OVERVIEW

We are a biotechnology company focused on the research, development and commercialization of cell therapies for the treatment of solid tumors. We focus on developing TIL therapies that do not require high-intensity lymphodepletion chemotherapy or IL-2 administration, are designed to address both cold and hot tumors, utilize a time-segmented manufacturing process and eliminate feeder cells during manufacturing. Our Core Product candidate, GC101, is the world's first tumor-infiltrating lymphocyte (TIL) therapy that does not require high-intensity lymphodepletion chemotherapy or the use of IL-2 administration, according to Frost & Sullivan. According to Frost & Sullivan, we have obtained the first manufacturing certificate for TIL therapies in China. Subject to successful clinical development and regulatory approval, GC101 may become the first domestically approved TIL therapy in China.

Driven by the clinical needs in solid tumor treatment, we are committed to developing the next generation immunotherapies. Our product pipeline covers both high-incidence and difficult-to-treat solid tumors and includes product candidates at different stages of development.

Unmet Clinical Needs in Solid Tumor Treatment

Cancer, particularly solid tumors, imposes a significant burden on patients, families, and healthcare systems worldwide. Globally, nearly 20 million new cancer cases are diagnosed each year, with solid tumors representing more than 90% of all cases. In 2025, new solid tumor cases reached approximately 20.5 million worldwide, indicating substantial clinical demand. The global oncology drug market has expanded in recent years, reaching RMB2,000.0 billion in 2025, and is projected to grow to RMB3,131.4 billion by 2030 and RMB4,909.9 billion by 2035. In China, the market reached RMB279.1 billion in 2025 and is expected to increase to RMB504.0 billion by 2030 and RMB980.0 billion by 2035.

Immune checkpoint inhibitors (ICIs), including PD-(L)1 antibodies, exert their therapeutic effect by activating TILs within the body and have demonstrated clinical utility across multiple solid tumor types. They are widely used as part of combination treatment. However, PD-(L)1 antibodies act through a single pathway and may not fully activate TILs, resulting in an objective response rate (ORR) of approximately 20% when used as monotherapies, based on data from 28,304 patients across 160 prospective trials as reported in a published article[1]. Although dual- and multi-target ICIs have been developed, they may have limited *in vivo* adaptability and may increase the risk of adverse effects.

TIL therapy involves isolating TILs from a patient's tumor tissue, expanding and activating them *ex vivo*, and infusing them to induce an anti-tumor immune response. *Ex vivo* activation enables functional enhancement of TILs and may improve clinical response. As a cell-based therapy, TILs may exhibit *in vivo* adaptability. With tumor reactivity and tumor-homing properties, TILs can target tumor cells and provide anti-tumor activity. TIL therapy has been studied in solid tumors and has demonstrated clinical activity in certain settings.

TIL therapy is not dependent on fixed tumor targets and may have potential applicability across multiple tumor types and disease stages. It may also be used in combination with other treatment modalities. Based on these characteristics, TIL therapy represents an additional therapeutic approach within cancer immunotherapy following the adoption of PD-(L)1 antibodies.

1 Zhao, B., Zhao, H., & Zhao, J. (2020). Efficacy of PD-1/PD-L1 blockade monotherapy in clinical trials. *Therapeutic advances in medical oncology*, *12*, 1758835920937612.

Path to Developing Differentiated and Commercially Competitive TIL Therapies

A single dose of TIL therapy has shown the potential to produce durable responses in some patients with advanced cancer. Clinical data indicate that TIL therapy may provide sustained clinical benefits across multiple solid tumor types, including advanced melanoma, NSCLC, breast cancer, cholangiocarcinoma, cervical cancer, endometrial cancer, HNSCC, and gastrointestinal tumors. According to a published journal article[2], in a pooled analysis of 410 heavily pretreated patients with advanced melanoma, the ORR was 41% and the complete response rate (CRR) was 12.0%. After a median follow-up of 40 months, 96.4% of patients who achieved a complete response remained in remission.

TIL therapy is a personalized treatment modality. While it has demonstrated clinical activity, its limitations include a complex manufacturing process and clinical protocols, which contribute to higher costs and limited accessibility. To improve accessibility, we have introduced modifications in both production and clinical application, including efforts to streamline the production process and simplify the treatment regimen to support broader use. To date, certain patients with advanced cancer have achieved complete tumor clearance, with the longest observed tumor-free survival exceeding four years.

