferation, including the PI3K-AKT signaling pathway, the RAS-RAF-MEK-ERK signaling pathway, and the Ral-GEF signaling pathway. The stimulation of these pathways will drive continuous cell proliferation and tumor formation. KRAS inhibitors inhibit these signaling pathways by preventing KRAS activation, thereby suppressing cell proliferation.

BUSINESS

Summary of Clinical Trials

The following sets forth an overview of the key clinical trials of garsorasib (D-1553).

Phase	Study design	Sponsor	Sites	Subjects	Status	Subject enrollment
I/II . .	Evaluate the safety, tolerability, PK and efficacy of garsorasib (D-1553)	The Group	Multiple regions (Chinese Mainland, U.S., Australia, South Korea, and Taiwan)	Patients with KRAS G12C mutated locally advanced or metastatic solid tumors	Completed	180 (Actual)
I . . .	Evaluate the safety, tolerability, PK and efficacy of garsorasib (D-1553)	The Group	China	Patients with KRAS G12C mutated locally advanced or metastatic solid tumors	Completed	79 (Actual)
II . . .	Evaluate the safety, tolerability, PK and efficacy of garsorasib (D-1553)	The Group	China	Patients with KRAS G12C mutated locally advanced or metastatic solid tumors	Completed	123 (Actual)

A Phase I/II clinical trial to evaluate the safety, tolerability, PK and efficacy of garsorasib (D-1553) in patients with KRAS G12C mutated locally advanced or metastatic solid tumors in multiple regions (Chinese Mainland, U.S., Australia, South Korea, and Taiwan) sponsored by us

Overview. This is an open-label, international multicohort Phase I/II clinical trial to evaluate the safety, tolerability, PK and efficacy of garsorasib (D-1553) in patients with KRAS G12C mutated locally advanced or metastatic solid tumors. The trial was divided into Phase I and Phase II portions.

Phase I portion:

The primary objectives were to evaluate the safety and tolerability of garsorasib (D-1553) as a single agent and in combination with standard immunotherapy/chemotherapy or targeted therapy in subjects with advanced or metastatic solid tumors harboring the KRAS G12C mutation, to determine the MTD and RP2D, and to assess its PK properties and antitumor activity. The secondary objectives were to evaluate the PK and antitumor activity of garsorasib (D-1553) alone and in combination with immunotherapy/chemotherapy or targeted therapy in subjects with advanced or metastatic solid tumors with KRAS G12C mutation.

Phase I trial design. Phase I consisted of 2 parts: Phase Ia (dose escalation) and Phase Ib (dose combination).

The Phase Ia part enrolled 22 patients. Each patient received daily oral doses of garsorasib (D-1553) from Day 1 to Day 21 on an empty stomach in the 21-day treatment cycle. Phase Ia started to evaluate 4 sequential cohorts administered with once daily oral doses of garsorasib (D-1553): Cohort 1 (150 mg once daily), Cohort 2 (300 mg once daily), Cohort 3 (600 mg once daily) and Cohort 4 (1200 mg once daily). An additional 3 sequential cohorts administered with twice daily oral doses of garsorasib (D-1553) were also evaluated: Cohort 5 (400 mg twice daily; total 800 mg

BUSINESS

daily), Cohort 6 (600 mg twice daily; total 1200 mg daily) and Cohort 7 (800 mg twice daily; total 1600 mg daily). After the safety of Cohort 3 had been determined, the dose escalation of the twice daily administered cohorts (Cohorts 5 to 7) would be conducted in parallel to the once daily administered cohort 4.

The Phase Ib part enrolled 27 patients. There were four groups in Phase Ib for different tumor types and combinations. In Group 1, 17 NSCLC patients received garsorasib (D-1553) 600 mg QD or 600 mg BID in combination with pembrolizumab and platinum-based chemotherapy. In Group 2, 3 CRC patients received garsorasib (D-1553) 600 mg BID in combination with oxaliplatin based chemotherapy. In Group 3, 4 solid tumor patients received garsorasib (D-1553) 600 mg BID in combination with trametinib. In Group 4, 3 CRC patients received garsorasib (D-1553) 600 mg BID in combination with cetuximab. The patients in the four groups were subject to a 21-day or 28-day treatment cycle depending on the combination therapy.

The primary endpoints included AE and DLT. The secondary endpoints included PK profile, ORR, DCR, PFS and DOR.

Phase I trial status. We initiated the trial in December 2020 and completed the trial in November 2024. SRC confirmed 600 mg BID to be the RP2D of garsorasib (D-1553) monotherapy for KRAS G12C mutation solid tumors.

Phase I trial safety data. garsorasib (D-1553) monotherapy or in combination therapy demonstrated a manageable safety profile in advanced or metastatic solid tumor with KRAS G12C mutation. No patients in Phase 1a, Phase 1b Group 2, and Phase 1b Group 4 experienced DLTs. One of 17 patients (5.9%) had a DLT of Grade 2 diarrhea in Phase 1b Group 1, and 1 patient in Phase 1b Group 3 experienced a DLT of Grade 3 fatigue. Both DLTs were non-serious events. The MTD was not reached in the trial. Most patients experienced TEAEs and garsorasib (D-1553) related TEAEs. Grade 3 or above garsorasib (D-1553)-related TEAEs occurred in 18.2% of the patients in the Phase 1a part; there were no such TEAEs reported in Phase 1b Group 2 and Phase 1b Group 4.

Phase II portion:

The primary objective was to evaluate the anti-tumor effects of garsorasib (D-1553) alone and in combination with immunotherapy, chemotherapy, or targeted therapy in subjects with advanced or metastatic solid tumors harboring the KRAS G12C mutation. The secondary objectives of the Phase II clinical trial were to evaluate the safety, tolerability and PK of garsorasib (D-1553) in subjects with advanced or metastatic solid tumors harboring the KRAS G12C mutation.

Phase II trial design. The Phase II trial enrolled 131 patients in four arms. Arm 1 included 21 NSCLC patients treated with garsorasib (D-1553) single agent at 600 mg BID. Arm 2 included 62 non-NSCLC solid tumor patients treated with garsorasib (D-1553) single agent at 600 mg BID. Arm 3 included 6 CRC patients treated with garsorasib (D-1553) at 600 mg BID in combination with oxaliplatin based chemotherapy. Arm 4 included 42 CRC patients treated with garsorasib (D-1553) at 600 mg BID in combination with cetuximab. Each 21- or 28-day treatment cycle was considered a treatment cycle. The primary endpoint was ORR. Secondary endpoints included DCR, PFS, DOR, OS, AE and PK profile.

Phase II trial status. We initiated the Phase II clinical trial January 2022 and completed the trial in November 2024.

Phase II efficacy data. Promising efficacy of garsorasib (D-1553) monotherapy or in combination therapy were observed in advanced or metastatic solid tumor with KRAS G12C mutation. In advanced NSCLC patients, the ORR was 42.9%, the median DOR was 9.7 months (95% CI: 4.7, NA), the median PFS was 11.0 months (95% CI: 3.5, NA), and the median OS was 17.5 months (95% CI: 6.0, NA). In previously heavily treated metastatic CRC patients, the ORR was 45.2%, the median DOR was 8.2 months (95% CI: 4.2, NA), the median PFS was 7.5 months (95% CI: 5.5, 8.1), and the median OS was not reached (95% CI: 11.3, NA) with survival rate of 67.5% at 12 months.

BUSINESS

Phase II safety data. Single agent of garsorasib (D-1553) or in combination therapy were well tolerated and adverse events were generally manageable in the treatment of advanced or metastatic solid tumor with KRAS G12C mutation. Most garsorasib (D-1553) or combination-related TEAEs were of Grade 1/2 severity. There were 28.6% of the patients in Arm 1, 19.4% in Arm 2, 66.7% in Arm 3, and 14.3% in Arm 4 that experienced treatment-related TEAEs of Grade 3 or above severity, respectively.

A Phase II clinical trial to evaluate the safety, tolerability, PK and efficacy of garsorasib (D-1553) in patients with KRAS G12C mutated locally advanced or metastatic solid tumors in China sponsored by us

Overview. This is an open-label, single-arm, multicenter Phase II clinical trial to evaluate the safety and efficacy of garsorasib (D-1553) in patients with KRAS G12C mutated locally advanced or metastatic solid tumors. The primary objective was to evaluate the ORR of garsorasib (D-1553) in patients with KRAS G12C mutated locally advanced or metastatic solid tumors.

Trial status. We initiated the trial in June 2022 and completed the trial in December 2023.

Efficacy data. garsorasib (D-1553) achieved a high proportion of sustained objective remissions among the enrolled patients, with ORR of 52.0%, DCR of 88.6%, median PFS of 9.1 months and a median OS of 14.1 months, thus making it the targeted drug with the longest OS among currently marketed KRAS G12C inhibitors in the world.

Material Communications with Competent Authorities

We received IND approvals from the U.S. FDA, the NMPA, the Ministry of Food and Drug Safety of South Korea and the Taiwan FDA to conduct the Phase I/II clinical trial of garsorasib (D-1553) in September 2020, November 2020, November 2020 and December 2020, respectively. We received acknowledgment from Australia’s TGA for the Phase I/II clinical trial of garsorasib (D-1553) in September 2020.

Licenses, Rights and Obligations

In August 2023, we entered into a License and Collaboration Agreement with CTTQ, under which we granted CTTQ an exclusive license to develop, register, manufacture and commercialize garsorasib (D-1553) in Chinese Mainland (the “CTTQ Agreement”). Pursuant to the CTTQ Agreement, we will be entitled to receive upfront and development milestone payments of up to RMB260 million, as well as commercial milestone payments of up to RMB290 million. Also, we will be entitled to receive royalty payments based on the annual net sales of garsorasib (D-1553).

In September 2021, we entered into a collaboration agreement with InxMed for the joint development of ifebemtinib in combination with garsorasib (D-1553) as a cancer treatment. Under the agreement, InxMed shall provide ifebemtinib free of charge and we shall provide garsorasib free of charge for the joint clinical development of the combination therapy. In October 2023, we entered into a supplemental agreement with InxMed in connection with the 2021 InxMed Agreement, after we signed the aforementioned CTTQ Agreement in August 2023. Under the supplemental agreement, InxMed shall lead the remaining work for the Phase Ib clinical trial for garsorasib (D-1553), and we shall continue to provide garsorasib (D-1553) for the clinical development of the combination therapy.

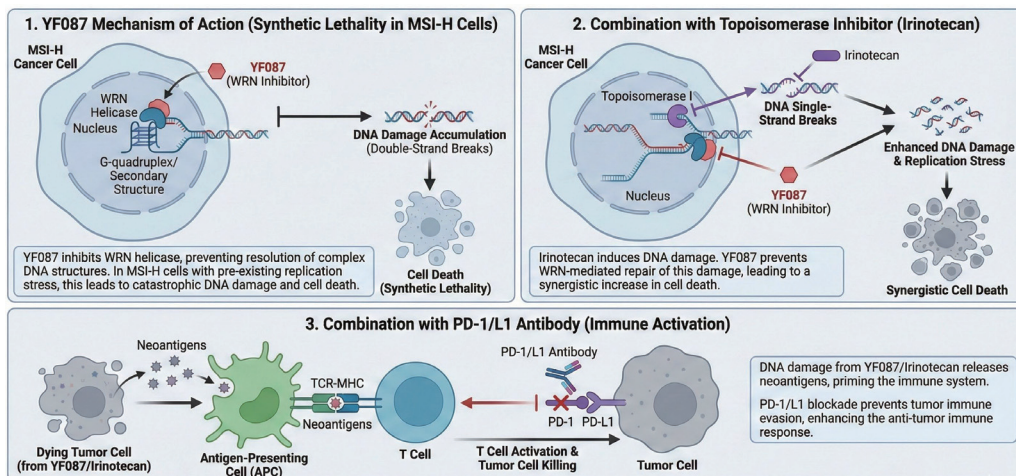
For details, please refer to “— Major Collaboration Arrangements.”

YF087: A Synthetic Lethal Drug Candidate Targeting Tumors with Impaired DNA Mismatch Repair

YF087 is a preclinical-stage drug candidate. It is a potent and selective inhibitor of WRN, specifically targeting MSI-H cancer cells. We received IND approval from the NMPA for YF087 in May 2026 and expect to initiate a Phase I clinical trial in MSI-H/dMMR cancer patients in China in the fourth quarter of 2026.

BUSINESS

The impairment of DNA mismatch repair (“MMR”) function occurs in various cancers. MMR-deficient (“dMMR”) cancers are characterized by a high mutational load, a condition known as MSI-H. WRN is a helicase involved in maintaining genomic stability and is essential for the survival of MSI-H cancer cells. Thus, WRN represents a synthetic lethal target for MSI-H/dMMR cancers. YF087 may exert an anti-proliferation effect on such cancers as a selective, reversible, and potent WRN inhibitor. Below is a diagram illustrating the MOA of YF087.