We seek to improve accessibility and affordability across three dimensions.

- From a production perspective, we have developed a proprietary TIL production process that does not require high-concentration IL-2 or feeder cells (irradiated human peripheral blood mononuclear cells from multiple donors). This approach is applicable to 30 types of both "cold" and "hot" tumors and have reduced reliance on IL-2 and associated manufacturing complexity and cost.

- From a clinical perspective, because the TILs expanded *ex vivo* are designed to be IL-2 independent, patients do not require IL-2 injections (which carry boxed warnings) or high-intensity lymphodepletion (which involves high-dose chemotherapy to deplete the patient's extramedullary lymphocytes). Treatment may therefore be administered in less intensive hospital settings with shorter discharge times, which may improve tolerability and reduce overall treatment cost.

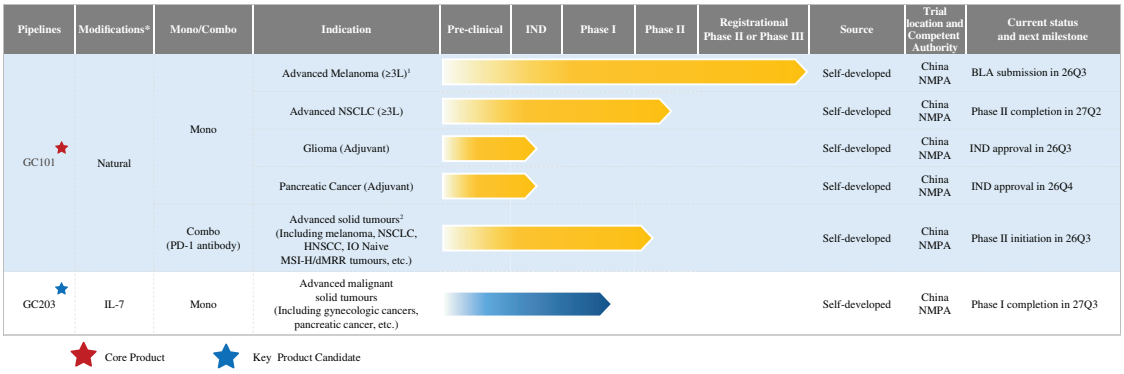
- From a commercialization perspective, we have developed a time-segmented TIL production process that involves collecting tumor tissue when surgery is feasible, producing seed TILs (a small population of expanded TILs), and storing them for later use. This approach is intended to address challenges such as surgical sampling in late-line patients and potential decline in TIL quantity and quality at advanced stages, and may improve accessibility of TIL therapy and support earlier use in the treatment process.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT.

2 Dafni, U., Michielin, O., Lluesma, S. M., Tsourti, Z., Polydoropoulou, V., Karlis, D., Besser, M. J., Haanen, J., Svane, I. M., Ohashi, P. S., Kammula, U. S., Orcurto, A., Zimmermann, S., Trueb, L., Klebanoff, C. A., Lotze, M. T., Kandalaft, L. E., & Coukos, G. (2019). Efficacy of adoptive therapy with tumor-infiltrating lymphocytes and recombinant interleukin-2 in advanced cutaneous melanoma: a systematic review and meta-analysis. *Annals of oncology : official journal of the European Society for Medical Oncology*, *30*(12), 1902-1913.

Development of TIL and Pan-Tumor Therapies

According to Frost & Sullivan, we obtained the first manufacturing certificate for TIL therapies in China. Our pipeline includes multiple product candidates targeting solid tumors at different stages of clinical development. Our pipeline includes multiple product candidates at different stages of clinical development, covering high-incidence tumors such as lung, breast, head and neck, and colorectal cancers, as well as tumors that are more difficult to treat, including glioma, pancreatic cancer, ovarian cancer, and melanoma. These programs span multiple disease stages and treatment settings, from early to late stages and from adjuvant to later-line therapies.