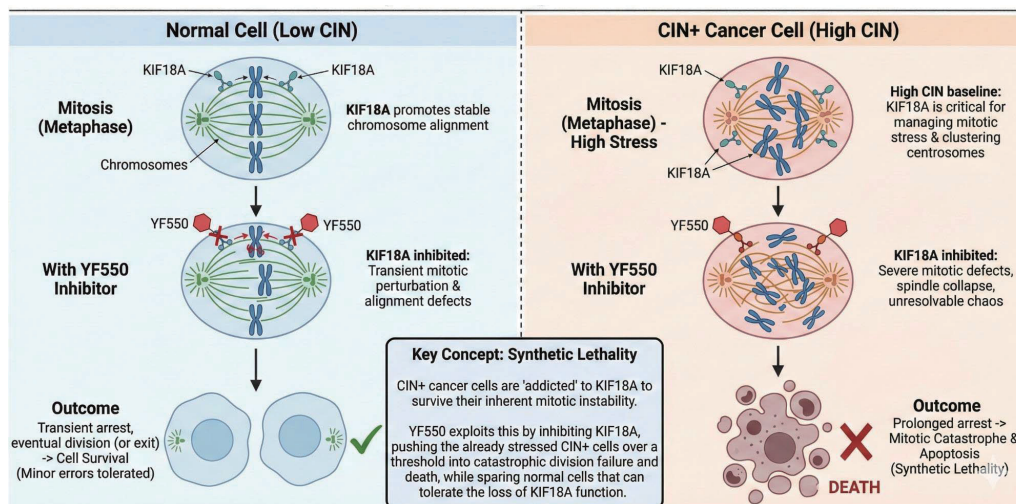


WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET YF087 SUCCESSFULLY.

YF550: A Synthetic Lethal Drug Candidate Targeting Tumors with Chromosomal Instability

YF550 is a preclinical-stage drug candidate. It is a selective and potent inhibitor of KIF18A (a protein critically involved in cell division), specifically targeting CIN+ cancer cells. We submitted an IND application for YF550 with the NMPA in July 2026 and expect to obtain IND approval in the fourth quarter of 2026.

CIN+ is a prevalent vulnerability of cancer cells characterized by a continuous dysfunction in cell division commonly observed in various human cancers, including ovarian, triple-negative breast (“TNBC”), and head-and-neck tumors. KIF18A is critical for the proliferation of CIN+ cells but dispensable in normal cells. As a result, CIN+ cancer cells are particularly vulnerable to KIF18A inhibition, while KIF18A inhibition has little impact on normal cells. YF550 may exert an anti-proliferation effect on CIN+ cancer cells as a selective and potent inhibitor of KIF18A. Below is a diagram illustrating the MOA of YF550.

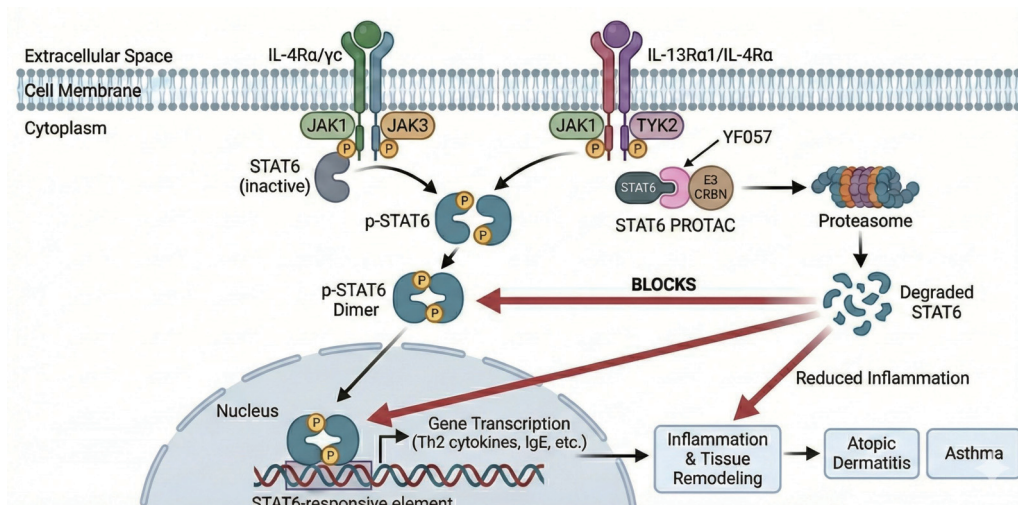


BUSINESS

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET YF550 SUCCESSFULLY.

YF057: An Oral STAT6 Degradar Targeting AD and Asthma

YF057 is a preclinical-stage drug candidate. It is an oral degrader targeting STAT6, a key signal transduction protein involved in the regulation of immune processes and the pathogenesis of multiple autoimmune diseases. We are developing YF057 as a potential transformative treatment for atopic dermatitis and asthma, by offering a differentiated oral alternative to IL-4R α and IL-13 antibody injections which are existing treatments for these autoimmune diseases. We expect to submit an IND application for YF057 with the FDA in the second quarter of 2027. Below is a diagram illustrating the MOA of YF057.



WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET YF057 SUCCESSFULLY.

OUR TECHNOLOGY PLATFORM

Integrated and Intelligent Molecular Design Platform

How Our Platform Works

Through years of dedicated R&D, we have accumulated a wealth of research data and software resources in computational chemistry. Leveraging these assets, we have established an integrated and intelligent molecular design platform that incorporates key technologies such as CADD, AIDD, pharmacokinetic analysis, and early toxicology assessment. Compared to traditional drug design methods, our platform significantly improves the success rate of transforming lead compounds to clinical candidates, effectively reducing the R&D costs and accelerating development cycles.

Within our CADD framework, we have integrated quantum mechanics and molecular dynamics modeling to develop a robust suite of computational tools. Our capabilities include multiple computational techniques to simulate and predict interactions among proteins and small molecules that can be used for drug candidate screening and design (such as molecular docking, virtual screening, protein-protein docking, and free energy perturbation), alongside specialized analytical tools to calculate and predict multiple physical and chemical features of different molecules (such as the electron density distribution of the compound, ligand conformation analysis, and pKa calculation). Furthermore, we offer predictive modeling to evaluate the reactivity of molecules by covalent binding and the ability of molecules to penetrate the blood-brain barrier. Together, these techniques provide comprehensive support for drug design.

BUSINESS

In AIDD, we leverage advanced multimodal and multi-framework deep learning algorithms to build machine learning models that rival industry benchmarks. We also have developed a suite of internal AI-powered online service tools that streamline the drug design process. These tools offer a broad range of functions, including molecular generation, scaffold hopping (analyzing and replacing core chemical scaffold of a compound to achieve desired biological activities), and protein structure prediction. Additionally, our platform provides robust metabolic site prediction (using machine learning models to predict the most likely sites of biotransformation on an enzyme) and comprehensive modeling of the pharmacokinetic and toxicological properties of compounds (i.e., ADMET properties). With these techniques, AIDD is able to significantly enhance overall R&D efficiency.

In pharmacokinetic analysis, we characterize the dynamic behavior of compounds *in vivo* by quantitatively studying their ADME processes. Additionally, we leverage AI technologies (such as machine learning algorithms) to conduct early predictions of the pharmacokinetic properties of compounds, so as to assist efficient screening of lead compounds.

In early toxicology assessment, we conduct comprehensive evaluations of the systemic toxicity and genotoxicity to provide early safety insights. By integrating effective dose prediction with our toxicity assessment system, we ensure the rapid and efficient screening of clinical candidates, effectively de-risking the development process at an early stage.

What Our Platform Has Achieved

Our integrated, intelligent molecular design platform has contributed to the discovery of several of our product candidates.

Garsorasib (D-1553). Starting with lead compounds, we designed a series of compounds with chiral axis-free structural variants based on our CADD technologies. After further optimization, we obtained garsorasib (D-1553).

Taragarestrant (D-0502). Through comprehensive analysis of protein-small molecule co-crystal structures, we have identified promising research directions that can effectively enhance activity. By leveraging our CADD, we elucidated the possible mechanisms driving the rapid metabolism of SERDs in the human body. These insights enabled us to overcome the low oral bioavailability issue common to SERDs, leading to the discovery of taragarestrant (D-0502).

D-2570. In the development of D-2570, we employed our CADD technologies to evaluate the variation of ligand binding modes between TYK2 and its homologous proteins at the atomic level. By precisely analyzing key amino acid variations, we rationally modified the structure of potential drug candidates to improve binding selectivity toward TYK2. Concurrently, we integrated use our AIDD technologies to comprehensively evaluate the metabolic, pharmacokinetic, and toxicological properties of potential drug candidates. This approach enabled us to rapidly screen for compounds possessing both high TYK2 selectivity and desirable pharmacokinetic properties. After further optimization, we obtained D-2570.

MAJOR COLLABORATION ARRANGEMENTS

When selecting collaboration partners, we primarily evaluate them based on the following criteria: the partner's market position in the pharmaceutical industry, commercialization capabilities, regulatory compliance history, financial stability, and strategic synergy. We conduct comprehensive due diligence and prioritize selecting reputable local pharmaceutical companies to ensure that the partnership aligns with our long-term development strategy and shareholder interests. To ensure our partners adhere to contractual terms and operate in line with relevant laws and regulations, we implement ongoing monitoring and enforcement measures: (i) contractual safeguards: our collaboration agreements include clear clauses on performance metrics, compliance requirements, audit rights, confidentiality, and termination provisions for non-compliance, and partners are required to certify adherence to anticorruption policies and applicable laws; (ii) monitoring: regular performance reviews and onsite inspections are conducted, and any deviations

BUSINESS

shall trigger corrective action plans; (iii) training and reporting: internal reporting mechanisms, such as whistleblower channels, are in place to flag potential issues, and compliance is further supported through integration with our broader ESG Compliance Management framework, which addresses ethical and regulatory risks; (iv) risk management: potential risks, including bribery or regulatory violations, are mitigated through enhanced due diligence and periodic reevaluations of partnerships.

In the event of any non-compliance involving partners, we follow a clear escalation process: issues are first detected through monitoring, audits, or whistleblower channels and assessed by operational teams with legal/compliance support. Minor issues are resolved at the departmental level with corrective action plans, while serious matters will be escalated to senior management for investigation and remediation. Material or high-risk cases are further escalated to the Board of Directors for oversight and strategic decisions. With partners, we enforce contractual obligations for prompt notification, joint investigation, and remediation; failure to resolve may lead to enhanced monitoring, suspension of activities, payment withholding, contract termination, or legal action. All incidents trigger root cause analysis, preventive measures, and, where required, regulatory notifications to ensure compliance and risk mitigation.

Collaboration Agreement with Betta

In December 2018, we entered into a collaboration agreement (the “Betta Agreement”) with Betta, a publicly listed pharmaceutical company in China, to have exclusive rights for research, development, manufacturing and commercialization of befotertinib (BPI-D0316) in Chinese Mainland, Hong Kong, and Taiwan (the “Licensed Territories”). Betta is an Independent Third Party.

The sharing of sales revenue, R&D expenses and intellectual properties between the parties under the Betta Collaboration Agreement is as follows.

	Inside Licensed Territories	Outside Licensed Territories
Sales revenue	We are eligible to receive tiered royalties on annual net sales of befotertinib (BPI-D0316) within the Licensed Territories during the prescribed royalty term. The royalty term will begin, for a particular product, from its first commercial sale in a region and end upon expiration of the last valid patent in that region that covers the product’s chemical composition.	Betta can receive a certain percentage of net income deriving from befotertinib (BPI-D0316) outside the Licensed Territories.
R&D expenses	We shall cover the R&D expenses incurred before completion of the Phase I clinical trial of befotertinib (BPI-D0316). Betta shall cover the R&D expenses incurred for expansion of the Phase I clinical trial and those already incurred for the Phase II clinical trial of befotertinib (BPI-D0316). Beyond the said Phase I and Phase II clinical trials, Betta shall cover the expenses for further clinical development and registration of befotertinib (BPI-D0316).	N/A

BUSINESS

	Inside Licensed Territories	Outside Licensed Territories
Intellectual properties . . .	We and Betta shall each have exclusive ownership of intellectual properties independently developed by each party. We and Betta shall jointly own all intellectual properties jointly developed by the parties in connection with the agreement. In addition, we and Betta shall be joint owners of several patents regarding befortertinib (BPI-D0316) that were previously solely owned by us. We also transferred to Betta certain proprietary manufacturing technologies and materials regarding befortertinib (BPI-D0316).	N/A

We are eligible to receive an upfront payment, as well as milestone payments upon achievements of certain future pre-specified regulatory and sales milestones. We received milestone payment of RMB80 million from Betta in December 2025. As of the Latest Practicable Date, RMB100 million of regulatory milestone payments had been triggered and become payable by Betta to us. Betta and we are currently engaged in active, good-faith discussions regarding the timing, mechanics, and related commercial aspects of settlement of the outstanding payment. Both parties remain constructively engaged and are working toward an agreed resolution through ongoing negotiations.

A joint development committee (“JDC”) was formed under the Betta Agreement, to coordinate the collaboration under the agreement. Each party has three representatives in the JDC. The Betta Agreement did not provide the JDC’s decision-making mechanism.

The parties’ management teams or representatives shall first attempt to resolve any dispute arising from the Betta Agreement. If the parties cannot resolve the dispute by negotiation, the dispute shall be resolved by litigation in a court with competent jurisdiction. We have not experienced any dispute with Betta under the Betta Agreement.

Unless terminated earlier, the agreement will expire, on a region-by-region basis, upon the termination of Betta’s payment obligations with respect to all licensed products in all regions, and, in its entirety, upon the termination of Betta’s payment obligations with respect to the last commercialized product in the last region. The agreement may be terminated (i) by either party for uncured material breach by the other party; (ii) by us if Betta abandons the development of befortertinib (BPI-D0316), develop other EGFR-T790M targeted drugs, or continuously fail to undertake substantial activities in relation to clinical trials of befortertinib (BPI-D0316) for three months; or (iii) by Betta if certain befortertinib (BPI-D0316) compound fails to be patented or such patents are later invalidated.

The key milestones achieved under the Betta Agreement are as follows:

Key milestone	Time achieved
Grant of the Chinese patent covering the chemical composition of BPI-D0316	March 2019
Marketing approval of BPI-D0316 as a second-line treatment of NSCLC	May 2023
Marketing approval of BPI-D0316 as a first-line treatment of NSCLC	October 2023

BUSINESS

Collaboration Agreement with CTTQ

In August 2023, we entered into a License and Collaboration Agreement with CTTQ, under which we granted CTTQ an exclusive license to develop, register, manufacture and commercialize garsorasib (D-1553) in Chinese Mainland (the “CTTQ Agreement”). CTTQ is a subsidiary of Sino Biopharmaceutical Limited, a public listed pharmaceutical company registered in Cayman. CTTQ is an Independent Third Party.

The sharing of sales revenue, R&D expenses and intellectual properties between the parties under the CTTQ Agreement is as follows.

	Inside Chinese Mainland	Outside Chinese Mainland
Sales revenue	We will be entitled to receive royalty payments based on the annual net sales of garsorasib (D-1553) with in Chinese Mainland.	If the data obtained by CTTQ in the development of garsorasib (D-1553) in Chinese Mainland are reasonably useful to us for the subsequent development, registration, or commercialization of garsorasib (D-1553) outside Chinese Mainland, and we have used such data and obtained revenue outside Chinese Mainland as a result, CTTQ shall be entitled to a certain proportion of such revenue.
R&D expenses	We shall conduct and cover the costs of conducting the registrational clinical trial and other studies needed to obtain conditional marketing approval, for garsorasib (D-1553) as second-line treatment of NSCLC in Chinese Mainland. CTTQ shall conduct and cover the costs of conducting the confirmatory clinical trial and other studies needed to obtain regulatory marketing approval, for garsorasib (D-1553) as second-line treatment of NSCLC in Chinese Mainland, as well as other development efforts for garsorasib (D-1553), such as developing garsorasib (D-1553) as first-line treatment of NSCLC.	N/A
Intellectual properties . . .	We retain ownership of the patents relating to garsorasib (D-1553) exclusively licensed to CTTQ. CTTQ is allowed to grant sub-license of such patents to a third party, with our prior written consent, and such sub-license will not change CTTQ’s obligations under the CTTQ Agreement. CTTQ shall own any patent arising from any improvement it makes based on our patents relating to garsorasib (D-1553).	N/A

BUSINESS

Pursuant to the CTTQ Agreement, we will be entitled to receive upfront and development milestone payments of up to RMB260 million, as well as commercial milestone payments of up to RMB290 million. We shall also transfer the MAH of garsorasib (D-1553) to CTTQ in Chinese Mainland.

A joint steering committee (“JSC”) was formed under the CTTQ Agreement, to lead and coordinate the collaboration under the agreement. Each party has four representatives in the JSC. Any decision shall be made by consensus of the members in the JSC. If the JSC cannot make a decision, CTTQ has the final decision-making authority for matters within Chinese Mainland, and we have the final decision-making authority for matters outside Chinese Mainland.

Unless terminated earlier, the agreement will expire upon the termination of CTTQ’s obligations to make royalty payments based on the annual net sales of garsorasib (D-1553).

Any dispute in connection with the agreement shall be referred to senior management of each party for attempted resolution. In the event senior management are unable to resolve the dispute, the dispute shall be settled by arbitration administered by the Beijing Arbitration Commission.

The key milestones achieved under the CTTQ Agreement are as follows:

Key milestone	Time achieved
Conditional marketing approval of D-1553 as a second-line treatment of NSCLC	November 2024
Completion of transfer of Marketing Authorisation Holder of D-1553 as a second-line treatment of NSCLC	November 2024
Enrolment of the first subject for the registrational clinical trial of D-1553 as a first-line treatment of NSCLC	February 2026

Collaboration Agreement with InxMed

2021 InxMed Agreement

In September 2021, we entered into a collaboration agreement with InxMed for the joint development of ifebemtinib in combination with garsorasib (D-1553) as a cancer treatment (the “2021 InxMed Agreement”). InxMed is a China-based clinical-stage biotech company established in 2018. It is dedicated to developing innovative therapies transform cancer treatment. InxMed is an Independent Third Party.

The scope of collaboration (including sharing of the parties’ interests, rights and expenses) under the 2021 InxMed Agreement is global, not limited to a particular jurisdiction. InxMed shall provide ifebemtinib free of charge and we shall provide garsorasib free of charge for the joint clinical development of the combination therapy. For the Phase I clinical trial, we shall lead the design of the trial protocol and conduct the trial, which shall be jointly reviewed and approved by both parties. We and InxMed shall each cover half of the expenses incurred for the Phase I clinical trial.

For the Phase II clinical trial and further development stages of the combination therapy, the parties shall jointly decide the collaboration model (including sales of any approved product) and development plan, for which the parties shall sign a supplemental collaboration agreement. The InxMed Agreement did not contain any specific provision on sub-licensing rights, milestones, or profit-sharing arrangements.

Any intellectual property generated from the parties’ joint development regarding the combination therapy shall be jointly owned and applied for by the parties. The parties shall each cover half of the expenses incurred for the application and enforcement of such intellectual

BUSINESS

properties. Any decision regarding such application and enforcement shall be jointly made by the parties and cannot be unilaterally made. Any data generated from the Phase I clinical trial of the combination therapy shall be jointly owned and applied for by the parties.

The 2021 InxMed Agreement established a joint development committee (“JDC”) to lead and coordinate the joint development. Any decision shall be made by consensus of the members in the JDC. If the JDC cannot make a decision, the relevant issue shall be determined by the parties’ chairman of the board or general manager upon discussion.

The term of the 2021 InxMed Agreement shall continue until 15 years after the date the combination therapy receives the first marketing approval. Before the preliminary results of the Phase I clinical trial of the combination therapy regarding dose escalation and indication expansion have been completed and obtained, the 2021 InxMed Agreement cannot be terminated without the parties’ mutual consent.

The parties shall amicably negotiate to resolve any dispute arising from the 2021 InxMed Agreement. If the parties cannot resolve the dispute by negotiation, the dispute shall be resolved by litigation in a court with competent jurisdiction.

Supplemental InxMed Agreement

In October 2023, we entered into a supplemental agreement with InxMed in connection with the 2021 InxMed Agreement (the “Supplemental InxMed Agreement”), in light of: (1) the CTTQ Agreement we signed in August 2023 that granted CTTQ the exclusive rights to develop, register, manufacture, and commercialize garsorasib (D-1553) in Chinese Mainland; and (2) obtaining of the preliminary results of the Phase I clinical trial of the combination therapy regarding dose escalation and indication expansion.

Under the Supplemental InxMed Agreement, InxMed shall lead the remaining work for the Phase I clinical trial and cover the expenses of the trial that occurred since October 2023. We shall continue to provide garsorasib (D-1553) for the clinical development of the combination therapy, which has been consented by CTTQ in writing.

Any data generated from the subjects enrolled in the Phase I clinical trial of the combination therapy before October 2023 shall be jointly owned by the parties. InxMed shall own the data generated from the subjects enrolled in the trial since October 2023. InxMed shall share with us the finalized clinical study report for the trial free of charge. We are allowed to disclose to CTTQ the summary clinical data in the report.

In the event that InxMed enters into a new collaboration agreement with CTTQ, the new collaboration agreement shall govern the ownership of data and IP regarding garsorasib (D-1553) between InxMed and CTTQ.

We and InxMed shall jointly own the patents, if any, arising from the Phase I clinical trial of the combination therapy. We are allowed to grant a non-exclusive license of our rights in such patents to CTTQ free of charge.

RESEARCH AND DEVELOPMENT

R&D Team

Our in-house R&D team consisted of 165 employees as of Latest Practicable Date, most of whom had obtained at least bachelor’s degrees, and over 49% members of our R&D team had obtained advanced degrees, including over 13% members with doctorate degrees and over 36% members with master’s degrees covering the fields of chemistry, biology, pharmacology and medicine. Our R&D team is led by a team of seasoned scientists with years of drug development experience. Our core R&D personnel consist of 24 members covering the fields of chemistry, biology, pharmacology and medicine, who have been working in the pharmaceutical industry for an average over 22 years. All of the core R&D personnel hold bachelor’s degrees. Among them, over

BUSINESS

90% hold advanced degrees (with 50% having doctorate degrees) and over 30% have overseas work experience in multinational corporations. During the Track Record Period and as of the Latest Practicable Date, the key R&D personnel involved in the development of the Core Products all remain employed by us. As of the Latest Practicable Date, 80, 68 and 17 R&D team members were in the functions of (i) drug discovery and pre-clinical development, (ii) clinical development, and (iii) CMC, respectively.

In 2024 and 2025 and for the six months ended June 30, 2025 and 2026, our R&D costs accounted for 88.0%, 87.8%, 83.5% and 91.7% of our total operating expenses in the corresponding years/periods, respectively. Our R&D costs decreased from RMB384.3 million in 2024 to RMB325.8 million in 2025, primarily attributable to substantial R&D costs incurred in 2024 for the Phase I/II clinical trial of garsorasib (D-1553) in patients with KRAS G12C mutated locally advanced or metastatic solid tumors in multiple regions, which was completed in November 2024. Our R&D costs increased from RMB116.5 million for the six months ended June 30, 2025 to RMB184.7 million for the six months ended June 30, 2026, primarily attributable to the increase of clinical trial expenses related to D-2570.

We engaged a third-party human resources agency to pay social insurance premium and housing provident funds for 12 employees. Pursuant to the agreement entered into between such third-party human resources agency and us, the third-party human resources agency would pay social insurance premium and housing provident funds for such employee on behalf of us. As of the Latest Practicable Date, (i) the employees had confirmed such arrangement and had raised no objections in relation thereto; (ii) there had been no disputes between us, such employees and/or the third-party human resources agency with regard to such arrangement, as the case may be; and (iii) we had not received any notice of rectification from, or been imposed any administrative penalty by, the relevant governmental authorities as a result of such arrangement or nonpayment for employees who are not PRC citizens. For details, please refer to “Risk Factors — Risks Relating to Our Operations — We are subject to risks in relation to our social insurance and housing provident fund contributions.”

Drug Discovery and Pre-clinical Development

Our drug discovery and pre-clinical development is led by Dr. Yaolin Wang. Based on our proprietary integrated and intelligent molecular design platform, we have established unique advantages in rational compound structural design, efficacy, and physicochemical property prediction and optimization, thereby systematically enhancing the success rate of our drug discovery efforts. Besides, we have entered into agreements with CROs, hospitals, and principal investigators located in China and the U.S.

Clinical Development

Clinical Development Team

Our clinical development team is led by Dr. Ling Zhang, our Chief Medical Officer. Led by Dr. Zhang, we have built a clinical development team with profound professional knowledge and an international perspective, covering core functions such as clinical medicine, pharmacovigilance, quality management and clinical pharmacology. Our members possess backgrounds in multinational pharmaceutical companies and global project execution capabilities. As of Latest Practicable Date, our clinical development team consisted of 68 members, including professionals with extensive drug development experience, who participate in clinical development strategy development, clinical trial protocol design, clinical trial operations, drug safety monitoring, and clinical trial quality control. Many of our clinical development team members had extensive relevant work experience. Among them, over 41% have obtained post-graduate degrees. Our clinical development team is generally responsible for the clinical development of our Core Products and other product candidates.

BUSINESS

The substantial work experience of our core R&D personnel, including Dr. Zhang, is an essential part of our R&D capabilities. However, our Directors are of the view that our R&D capabilities do not rely on any single employee. Our R&D team has over 160 employees covering the fields of chemistry, biology, pharmacology and medicine, including 24 core R&D personnel who have been working in the pharmaceutical industry for an average over 22 years. We have taken measures to effectively contain the impact on its R&D capabilities due to the departure of a core R&D personnel. For example, our employment agreements with these core R&D personnel include IP assignment and non-compete clauses, which will protect our IP and competitive advantages that derive from such core R&D personnel in the event of their departure. Nevertheless, the potential departure of any of our senior executive, including Dr. Zhang, may have a negative impact on our operations.

Clinical Trial Design and Implementation

We have established a differentiated clinical pathway decision-making system centered on accelerating the R&D cycle, relying on a three-dimensional driving model to achieve efficient implementation: (1) accurately locating the registration path based on deep insights into the disease target and pathology; (2) prioritizing indications that can be quickly verified by focusing on the advantages of drug candidates (such as penetrability across the brain barrier); and (3) integrating the systematic experience and professional judgment of the clinical development team. The synergy of the three drivers enables rapid advancement of our pipeline products towards the NDA along an optimal path. To support the global clinical development of pipeline products, we have established extensive and in-depth strategic partnerships with numerous established hospitals in China, renowned medical centers overseas, and leading experts in the field. We achieve efficient resource integration through a differentiated operating model between China and the U.S. In China, we leverage our own clinical development capabilities to strengthen quality control and enrollment efficiency in mid-to-late-stage trials. In the U.S., we utilize our long-term CRO network to advance project execution and employ local clinical project management specialists to ensure efficacious trial management. All our clinical development activities are conducted in both Chinese and English, and the registration matters are directly managed by our regulatory team, forming a closed-loop management system from IND application to clinical execution.

In 2024 and 2025 and for the six months ended June 30, 2026, we cooperated with 208, 231 and 314 PIs, respectively, to conduct the clinical trials of our product candidates. To the best of our knowledge, none of them have any past or present relationships with our Group, our Directors, Shareholders, senior management or any of their respective associates. The PIs are responsible for conducting site-level clinical research activities according to our trial protocols and in accordance with laws, regulations, and the GCP guideline, a quality standard for the overall conduct of the clinical trial. Each trial has a leading PI with primary responsibility to ensure compliance with trial protocol and GCP over the entire trial.

Relationship with CROs

During the Track Record Period, we engaged seven CROs to support our clinical trials for our Core Products. We select CROs based on various factors including qualifications, experience, industry reputation, adequacy of clinical trial equipment and data management capability. Our clinical development department closely supervises and monitors the performance of CROs to ensure they conduct clinical trials in accordance with our protocols and GCP requirements. CROs are typically responsible for facilitating the selection of investigators, locating trial sites, local vendors, making local regulatory filings with our review and approvals, purchasing equipment and materials, engaging other third parties to further facilitate the clinical trials, enrolling qualifying trial participants, routine trial site monitoring, and trial data management and analysis. Our engagement of CROs for preclinical and clinical studies is in line with the industry practice.

BUSINESS

Regulatory Affairs

Our regulatory affairs team is directly responsible for the regulatory process of our product candidates in China and the U.S., including assembling application dossiers for IND and NDA, addressing inquiries from relevant authorities, regular maintenance of opened INDs and monitoring our R&D projects to ensure their compliance with relevant regulations. Our regulatory affairs team manages the regulatory submission process, which generally requires filings to be made to and approved by the regulatory authorities before clinical trials and commercialization of our products can be initiated. The regulatory affairs team prepares and manages regulatory filings by coordinating filing dossiers drafting, addressing regulatory questions and submitting safety information for our pipeline products. We possess extensive knowledge and experience in regulatory filings. Leveraging our expertise and established presence in the industry, we are able to design clinical trials that maximize regulatory alignment and operational efficiency.

CHEMISTRY, MANUFACTURING & CONTROLS (“CMC”)

CMC Team

As of Latest Practicable Date, our CMC team consisted of 17 professionals with extensive experience in process development, production and quality management from well-known biopharmaceutical and pharmaceutical companies. Our CMC team is involved in preclinical and clinical support throughout the drug development process. In lead compound optimization, the CMC team proactively collaborates with the R&D team to address challenges in molecule design and development. In process development and cGMP manufacturing, the CMC team leverages our platform technologies and partnerships with external CDMOs to ensure robustness, reliability, and scalability at every step. Furthermore, the CMC team has established a comprehensive quality management system, to ensure consistent quality of our products from initial clinical use to future commercial production. Over the years, our CMC team has facilitated the clinical translation of multiple drug candidates. The substantial work experience of our CMC team is an essential part of our R&D capabilities. However, our Directors are of the view that our R&D capabilities do not rely on any single employee. Also, our employment agreements with these core R&D personnel include IP assignment and non-compete clauses, which will protect our IP and competitive advantages that derive from such core R&D personnel in the event of their departure.

D-2570. The CMC team optimized the synthetic route of the API of D-2570, avoiding the hazardous reagents used in the original route, thereby rapidly scaling up the synthetic process and ensuring supply of D-2570 for clinical use. We also explored various crystallization methods to address the polymorphic nature of the API molecule and selected the most stable crystal form for further development. This ensured the stability of the API during production and storage, hence the quality of D-2570 for clinical use. Meanwhile, the formulation and manufacturing process were also optimized to enhance its *in vivo* absorption properties. Subsequent data from both animal studies and human clinical trials demonstrated that the optimized formulation achieved high plasma exposure. The formulations thus developed have been validated in the Phase I and Phase II clinical trials of D-2570; currently, the Phase III clinical trial is ongoing as planned. Also, the formulation and manufacturing process developed by the CMC team have demonstrated robustness and scalability under cGMP standards.

Taragarestrant (D-0502). We employed a convergent route for the synthesis of taragarestrant (D-0502)’s API to improve the synthesis efficiency. Further, based on the physicochemical properties of the API, the CMC team performed salt formation screening for suitable salt and crystal forms for subsequent drug development. Also, the CMC team employed solubilization technologies in formulation development to improve taragarestrant (D-0502)’s solubility of in water and *in vivo* bioavailability, ultimately enhancing the drug efficacy. The CMC team completed the API process development within a relatively short time, thereby ensuring supply of taragarestrant (D-0502) for clinical use.

Darbinurad (D-0120). The CMC team significantly shortened the synthesis route of the API of darbinurad (D-0120), which has been boiled down to a “three-step synthesis” method. The shortened synthesis route can reduce the production cost and lay a good foundation for cost control in future commercialization.

BUSINESS

In-house Manufacturing and Collaboration with CDMOs

For manufacturing of our product candidates, we currently outsource such production to a number of CDMOs. We engaged CDMOs to manufacture drug candidates for our preclinical and clinical supplies during the Track Record Period and up to the Latest Practicable Date. We did not experience any material product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period. We intend to continue collaborating with these CDMOs for future commercial manufacturing of our Core Products. Below is a summary of the key terms of an agreement that we typically enter into with CROs/CDMOs:

Services. The CRO/CDMO provides us with services, such as the implementation of a clinical research project or manufacturing of certain compounds, as specified in the master agreement or a work order.

Term. The CRO/CDMO is required to perform its services within the prescribed time limit set out in each work order and in accordance with the KPIs agreed by both parties.

Payments. We are required to make payments to the CRO/CDMO in accordance with the payment schedule agreed by the parties.

Risk allocation. Each party should indemnify the other party for losses caused by its negligence, recklessness, intentional misconduct or material breach of the master agreement or the work order.

Intellectual property. All IP generated from the collaboration under the CRO/CDMO agreement shall be solely and exclusively owned by us. The CRO/CDMO agreement does not allow the CRO/CDMO to disclose our IP to a third party without our prior written consent.

COMMERCIALIZATION, MARKETING AND BUSINESS DEVELOPMENT

We adopt a combined approach of licensing partnerships, contract sales, and relying on our in-house sales team for product commercialization. In selecting the commercialization approach of a product, we comprehensively consider the market potential of its therapeutic area, the competitive landscape, and the commercial environment of different countries or regions. Our current primary target markets are Chinese Mainland and the U.S. In Chinese Mainland, we intend to: (i) engage a contract sales organization (“CSO”) or establish our in-house sales teams, for the commercialization of D-2570; (ii) engage a CSO for the commercialization of D-0502; and (iii) establish licensing agreement with a collaboration partner for the commercialization of D-0120. In the U.S., we intend to establish licensing agreement with a collaboration partner for the commercialization of D-2570, D-0502 and D-0120. We had not yet identified any target partner for such licensing arrangements as of the Latest Practicable Date.

Our commercialization strategy is implemented on a product-by-product and territory-specific basis. While we retain global rights for certain assets to enable overseas expansion, for other products we have adopted an out-licensing approach for specific regions. Such a strategy is aligned with our past practices. For example, we granted Betta the exclusive rights to develop, manufacture and commercialize befotertinib (BPI-D0316) in Chinese Mainland, Hong Kong, and Taiwan. Also, we granted CTTQ an exclusive license to develop, register, manufacture and commercialize garsorasib (D-1553) in Chinese Mainland. Leveraging the extensive development, market expansion, and sales experience of Betta and CTTQ, we aim to maximize the commercial value of our products. This collaboration model will help us reduce R&D costs, generate cash flow before product launch, mitigate operational risks, and ensure successful commercialization. Such arrangements reflect our flexible strategy to optimize resource allocation, leverage local partners’ development and commercialization capabilities, and maximize the overall value of our product portfolio across different markets.

BUSINESS

Subject to market conditions and regulatory approval, we expect to commercialize our Core Products in 2029. We are currently focused on the R&D of our Core Products and have not yet finalized a detailed pricing strategy for such products. However, we currently expect to adopt a competitive and market-oriented pricing approach in both Chinese Mainland and overseas markets, taking into account comparable therapies in the same therapeutic areas, the clinical profile and potential advantages of our Core Products, and the applicable reimbursement environment.

In Chinese Mainland, the pricing of Core Products is expected to be influenced by national healthcare policies, including inclusion in the NRDL, centralized procurement mechanisms, and patients’ affordability considerations. While potential inclusion in the NRDL may lead to lower unit pricing, it may also facilitate broader patient access and higher treatment volumes, which could support overall revenue growth. In overseas markets, including the U.S., the pricing of Core Products is expected to reflect differences in healthcare systems, reimbursement frameworks, purchasing power, and market dynamics. Pricing in these markets may be higher than in Chinese Mainland, subject to negotiation with payors and commercial partners.

Overall, we expect that our pricing strategy will seek to balance affordability and market access with commercial sustainability. The revenue and profitability of the Core Products will depend on a combination of factors, including pricing levels, reimbursement coverage, patient uptake, market competition, and commercialization arrangements with our potential partners, if any.

OUR SUPPLIERS

During the Track Record Period, our suppliers are mainly comprised of service providers and equipment and consumables suppliers. Although we primarily use a limited number of suppliers, there are alternate suppliers available for our needs for services, equipment and consumables. With respect to procuring our major equipment and consumables, we generally enter into supply agreements with our suppliers. Our agreements with the suppliers specifically list our quality requirements. We will decide whether to accept the supply upon inspecting and examining the materials. Most of our suppliers for consumables currently do not provide us with credit terms. To the best knowledge of our Directors, there was no material breach of procurement agreements with our suppliers during the Track Record Period. Our Directors believe that we would not experience any material difficulties in procuring our major consumables.

In 2024 and 2025 and for the six months ended June 30, 2026, purchases from our five largest suppliers in each year/period during the Track Record Period amounted to RMB122.2 million, RMB117.2 million and RMB44.3 million, representing 59.9%, 58.3% and 29.7% of our total purchases for the respective year/period. In 2024 and 2025 and for the six months ended June 30, 2026, our purchases from our largest supplier in each year/period during the Track Record Period amounted to RMB53.0 million, RMB37.7 million and RMB14.0 million, representing 26.0%, 18.8% and 9.4% of our total purchases for the respective year/period. All of our five largest suppliers in each year/period during the Track Record Period are Independent Third Parties. None of our Directors, Shareholders who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED] nor any of their respective close associates had any interest in any of our five largest suppliers in each year/period during the Track Record Period and up to the Latest Practicable Date.

Details regarding our five largest suppliers in 2024 were as follows. (i) Supplier A, founded in 1997, is a global, late-stage CRO that provides comprehensive phase 1 through phase 4 clinical trial management, clinical pharmacology, and patient access solutions. Our relationship commenced in 2018. Purchases amounted to RMB53.0 million, representing 26.0% of our total purchases, mainly for CRO services, with payment terms of 30 days. (ii) Supplier B, founded in 1999, is a global integrated CDMO providing drug R&D and manufacturing for pharmaceutical and biotech companies. Our relationship commenced in 2020. Purchases amounted to RMB34.2 million, representing 16.8% of our total purchases, mainly for CRO services, with payment terms between 10 business days and 30 days. (iii) Supplier C, founded in 2000, is a group with global operations, providing integrated, end-to-end services including chemistry drug CRDMO, biology discovery, preclinical testing and clinical research services. Our relationship commenced in 2018. Purchases amounted to RMB16.0 million, representing 7.8% of our total purchases, mainly for CRO services, with payment terms between 5 business days and 30 days. (iv) Supplier D, founded in 1995, is an innovation-driven pharmaceutical company in China that focuses on major disease therapeutic areas including oncology, anti-infections, central nervous system, metabolism and autoimmunity. Our

BUSINESS

relationship commenced in 2024. Purchases amounted to RMB13.9 million, representing 6.8% of our total purchases, mainly for technical services, with payment terms of 15 business days. (v) Supplier E, founded in 2004, is a life sciences service provider in China that offers a broad spectrum of research, development, and manufacturing services. Our relationship commenced in 2019. Purchases amounted to RMB5.1 million, representing 2.5% of our total purchases, mainly for CRO services, with payment terms between 10 business days and 45 days.

Details regarding our five largest suppliers in 2025 were as follows. (i) Supplier F, founded in 2003, is a leading pharmaceutical company focusing on R&D of innovative drugs, with complete closed loops of R&D, manufacturing, and sales. Our relationship commenced in 2018. Purchases amounted to RMB37.7 million, representing 18.8% of our total purchases, mainly for R&D services, with payment terms of 15 business days. (ii) Purchases from Supplier A amounted to RMB28.9 million, representing 14.4% of our total purchases, primarily for CRO services. Payment terms were 30 days. (iii) Purchases from Supplier C amounted to RMB26.2 million, representing 13.0% of our total purchases, mainly for CRO services. Payment terms were between 10 business days and 30 days. (iv) Supplier G, founded 1989, is an international generic active pharmaceutical ingredients supplier. Our relationship commenced in 2025. Purchases amounted to RMB13.6 million, representing 6.8% of our total purchases, mainly for raw materials, with payment terms of 20 business days. (v) Purchases from Supplier E amounted to RMB10.8 million, representing 5.4% of our total purchases, mainly for CRO services. Payment terms were between 10 business days and 30 days.

Details regarding our five largest suppliers for the six months ended June 30, 2026 were as follows. (i) Purchases from Supplier E amounted to RMB14.0 million, representing 9.4% of our total purchases, mainly for CRO services. Payment terms were between 10 business days and 30 days. (ii) Purchases from Supplier C amounted to RMB12.1 million, representing 8.1% of our total purchases, mainly for CRO services. Payment terms were between 10 business days and 30 days. (iii) Purchases from Supplier A amounted to RMB7.1 million, representing 4.8% of our total purchases, primarily for CRO services. Payment terms were 30 days. (vi) Purchases from Supplier G amounted to RMB5.8 million, representing 3.9% of our total purchases, primarily for raw materials. Payment terms were 20 business days. (v) Supplier H, founded in 2017, provides comprehensive, integrated professional services for the entire life cycle of new drug clinical trials. Our relationship commenced in 2022. Purchases amounted to RMB5.3 million, representing 3.6% of our total purchases, mainly for CRO services, with payment terms of 10 business days.

CUSTOMERS

During the Track Record Period, all our revenue was generated from two customers who were both pharmaceutical companies. In 2024 and 2025 and for the six months ended June 30, 2026, the aggregate revenue from our two customers in each year/period was RMB168.8 million, RMB37.3 million and RMB53.3 million, respectively. In 2024 and 2025 and for the six months ended June 30, 2026, revenue from our single largest customer in each year/period accounted for 90.3%, 75.1% and 68.9% of our total sales amount for the respective year/period. All of our customers in each year/period during the Track Record Period are Independent Third Parties. During the Track Record Period and up to the Latest Practicable Date, to the knowledge of our Directors, none of our Directors, their close associates or any Shareholder owns more than 5% of our share capital had any interest in any of our customers in each year.

Details regarding our two customers in 2024 were as follows. (i) CTTQ, founded in 1997, is a Chinese pharmaceutical company with integrated R&D, manufacturing, marketing, sales and distribution capabilities. Our relationship commenced in 2023, and we provided CTTQ licensing of a commercialized product. Our revenue from CTTQ was RMB152.4 million, representing 90.3% of total revenue. (ii) Customer B, founded in 2003, is a leading pharmaceutical company focusing on R&D of innovative drugs, with complete closed loops of R&D, manufacturing, and sales. Our relationship commenced in 2018, and we provided Customer B licensing of a commercialized product. Our revenue from Customer B was RMB16.4 million, representing 9.7% of total revenue.

Details regarding our two customers in 2025 were as follows. (i) We provided Customer B licensing of a commercialized product. Our revenue from Customer B was RMB28.0 million, representing 75.1% of total revenue. (ii) We provided CTTQ licensing of a commercialized product. Our revenue from CTTQ was RMB9.3 million, representing 24.9% of total revenue.

BUSINESS

Details regarding our two customers for the six months ended June 30, 2026 were as follows. (i) We provided Customer B licensing of a commercialized product. Our revenue from Customer B was RMB16.6 million, representing 31.1% of total revenue. (ii) We provided CTTQ licensing of a commercialized product. Our revenue from CTTQ was RMB36.8 million, representing 68.9% of total revenue.

In 2025, one customer of ours was also our supplier (the “customer-supplier”): the sales to this customer-supplier amounted to RMB28.0 million, representing 75.1% of our total revenue in 2025, and the purchase from it amounted to RMB37.7 million, representing 18.8% of our total purchase in 2025. In 2024 and the six months ended June 30, 2026, none of our customers were also our suppliers, and none of our five largest suppliers were also our customers. Our sales to the customer-supplier was based on our provision of licensing of a commercialized product. Our procurement from the customer-supplier in 2025 was based on our agreement to partially fund a clinical program sponsored by the customer-supplier, as we expect to economically benefit from the clinical program.

As confirmed by the Frost & Sullivan, our arrangements with the customer-supplier are in line with the industry practice. We and the customer-supplier are not related to each other and do not hold any equity interest in each other or each other’s group companies.

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we held 215 patents and patent applications, 55 of which relate to our Core Products. We have full ownership of the intellectual property rights relating to the Core Products. As of the Latest Practicable Date, with respect to our Core Products, we owned 34 issued patents, including six in China, seven in the U.S., and 21 in other jurisdictions, and 21 patent applications, including eight in China, three in the U.S., one under the Patent Cooperation Treaty (“PCT”) which may enter into national phase, and nine in other jurisdictions. As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that makes us to believe that any of the pending patent applications will be rejected. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our Core Products as of the Latest Practicable Date:

Product	Name of Patent ⁽¹⁾	Type	Owner	Jurisdiction	Status	Patent Expiration ⁽²⁾
Taragarestrant (D-0502)	Selective estrogen receptor degraders and uses thereof	Invention	InventisBio	Chinese Mainland, Hong Kong, U.S., EU, Japan, Australia, Brazil, Canada, Israel, India, Korea, Mexico, New Zealand, Russia, South Africa	Granted	February 3, 2037
Taragarestrant (D-0502)	Selective estrogen receptor degraders and uses thereof	Invention	InventisBio	Chinese Mainland	Pending	N/A
Taragarestrant (D-0502)	Salts of selective estrogen receptor degraders	Invention	InventisBio	Chinese Mainland, Hong Kong, U.S., EU, Japan, Korea, Mexico	Granted	December 24, 2038
Taragarestrant (D-0502)	Salts of selective estrogen receptor degraders	Invention	InventisBio	Canada	Pending	N/A
Taragarestrant (D-0502)	Oral formulations and uses thereof	Invention	InventisBio	EU, Japan	Granted	June 18, 2041
Taragarestrant (D-0502)	Oral formulations and uses thereof	Invention	InventisBio	Chinese Mainland, Hong Kong, U.S., Australia, Canada, Korea, Mexico	Pending	N/A

BUSINESS

Product	Name of Patent ⁽¹⁾	Type	Owner	Jurisdiction	Status	Patent Expiration ⁽²⁾
D-2570	Heteroaryl compounds, preparation methods and uses thereof	Invention	InventisBio	Chinese Mainland, Hong Kong	Granted	December 22, 2041
D-2570	Heteroaryl compounds, preparation methods and uses thereof	Invention	InventisBio	U.S.	Granted	December 20, 2042
D-2570	Heteroaryl compounds, preparation methods and uses thereof	Invention	InventisBio	Chinese Mainland, U.S., EU	Pending	N/A
D-2570	Heteroaryl compounds, solid forms, preparation methods and uses thereof	Invention	InventisBio	Chinese Mainland, U.S.	Granted	June 20, 2043
D-2570	Heteroaryl compounds, solid forms, preparation methods and uses thereof	Invention	InventisBio	Chinese Mainland, U.S., Hong Kong	Pending	N/A
D-2570	Pharmaceutical composition and use thereof	Invention	InventisBio	Chinese Mainland	Granted	June 20, 2043
D-2570	Pharmaceutical composition and use thereof	Invention	InventisBio	Chinese Mainland, Hong Kong	Pending	N/A
D-2570	Method for treating psoriasis	Invention	InventisBio	PCT	Pending	N/A

Notes:

- (1) Unless otherwise indicated, the patent for applications within the same family is the same and is therefore disclosed once.
- (2) The patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

BUSINESS

We may rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our product candidates. We seek to protect our proprietary product candidates and processes, in part, by entering into confidentiality agreements with consultants, scientific advisers and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we use to employ each of our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. Please see “Risk Factors — Risks Relating to Our Intellectual Property Rights” in this Document for a description of risks related to our intellectual property.

According to the freedom-to-operate searches and analyses (“FTO Analysis”) conducted covering China and the U.S. in relation to our Core Products and darbinurad (D-0120), and covering China in relation to beforterinib (BPI-D0316) and garsorasib (D-1553), our Directors were not aware of a substantial risk of infringement in relation to the above products. China and the U.S. are the primary target markets for our Core Products in the near term. The FTO Analysis covers two fundamental aspects for FTO assessments of small molecule pharmaceuticals, namely the chemical structures and target indications of the drug candidates, which is in line with industry practice. The chemical structure-based analysis focused on the molecular structures of the drug candidates, which forms the essential basis of the implementation of the drug candidates, while the indication-based analysis focused on the specific therapeutic indications under development for the drug candidates, which is essential for the implementation of the drug candidates in the intended uses. Based on the FTO Analysis, our Directors are of the view that there are no valid and enforceable patents of any third party in China and the U.S. covering chemical structures or indications currently under development of the aforementioned drug candidates and the FTO Analysis is sufficient as to both scope of analysis and geographical coverage, having regard to our near-term plans for overseas expansion.

As of the Latest Practicable Date, we held 20 registered trademarks in Chinese Mainland and one registered trademark in Hong Kong. We are also the owner of five domain names.

During the Track Record Period and up to the Latest Practicable Date, (i) we were not involved in any material 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 regarding our product candidates; and (ii) we were not involved in any material proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on the R&D for any of our product candidates in which we may be a claimant or a respondent. Also, to the best knowledge of the Directors having made reasonable enquiries, none of our employees were in breach of any non-competition undertaking or wrongfully made use of trade secrets of their former employers.

COMPETITION

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition and a strong emphasis on proprietary drugs. While we believe our pipeline of clinical and preclinical stage proprietary assets, leading R&D capability, technology platforms and seasoned management team provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future.

BUSINESS

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 employee benefits liability and adverse events in clinical trials. We currently do not maintain insurance for environmental liability or property loss. Please refer to “Risk Factors — Risks Relating to our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.” We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

EMPLOYEES

As of June 30, 2026, we had 191 employees in total, which included (i) 88 in early research and development, (ii) 68 in clinical development, (iii) 17 in CMC, (iv) 1 in business strategy and corporate development and (v) 17 in general and administrative, representing 46.1%, 35.6%, 8.9%, 0.5% and 8.9% of our total employees, respectively.

We enter into individual employment contracts with our employees covering salaries, bonuses, employee benefits, workplace safety, confidentiality and non-competition, work product assignment clause and grounds for termination. To maintain our workforce’s quality, knowledge, and skill levels, we provide continuing education and training programs, including internal training, to improve their technical, professional or management skills. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including competitive salaries, bonuses and share-based payment, particularly our key employees.

Workplace Safety

We have adopted and maintained a series of rules, standard operating procedures, and measures to maintain our employees’ healthy and safe environment. We implement safety guidelines to set out information about potential safety hazards and procedures. We require employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. Also, we have policies in place and have adopted relevant measures to ensure the hygiene of our work environment and the health of our employees. Our PRC Legal Adviser has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to health, work safety, social and environmental protection.

PROPERTIES

As of Latest Practicable Date, we did not own real properties. We leased seven properties in Chinese Mainland with an aggregate GFA of approximately 5,844 sq.m. We did not own or lease any properties overseas. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs. As of the Latest Practicable Date, no single property interest that formed part of non-property activities had a carrying amount of 15%, and no single property interest that formed part of property activities had a carrying amount of 1% of our total assets as of June 30, 2026. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong), this Document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which requires a valuation report with respect to our Group’s interests in land or buildings.

BUSINESS

PERMITS, LICENSES AND OTHER APPROVALS

During the Track Record Period and up to the Latest Practicable Date, as advised by our PRC Legal Advisor, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations and such licenses, permits in the PRC and these certifications all remain in full effect. As advised by our U.S. Legal Advisor, the Group had obtained all requisite licenses, approvals and permits from relevant authorities that are material for InventisBio US to conduct its business in the state where its principal office is located during the Track Record Period and up to the Latest Practicable Date. 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. There is no material legal impediment in renewing such licenses, permits, approvals and certificates as they expire in the future as long as we are in compliance with applicable laws, regulations and rules. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates. The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

License/Permit	Issuing Authority	Grant Date	Expiration Date
Drug Manufacturing License	Shanghai Municipal Drug Administration	October 12, 2023	October 11, 2028

ENVIRONMENT, SOCIAL AND GOVERNANCE

Overview

We recognize our environmental protection and social responsibilities and are aware of the potential impacts that our business operations may have on various environmental and social matters. We are committed to promoting sustainable development practices, fulfilling our social responsibilities and upholding stringent governance standards, reflecting our dedication to the principles of environmental, social and governance (“ESG”). We are committed to complying with applicable ESG reporting requirements and have established the *ESG Comprehensive Management Policy* in accordance with Appendix C2 to the Listing Rules to regulate the Group’s ESG compliance.

Our ESG policy sets out the responsibilities and duties of different parties in managing ESG matters. Our Board will take primary responsibility for overseeing and identifying environmental and social risks and opportunities that may affect us, formulating and adopting our ESG policies and targets, and reviewing our performance against such targets on an annual basis. Our Board will also make appropriate adjustments to our ESG strategies if any material deviation from the established targets is identified.

A Strategy and ESG Committee has been established by our Board to provide support in the following areas: implementing ESG policies and targets; formulating and reviewing ESG strategies; executing and supervising the implementation of ESG management policies, strategies and targets across the Company, monitoring the progress in achieving targets and providing timely reports; conducting materiality assessments of ESG-related risks; continuously monitoring the implementation of the Group’s ESG risk mitigation measures; organizing the preparation of ESG reports; and carrying out ESG management and enhancement initiatives. Our Strategy and ESG Committee is required to report to our Board on the Group’s ESG performance and the effectiveness of our ESG management systems on an annual basis. We plan to introduce members with ESG expertise (or more environmental and social background) to our Board and our Strategy and ESG Committee, in order to continuously enhance the Group’s ESG management capacity and improve the Group’s ESG performance.

BUSINESS

During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material claims, penalties or accidents in relation to workplace health and safety, social or environmental protection matters. The Directors confirm that, we have complied with all relevant PRC laws and regulations in relation to workplace health and safety, social or environmental protection matters in all material aspects.

Potential Impact of ESG-related Risks and Our Solutions

We have complied with applicable laws and regulations relating to environmental protection, social, and workplace health and safety. Under the supervision of the Board, we actively identify and monitor short-term, medium-term and long-term ESG-related risks. We have adopted various strategies and measures to identify, evaluate, manage and mitigate such risks, including: reviewing and assessing the ESG reports of comparable companies in our industry to ensure timely identification of common ESG-related risks and targets. Through this benchmarking process, we seek to ensure that our ESG targets and policies remain comparable; arranging periodic discussions and meetings with management to seek to ensure that all material ESG risks are identified and reported; engaging with key stakeholders on major ESG principles and practices to seek to ensure all material issues are addressed; formulating detailed ESG risk warning systems and management measures, quantifying performance indicators, identifying and considering ESG risks and opportunities separately from other business risks and opportunities; and setting short-term and long-term targets for key environmental and social performance indicators. For example, regarding environmental matters, we set targets to reduce emissions, pollution and other environmental impacts, as well as lower consumption of natural resource, in support of China’s “30-60” dual carbon goal as a national strategy that reflects internationally recognized sustainability expectations.

Our Strategy and ESG Committee, in accordance with the disclosure requirements under Appendix C2 to the Hong Kong Listing Rules, will set targets for each major key performance indicator for each financial year. Our Board will review the relevant targets for major key performance indicators annually to ensure that such targets align with the Group’s demands. In setting the targets for key performance indicators, we will take into account relevant historical performance and carefully consider our future business expansion plan. We target to achieve balance between business growth and ESG issues to achieve sustainable development.

Among others, we have identified the following ESG risks and opportunities as material issues that may affect our business, strategies or financial performance. We have formulated and implemented strategies and internal policies and procedures to manage and mitigate such risks, and we may update such strategies and policies based on our understandings to our stakeholders’ changeable expectations. During the Track Record Period, we kept monitoring a number of ESG indicators (the key ones are set out below) to further assess and manage the environmental and social risks and opportunities arising from our business operations.

Environmental Protection

We fully recognize the potential environmental impacts arising from our business operations. We comply with applicable environmental laws and regulations, including the *Environmental Protection Law of the PRC*, to standardize and implement emissions, discharges and waste management, improve resource utilization efficiency, and fulfill our environmental responsibilities. We have formulated and implemented the *Policy on Environmental Protection and Responsibility Management* to mitigate and prevent potential risks to the environment during our operations. We have established a dedicated EHS department responsible for implementing our environmental policies and supervising environmental compliance. Furthermore, we conduct education and publicity on environmental protection laws and regulations for our employees to enhance their environmental protection awareness and conduct post-training assessments for employees in environmental protection positions. We aim to continuously strengthen the environmental management system across our R&D and production processes, ensure that the pollutant emissions

BUSINESS

comply with applicable environmental laws and regulations, and enhance employee awareness of water conservation through targeted education and publicity — thereby maintaining a strong track record in environmental regulatory compliance in all material respects.

Waste Management

We strive to operate our facilities in an environmentally protective manner. We are not classified as an enterprise in high-pollution industries; however, our product R&D process involve the use of hazardous and biological raw materials, and may discharge waste gas as well as wastewater, solid waste and hazardous waste. Accordingly, we have established and implemented various internal policies such as the *Waste Disposal and Management Policy*, the *Water Pollutant Discharge Control Procedure* and the *Atmospheric Pollutant Discharge Control Procedure* designed to mitigate environmental risks and ensure compliance with applicable national, industry and local standards, laws, regulations and policy requirements. In particular,

General Solid Waste: We collect, store and dispose of general solid waste in accordance with applicable laws and regulations.

Hazardous Waste: Pursuant to the *National Hazardous Waste List* and our Environmental Impact Assessment document, our hazardous waste includes medical waste generated during experiments, laboratory waste, waste activated carbon and waste filter screens. Those hazardous waste would be collected and processed by qualified third-party waste disposal companies. Where necessary, we will first decontaminate such waste prior to transfer to the disposal companies. The waste disposal companies would issue us written records for the transfer of hazardous waste, which we would retain for internal audit and compliance inspection purposes. We have established management processes and conduct training and assessments on knowledge and skills related to the collection and transfer of hazardous waste for newly recruited employees.

Wastewater: Our wastewater is disposed through process technologies and discharged into the municipal sewage pipeline network via the total discharge outlet; domestic sewage is discharged through the specific sewage pipeline network of the industrial park where we are located. Meanwhile, we conduct wastewater discharge monitoring and operational inspections of treatment facilities designed to ensure stable compliance with discharge standards, such as the *Integrated Wastewater Discharge Standard*.

Waste Gas: We control the emission volume of factory waste gas. We utilize activated carbon absorption and filtration technologies to absorb hazardous gaseous pollutants from our waste gas and maintain a treatment efficiency of not less than 95%, ensuring compliance with emission standards, including the *Emission Standard of Air Pollutants for Pharmaceutical Industry*, the *Integrated Emission Standard of Air Pollutants* and the *Emission Standards for Odor Pollutants*.

Noise: The main equipment that generates noise includes laboratory equipment and fans. By adopting corresponding noise prevention and control measures, optimizing the spatial arrangement of such equipment, and leveraging attenuation through spatial distance, the factory noise emissions comply with the Class 2 standard emission limit requirements specified in the *Emission Standards for Industrial Enterprise Boundary Noise*.

During the Track Record Period and up to the Latest Practicable Date, we have not been imposed with penalties whatsoever for the violation of any environmental laws or regulations in all material aspects. The total amount of hazardous waste generated and disposed of at our principal place of operation (Chinese Mainland) was as follows:

Indicator		For the year ended December 31,		For the six months ended June 30,
		2024	2025	2026
Hazardous Waste ¹	Medical Waste (tons)	1.12	0.85	0.40
	Other Hazardous Waste Excluding Medical Waste (tons)	53.57	42.91	28.72

BUSINESS

Indicator		For the year ended December 31,		For the six months ended June 30,
		2024	2025	2026
General Solid Waste²	Emissions (tons)	0.21	0.20	0.10
Exhaust Gas	Emissions (hundred million cubic meters)	2.458	2.129	0.967

Notes:

- 1 Hazardous waste generated from our business activities primarily includes organic laboratory waste liquids, solid laboratory waste (including reagent bottles, laboratory gloves, glassware contaminated with chemicals, etc.), waste activated carbon and waste chemical reagents.
- 2 General solid waste generated from our business activities primarily includes waste cardboard boxes, waste plastic packaging, and waste foam packaging.

Besides, we engage external maintenance service providers to conduct periodic maintenance on our environmental protection facilities on an annual basis, and repair or upgrade such facilities as needed. We invested approximately RMB12,000 and RMB235,000, respectively in 2024 and 2025 for the maintenance and upgrading of environmental protection facilities.

Consumption of Resources

To achieve our sustainable development objectives, we monitor our environmental performance in areas such as resource utilization efficiency and energy consumption. We also formulate environmental management plans to continuously enhance energy efficiency. We also seek to ensure that all operational activities comply with relevant government environmental laws and requirements, with the aim of avoiding or mitigating any adverse impact of our operations and services on the environment.

We have established a series of measures to monitor our electricity and water consumption levels and have adopted initiatives to improve energy efficiency. During the Track Record Period, the total amount of purchased electricity and water resources consumed at our principal place of operation (Chinese Mainland) was as follows:

Indicator		For the year ended December 31,		For the six months ended June 30,
		2024	2025	2026
Electricity Consumption	Total Electricity Consumption (MWh)	1,258.5	1,125.2	508.9
Water Consumption	Total Water Consumption (tons)	2,074	1,376	554

Note:

- 1 Our overseas entities are not involved in energy-intensive operations such as factories and have a relatively small workforce; therefore, they are currently excluded from resource consumption.

Climate Change

We understand that climate change may not have a direct negative impact on our business operations. Notwithstanding, climate change has become a key factor on the global economy and industrial development, and the green and low-carbon transition is now a key driver of sustainable social development — for instance, China’s “30-60” dual carbon goal is a national strategy that

BUSINESS

strengthens this trend. We believe that future regulatory trends and stakeholder expectations may impose stricter requirements on us, such as those related to carbon emission reduction or carbon footprint disclosure. As a matter of fact, we plan to systematically identify and assess climate-related risks and opportunities, by aligning with the “30-60” goal’s timeframe and objectives, to mitigate the impacts arising from climate change and extreme weather events.

Through the formulation and implementation of our “*Policy on Low-carbon Development and Climate Change Response*”, we have incorporated climate-related issues (including physical risks and transitional risks) into our risk assessment process and actively respond to climate change. During the Track Record Period and up to the Latest Practicable Date, we were not materially affected by climate-related matters, nor did we incur any material capital expenditure or compliance costs in this regard. In terms of actual risks, extreme weather events such as floods, rainstorms, and blizzards may disrupt utility supplies, cause system failures, or lead to data loss, thereby impacting our operational continuity and the stability of product delivery. Regarding transitional risks, evolving climate policies and tightening regulatory requirements may increase our compliance costs and investments in internal systems.

To further mitigate the impact of climate change, we periodically review and analyze statistics of carbon emissions generated from our business operations. Based on the tracking and verification of emission indicators, we actively take actions and explore solutions to reduce carbon emissions. We aim to proactively conduct carbon footprint tracking and explore the potential for decarbonization across all stages of our business operations, contributing to the China’s “30-60” dual carbon goal. At our principal place of operation (Chinese Mainland), we conducted a preliminary assessment and accounted for greenhouse gas (“GHG”) emissions in accordance with the *GHG Protocol Corporate Accounting and Reporting Standards*, covering Scope 1 and Scope 2 emissions. We plan to identify our boundaries of Scope 3 emissions gradually and calculate Scope 3 emissions as a part of our GHG emissions verification and accounting process when practicable. Scope 1 emissions refer to direct greenhouse gas emissions primarily from direct energy consumption in our operations. Scope 2 emissions refer to indirect greenhouse gas emissions primarily from purchased electricity consumption.

During the period from 2024 to 2025, we maintained a stable greenhouse gas emission intensity ranging from 3.28 to 3.67 tons of CO₂ equivalent per person. This performance is broadly in line with our industry peers who, similar to us, do not operate commercial-scale manufacturing facilities. Our greenhouse gas emission intensity is lower than that of industry peers with established typical commercial-scale production, primarily due to our current business model and the lower energy consumption profile associated with our operations.

The following table sets forth our Scope 1 and Scope 2 greenhouse gas emissions at our principal place of operation (Chinese Mainland) during the Track Record Period:

Indicator	For the year ended December 31,		For the six months ended June 30,
	2024	2025	2026
Greenhouse Gas Emissions¹			
Scope 1 Greenhouse Gas Emissions <i>(tons of CO₂ equivalent)</i>	0.00	0.00	0.00
Scope 2 Greenhouse Gas Emissions <i>(tons of CO₂ equivalent)</i>	667.76	597.03	270.02
Total Greenhouse Gas Emissions per Employee (tons of CO₂ <i>equivalent/person)²</i>	3.67	3.28	1.41
Year-on-year Change in Total Greenhouse Gas Emissions per Person	0.10	(0.11)	–

BUSINESS

Notes:

- 1 We calculate total greenhouse gas emissions for Chinese Mainland based on carbon emission factors recorded in government documents of the PRC such as the China Energy Statistical Yearbook and the Announcement on the Publication of 2023 Power Carbon Dioxide Emission Factors. Besides, our overseas entities are not involved in energy-intensive operations such as factories and have a relatively small workforce; therefore, they are currently excluded from greenhouse gas emission statistics and calculations.
- 2 Given the direct and stable correlation between the number of R&D personnel and our core R&D activities, as well as its primary sources of carbon emissions (e.g., laboratory energy consumption), we believe that carbon intensity per employee (i.e., total carbon emissions divided by the total number of employees) serves as the representative indicator. This metric better reflects our efficiency in managing operational carbon emissions and provides more comparable and material environmental performance information.

Identification of Scope 3 Emissions

In the future, we will gradually expand the data collection coverage of Scope 3 emission and continuously improve data quality and transparency. As the data collection mechanism is further refined, we plan to release a more detailed Scope 3 emissions inventory in the future, including a breakdown of emissions by type and key emission reduction targets. We expect to initiate the assessment of Scope 3 greenhouse gas emissions in 2027 if data availability and measurement methodologies evolve.

Social Responsibility

Employment and Care

We enter into employment contracts with our employees in accordance with applicable laws and regulations, including the Labor Law of the PRC and the Labor Contract Law of the PRC, the Fair Labor Standards Act in the U.S., etc. We have also established internal policies such as the *Employee Handbook* and the *SOP on Training*. We adhere to the principles of legality, fairness, equality, voluntariness, mutual consent and good faith, and recruit employees based on merit. We actively protect the rights of our female employees and strictly prohibit the use of child labor in any of our business operations. During the Track Record Period, the number of our employees and their composition were as follows:

Indicator	For the year ended December 31,		For the six months ended June 30,
	2024	2025	2026
Number of Employees . . .			
Male Employees (persons)	78	77	84
Female Employees (persons)	104	105	107
By Geography . .			
Employees in Chinese Mainland (persons)	179	179	188
Employees in Hong Kong, Macau, Taiwan and Overseas (persons)	3	3	3
By Age Group . .			
Below 30 years old (persons)	46	35	34
30 to 50 years old (persons)	127	138	147
Above 50 years old (persons)	9	9	10

Welfare and Benefits

We are dedicated to offering competitive remuneration packages to attract and retain employees. We provide appealing benefits and care initiatives, including marriage and childbirth benefits, festive gifts and community activities. We also provide our employees with subsidies for meals, transportation and communication to facilitate their daily work and life. In addition, we offer

BUSINESS

annual health check-ups, personal accident insurance and other medical benefits to safeguard our employees’ physical and mental health. We aim to cultivate an environment where employee growth and corporate advancement are mutually reinforcing, enabling individuals and the organization to thrive together.

Diversity is a core value of the Group. We are dedicated to creating an inclusive and supportive working environment where each employee’s personalities and differences are respected, with their dignity being upheld. By establishing the *Employee Diversity Policy*, we promote gender equality and gender diversity within our workforce, and provide equal opportunities in areas such as recruitment, training and development, remuneration, and career and promotion opportunities. Furthermore, from time to time, we provide training to employees on topics related to diversity and inclusion, ensuring that our vision and goals for diversity, equity and inclusion are accessible and understandable to all employees.

Our Board considers membership diversity as a key factor in upholding corporate governance standards and enhancing the effectiveness of the Board’s decision-making. We have formulated the Board Diversity Policy as an important guideline. The nomination and appointment of Board members will depend on our business development and risk management needs, by considering factors such as gender, age, cultural background, educational background and professional experience, to ensure a reasonable balance of skills, experience and perspectives on the Board and inject diverse wisdom into our strategic decision-making.

Clinical Trial Subject Safety

Regarding clinical trial subjects, we strictly adhere to the requirements of the Good Clinical Practice (“GCP”) and have established a full-process, systematic data protection system to effectively safeguard the legitimate rights and interests as well as data security of the subjects. We aim to strictly enforce clinical trial risk control mechanisms, promote high standards of subject protection, and preserve the core rights and interests of patients and clinical trial participants.

During the informed consent process, we provide the subjects (or their guardians) with comprehensive and detailed information on the purpose, procedures, potential risks and rights protection measures of the clinical trial in clear and understandable language, ensuring that the subjects sign the informed consent form on the basis of full informed decision and voluntary choice. For subject-related data, we adopt encrypted storage and hierarchical management mechanisms to strictly prevent data leakage or misuse.

In the context of outsourced R&D services, we impose strict compliance requirements on contracted institutions, clarify their data protection responsibilities, and seek to ensure that the entire chain of subject data management complies with regulatory standards to protect the rights and interests and data security of the subjects. We do not use animals in our R&D activities.

Animal Welfare

We are dedicated to complying with applicable domestic and international animal welfare laws and regulations, and managing necessary animal testing in accordance with the internationally recognized “3Rs” principle (Replace, Reduce, Refine). Such testing is conducted only where required by applicable laws and regulations or where scientifically essential and no viable alternatives exist, whether carried out internally or commissioned to qualified third-party organizations. Any such testing is subject to prior approval by an Institutional Animal Care and Use Committee (“IACUC”), with veterinary oversight of animal welfare throughout the process. The animal housing facilities we use for internal testing hold valid Laboratory Animal Use Permits. The animal housing facilities used for such testing are compliant, with controlled temperature, humidity, and ventilation, regular testing of feed and drinking water to ensure safety, and environmental enrichment measures in place. All practices adhere to applicable domestic and international animal welfare standards, including China’s Regulations on the Administration of Laboratory Animals.

BUSINESS

Workplace Safety

Since hazardous substances and biological materials are used during our production process, we place significant emphasis on workplace safety matters in our operation. We have adopted and maintained a series of rules, standard operating procedures and measures to safeguard a healthy and safe working environment for our employees, ensuring that our operations comply with applicable workplace safety regulations in the jurisdictions where we operate. Specifically, we: establish various policies, such as the *Work Safety Responsibility Policy*, *Safety Education and Training Management Policy*, *Occupational Disease Prevention and Control Responsibility Policy* and other procedures and guidelines, for the use, storage, handling, and disposal of hazardous substances and hazardous waste; given that our R&D process involves the use of biological materials such as adenoviruses, we further formulate the *Biosafety Manual* to establish dedicated control procedures, and have developed laboratory safety standards in compliance with applicable laws, so as to minimize the risk of employees' exposure to biological hazards; conduct periodic assessments of occupational health hazards and safety risks, and implement protective measures; follow the regulatory requirements and procedures when conducting experiments involving hazardous materials or hazardous chemical reactions; install appropriate safety and occupational protection facilities in workplaces, provide employees with necessary personal protective equipment, and supervise its appropriate use; conduct employee safety training; establish health records for all employees and provide annual physical examination benefits on a yearly basis; conduct pre-employment, on-the-job, and post-employment occupational disease health examinations for employees engaged in work involving occupational hazards; and conduct periodic fire safety inspections, seek to ensure the maintenance of fire-fighting equipment, organize daily emergency drills, and seek to enhance employees' emergency response capabilities.

To ensure compliance with applicable laws and regulations, our human resource and EHS department would consult our legal advisers, when necessary, to adjust our human resource as well as workplace health and safety policies in response to material changes in labor and safety laws and regulations. In the event of a workplace injury, we would intervene promptly to ensure that the affected employee receives immediate assistance and care. During the Track Record Period and up to the Latest Practicable Date, no material incidents occurred to us regarding the use of hazardous or toxic substances, health or safety.

Anti-corruption and Anti-bribery

We have formulated and implemented a series of policies, such as the *Anti-Bribery, Anti-corruption Policy* and the *Implementation Rules for Interactions with Third-Party Personnel or Organizations*, designed to ensure that our operations comply with applicable anti-bribery and anti-corruption laws and regulations in the jurisdictions where we operate. These policies set out potential bribery and corruption acts, our anti-bribery and anti-corruption measures, and reporting procedures. Prohibited improper payments and hospitality activities under these policies include bribes, kickbacks, excessive gifts or facilitation fees, or any other payments made or offered to obtain undue business advantages. We will investigate reported incidents and take appropriate actions where necessary. We also conduct background checks prior to the engagement of any third party and conduct ongoing monitoring to seek to ensure that the collaboration or hiring process is carried out in full compliance with our anti-bribery and anti-corruption policies. In addition, we provide training to our employees on anti-bribery and anti-corruption policies to strengthen the effective implementation of such policies.

Product Quality and Safety

We are deeply aware that our products are directly related to human health. To this end, we are dedicated to comply with the laws and regulations governing drug safety and clinical trials of pharmaceuticals, and have established a pharmacovigilance system designed to ensure drug quality and safety. Specifically, we have formulated and implemented a series of policies and procedures covering clinical trials, pharmacovigilance and quality audits, spanning from the product R&D phase to the post-marketing phase, designed to ensure the safety of our products. Such policies and

BUSINESS

procedures include, but are not limited to, the *SOP for the Clinical Trial Drug Safety Management Plan*, the *SOP for Clinical Quality Audit* and the *Emergency Plan for Drug Safety Issues (Investigation of Death Cases and Cluster Events)*. According to these policies, we (i) monitor adverse events related to drugs and drug candidates in clinical trials and accurately record event information for each trial; (ii) analyze the collected adverse events and assess relevant safety risks; (iii) report adverse events and potential safety risks; and (iv) communicate with relevant employees to ensure the implementation of clinical trial protocols. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any material claims or penalties in relation to product safety issues, major defects or malfunctions, or false advertising in all material aspects, and we have complied with applicable laws and regulations in all major respects.

Supply Chain Management

Even though we do not directly manufacture products or conduct clinical trials, we consider product quality and patients’ and clinical trial participants’ health and safety as core priorities. We require our suppliers (including clinical trial-related service providers such as CROs, SMOs, system service providers, laboratory testing institutions, and drug warehousing and courier service providers, etc.) to comply with laws, regulations and normative standards such as the *Drug Administration Law of the PRC*, the *Regulations for the Implementation of the Drug Administration Law of the PRC*, the *Measures for the Supervision and Administration of Pharmaceutical Distribution and Use Quality*, the *Good Manufacturing Practices for Pharmaceuticals* and its appendices, to seek to ensure that the products or services they provide comply with the requirements related to data integrity, patient safety and product quality, and that they establish and continuously improve a comprehensive quality management system.

We have established and implemented several supplier management policies, including the *SOP of Vendor Management* to specify the due diligence procedures, selection criteria, approval processes, and performance management when selecting and managing our service-providing partners. Our major suppliers are listed companies or large CROs/CDMOs that adhere to and operate their own quality management and ESG-related systems. In the process of supplier selection and management, we take into account their ESG-related performance. Through business collaboration and routine communication, we convey our requirements on clinical drug safety and pharmacovigilance requirements to them, and require them to assist us in identifying drug-related risks so that to ensure the compliance and safety of the entire clinical trial chain, jointly safeguard the rights and interests of patients as well as the quality of clinical research, and enable us to intervene promptly in the event of drug safety incidents. We are dedicated to continuously strengthening supplier management and establishing long-term partnerships with vendors that deliver good services, so as to ensure products and services procured through our supply chain comply with applicable laws, regulations and quality requirements.

Data Privacy and Personal Information Protection

We have established and implemented internal policies such as Clinical Data Review and Clean, Set-up and Maintenance of Electronic Data Capture Database to protect our data and information, designed to ensure compliance with all applicable national and international data protection and privacy laws and regulations. We strive to prevent unauthorized access, processing, or deletion of employees’ personal information, and have adopted appropriate physical, electronic, and administrative measures to safeguard such data.

LEGAL PROCEEDINGS AND NON-COMPLIANCE

Legal Proceedings

During the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened material legal or administrative proceedings. We are committed to maintaining the standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

BUSINESS

We were previously involved in several lawsuits with Mirati Therapeutics Inc. (“Mirati”), Beta Pharma Inc. (“Beta US”) and Beta Pharma (Shanghai) (“Beta Shanghai”). Beta US is Beta Shanghai’s affiliated entity in the U.S. (collectively, “Beta entities”). We, Betta and Beta entities are independent from each other and share no affiliation. These lawsuits, as described below, have been finally resolved in our favor. As such, our Directors are of the view that these lawsuits are not expected to have a material adverse impact on the Group’s financial and operational performance. Based on the due diligence conducted by the Sole Sponsor, nothing has come to the Sole Sponsor’s attention that would reasonably cause the Sole Sponsor to disagree with the Directors’ view that these lawsuits are not expected to have a material adverse impact on the Group’s financial and operation performance.

In 2022, Mirati filed a lawsuit in Shanghai, China, alleging we misappropriated Mirati’s trade secret regarding certain compounds. The Shanghai court dismissed the lawsuit in 2024 in its entirety and rejected Mirati’s appeal in 2025. Mirati has not initiated any further legal proceedings related to the lawsuit.

In 2022, Beta Shanghai filed a lawsuit in Shanghai, China, alleging we and Betta misappropriated Beta Shanghai’s trade secret regarding certain compounds. In 2023, Beta Shanghai withdrew the lawsuit and did not subsequently refile.

In 2023, Beta US filed a lawsuit in New Jersey, U.S., alleging we misappropriated Beta’s trade secret regarding certain compounds. The New Jersey court dismissed the lawsuit in 2024 in its entirety. Beta US has not filed any appeal or initiated any additional legal proceedings in connection with the lawsuit.

Legal Compliance

According to our PRC Legal Adviser, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operation. Our Directors confirmed that we had complied with all material applicable laws and regulations for our operations in the PRC and the U.S. and we were not involved in any material or systemic non-compliance incidents in the PRC and the U.S. As advised by our U.S. Legal Advisor, the Group has been in material compliance with the U.S. laws or regulations applicable to InventisBio US in the state where its principal office is located during the Track Record Period and up to the Latest Practicable Date. Our management team is responsible for building, developing and improving our compliance management system to ensure our compliance culture is embedded into our everyday workflow. We conduct compliance training for our employees and identifies, assesses, and reports compliance risks and expectations in a timely manner. Our senior management team monitors and evaluates the effectiveness of our compliance function and structure to ensure that we comply with applicable laws and regulations.

Non-compliance

Our employees’ remuneration comprises salaries, bonuses, provident funds, social security contributions, and other welfare payments. We have made contributions to our employees’ social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations. We have complied with all statutory social security insurance fund and housing fund obligations applicable to us under the laws and regulations in China in all material aspects during the Track Record Period and as of the Latest Practicable Date, except that we did not make full social security insurance contributions for 2 employees who are not PRC citizens out of their own preference, which we estimate to be approximately RMB0.7 million. We currently plan to make full social insurance contributions for our employees by the second half of 2027. During the Track Record Period, we also engaged a third-party human resources agency to pay social insurance premium and housing provident funds for 12 employees. As of the Latest Practicable

BUSINESS

Date, (i) these employees had confirmed such arrangement and had raised no objections in relation thereto; (ii) there had been no disputes between us, such employees and/or the third-party human resources agency with regard to such arrangement, as the case may be; and (iii) we had not received any notice of rectification from, or been imposed any administrative penalty by, the relevant governmental authorities as a result of such arrangement or nonpayment for employees who are not PRC citizens. As advised by our PRC Legal Advisor, taking into consideration the above, the risk of us being subject to material penalties as a result of not paying social insurance premium for employees who are not PRC citizens, or paying the social insurance premium and housing provident funds for the relevant employee through the third-party agency, which thus have a material adverse effect on our financial condition or results of operations taken as a whole, is relatively low. Furthermore, with regard to Interpretation II of Labor Dispute Cases, our PRC Legal Advisor is of the view that the Interpretation is not expected to have a material adverse effect on our financial position and business based on the followings: (i) the estimated maximum potential penalty for our social insurance contribution shortfalls during the Track Record Period will not increase as a result of the Interpretation, as shortfalls arising from employee voluntary elections or mutual agreements have already been factored into such calculations; and (ii) the Interpretation has neither repealed nor amended the social insurance laws and regulations currently in force in the PRC. Please refer to the section headed “Risk Factors — Risks Relating to Doing Business in Jurisdictions Where We Operate — We are subject to risks in relation to our social insurance and housing provident fund contributions” in this Document.

As of the Latest Practicable Date, due to the difficulty of procuring our lessors’ cooperation to file such leases, five of our lease agreements for properties in China had not been registered with relevant authorities in China. Our PRC Legal Advisor is of the view that the non-registration of lease agreements will not affect the validity of the lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and if we fail to so rectify, we may be subject to a fine of between RMB1,000 and RMB10,000 for each of these leasing properties. During the Track Record Period and up to the Latest Practicable Date, we had not received any order from the relevant government authorities requiring us to register these lease agreements, and no administrative penalty had been imposed on us for non-registration of these lease agreements. We plan to comply with and are preparing the lease agreement registration requirement regarding our lease agreements. However, as the filing of the lease agreements requires the coordination of both lessors and lessees, the lessors may not cooperate and complete the registration in a timely manner. For further details, please see the sections headed “Risk Factors — Risks Relating to Doing Business in Jurisdictions Where We Operate — We are subject to risks associated with our leased properties.”

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We have prepared written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code and Corporate Governance Report as set out in Appendix C1 to the Listing Rules. To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures: establish an Audit Committee to review and supervise our financial reporting process and internal control system; adopt various policies to ensure compliance with the Listing Rules, including aspects related to risk management, connected transactions and information disclosure; provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations; and attend training sessions by our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies [REDACTED] in Hong Kong.

BUSINESS

Internal Control

We have employed an independent internal control consultant to assess our internal control system in connection with the [REDACTED]. We had improved our internal control system by adopting and implementing the corresponding enhanced internal control measures. Going forward, we will continue to regularly review and improve these internal control policies, measures and procedures.

We have also appointed external legal counsel to advise us on compliance matters, such as compliance with the regulatory requirements on clinical R&D, which is also monitored by our legal compliance team. Under our whistle blowing policy, we make our internal reporting channel open and available for our employees to report, on an anonymous basis, any non-compliance incidents and acts, including bribery and corruption. Reported incidents and persons will be investigated and appropriate measures will be taken in response to the findings. We have also established anti-bribery guidelines and compliance requirements. After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations. We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant laws and regulations regularly to proactively identify any concerns and issues relating to any potential non-compliance.

Anti-bribery

We maintain a strict code of conduct and anti-corruption policies among our employees and distributors. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses should be rejected and promptly reported. Misleading, incomplete or false entries in our books and records are never acceptable. We will also ensure that future commercialization team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

We have adopted comprehensive internal control measures for anti-corruption and anti-bribery by (i) providing regular anti-corruption and anti-bribery compliance training for senior management and employees, including daily compliance team meeting, annual compliance training and other ad hoc compliance training sessions, to enhance their knowledge and compliance with applicable law and regulations; (ii) monitoring books, records and accounts with respect to supplier management, tendering and bidding process management and financial payment management to identify any false, misleading or undisclosed entries; (iii) establishing whistle-blowing mechanisms and encouraging all employees, suppliers, customers and other third parties to report suspicious activities and violations of the policies.

Conflict of Interest and Non-Competition

Our code of conduct clearly defines the scope of conflicts of interest, including supplier and customer relationships, hospitality and gifts, financial interests and personnel matters. Our employees, including our Directors and R&D team members, may not have or be suspected of having a personal interest in business dealings with our suppliers, customers, competitors or distributors; accept monetary, financial or other benefits from our suppliers, customers, competitors or distributors; have close relatives who work for our suppliers, customers, competitors or distributors; serve as a consultant or director in an association or company in the same market or industry. At the same time, employees shall keep confidential information strictly confidential and agree on the definition of confidential information, the content covered, the use of intellectual properties, including any transfer of know-how, acquisition of technologies, and potential breach liabilities.

BUSINESS

Our employee agreements have included non-competition clauses, which prohibit employees from engaging in or directly or indirectly assisting any third party to engage in the same, similar and competitive business activities as ours for a period of two years from the date of termination of employment. Any of our employees shall not, without our prior written approval, own, manage, operate or control any other entity that competes with us.

Data Privacy Protection

We have established procedures to protect the confidentiality of patients’ data. During clinical operations, we collect de-identified personal data from clinical trial participants, including weight, height, prior treatment records, and disease conditions. Such patient data are used solely for our clinical development efforts. We implement strict internal policies to govern the collection, handling, storage, retrieval of, and access to our patients’ personal data and medical records and protect the security and confidentiality of personal information to ensure compliance with all applicable national or international rules and regulations on data protection and privacy. We usually require our personnel to collect and safeguard personal information in their possession. Our information technology network is configured with multiple layers of protection to secure our databases and servers. We have also implemented a variety of protocols and procedures to safeguard our data assets and prevent unauthorized access to our network. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel. In order to strengthen the management of our database, ensure the normal and effective operation of the database, and ensure the security of the database, we have designated database administrator to carry out the responsibilities of daily maintenance, authority control, security protection and other management of the database. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the informed consent form.

Furthermore, we enter into confidentiality agreements with our employees who have access to any aforementioned privacy information. The confidentiality agreements provide that, among other things, these employees are legally obligated not to misuse the confidential information while in office, to surrender all confidential information in possession while resigning, and to retain their confidential obligations after they leave office. We also implement a series of measures to ensure our employees’ compliance with our data security measures. For instance, we provide training to our employees on relevant data security policies.

Following the ICH GCP guidelines, we collected de-identified health-related information of subjects in our clinical trials, which included demographics, medical history, current medical conditions, medication history, laboratory test results, imaging data, electrocardiograms, adverse events, and efficacy data. The collected information was used for our clinical research, including preparation of clinical study reports and regulatory submissions. Such information was also used for preparing scientific publications and conference presentations.

We have implemented robust internal control measures and policies to ensure the security of personal data, including the protection of sensitive information of employees, customers, and partners, in compliance with relevant laws such as the General Data Protection Regulation (“GDPR”). Such measures and policies include: access controls — access is granted on a need-to-know basis using role-based access controls; encryption and storage — all personal data at rest and in transit is encrypted; training and Awareness — employees undergo mandatory training on data privacy policies, including handling personal information and recognizing phishing threats, which are integrated into the HR management framework to foster a culture of compliance; vendor and third-party management — contracts with external parties include data protection clauses requiring adherence to our privacy standards.

When a suspected or known violation or breach of data protection clauses occurs in contracts with external parties, we will activate a structured response process: incidents are promptly reported to the data protection/privacy officer or compliance team, followed by an initial assessment and immediate containment actions (e.g., revoking access or isolating systems); minor issues are

BUSINESS

managed at the operational level, while serious or material breaches escalate to senior management and, if necessary, the Board of Directors; a formal investigation is conducted – often with partner cooperation and possible external expertise – leading to root cause analysis and required remediation plans; we enforce contractual rights to demand notification, corrective actions, and cooperation on regulatory reporting (*e.g.*, to authorities under GDPR); depending on severity, responses may include enhanced monitoring, suspension of activities, payment withholding, contract termination, or legal action, followed by a post-incident review to strengthen controls and prevent recurrence.

We engage in limited cross-border data transfers, primarily related to international R&D collaborations and clinical trials, which may involve sharing data with partners in regions like the U.S. To ensure security, transfers are conducted under approved mechanisms, such as standard contractual clauses or adequacy decisions, in line with GDPR requirements.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any breach of confidential client information or any other client information-related incidents which could cause a material adverse effect on our business, financial condition or results of operations. During the Track Record Period and up to the Latest Practicable Date, we did not experience any leakage or material losses of patient data or other personal data in all applicable jurisdictions. As confirmed by our directors, we had neither incurred any related administrative penalties nor received any related administrative inquiry notice in all applicable jurisdictions. Our PRC Legal Adviser have confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to data privacy and cross-border data transfers, and had been in compliance with the relevant PRC laws and regulations in all material aspects in this regard.