Notes: Pre-clinical or IIT-stage pipelines were not shown. We are also developing GC301 (dual gene-modification with IL-7 and TGF-β chimeric switch-receptor), GC304 (dual gene-modification with IL-7 and KIR chimeric switch-receptor) and iGC101 (in vivo TIL).

Abbreviations: IL-7=Interleukin-7. PD-1=Programmed Cell Death Protein 1. NSCLC=Non-Small Cell Lung Cancer. HNSCC=Head and Neck Squamous Cell Carcinoma. MSI-H=Microsatellite Instability-High. dMMR=Mismatch Repair Deficient. IO=Immuno-Oncology. Q=Quarter. "IO naive MSI-H/dMMR" refers to patients with advanced solid tumors characterized by high microsatellite instability or mismatch repair deficiency who have not received prior immuno-oncology therapies.

* Modifications refer to whether the program is genetically modified, and if so, what the gene-modification is. Natural refers to no gene-modification.

1. GC101 for advanced melanoma would not undergo a Phase III clinical trial because it entered the registrational Phase II clinical trial directly following Phase I. According to NMPA's Interpretation of Relevant Issues under the Technical Guidelines for Research and Evaluation of Cell Therapy Products (Trial Version) , clinical studies for cell therapy products are generally divided into two functional stages: an early-stage clinical trial phase (focusing on safety and dose exploration) and a confirmatory clinical trial phase (focusing on definitive evidence for marketing approval). The CDE confirmed at the EOP1 meeting that this Phase II trial serves as the confirmatory trial for registration.

2. The Phase II combination trial was approved and initiated under a separate, standalone IND from the NMPA, without the requirement to conduct a separate Phase I combination trial. The NMPA granted this Phase II approval on the explicit condition that the trial be initiated after we fully analyzed the data from our completed Phase I monotherapy trial in advanced solid tumors, which provided the foundational safety and efficacy evidence to support transitioning directly into this Phase II study.

Our Core Product, GC101, is the world's first TIL therapy that does not require high-intensity lymphodepletion chemotherapy or the use of IL-2 injections, according to Frost & Sullivan. GC101 has been evaluated in a Phase I clinical trial involving a total of 43 patients with advanced metastatic solid tumors who had failed standard treatments across multiple tumor types. Overall, GC101 demonstrated a manageable safety profile and encouraging preliminary anti-tumor activity across multiple solid tumor types, including melanoma, NSCLC, and cervical cancer. Among 10 patients with metastatic advanced melanoma who had failed standard therapies (median prior lines of therapy: 3.5; 100% had received immunotherapy), GC101 achieved an ORR of 30% and a median progression-free survival of 5.5 months. In 12 patients with metastatic advanced NSCLC who had failed standard therapy (median prior lines of therapy: 3), at a median follow-up of 13.0 months, GC101 achieved an ORR of 41.7%, with the median duration of response not reached; the 12-month overall survival rate (OS) was 66.7%, and the median overall survival (mOS) had not been reached.

GC101 is currently being evaluated in a registrational Phase II clinical trial for advanced melanoma, and we expect to submit a Biologics License Application (BLA) in September 2026. The trial achieved its primary endpoint in May 2026, with the GC101 treatment group demonstrating a 57% reduction in the risk of disease progression or death compared with the control group. The results of the trial were accepted as a late-breaking abstract by the American Society of Clinical Oncology (ASCO) and were presented orally at the ASCO Annual Meeting in June 2026. According to Frost & Sullivan, this was the first cell therapy for solid tumors to be accepted as a late-breaking abstract in ASCO's history. In parallel, GC101 is under evaluation in a Phase Ib/II clinical trial for NSCLC, and development programs for early-line combination therapies and postoperative adjuvant therapies across multiple indications (such as melanoma, NSCLC, glioma, pancreatic cancer) are ongoing.

Our key product candidate, GC203, is the world's first non-viral gene-modified TIL therapy, according to Frost & Sullivan. Building on GC101, GC203 incorporates a proprietary membrane-bound, self-associating IL-7 designed to enhance *in vivo* activity of TILs and support activation of endogenous immune cells. In IIT studies in heavily pretreated ovarian cancer, GC203 achieved an ORR of 33.3%, a CRR of 11.1%, and a one-year OS rate of 68.8%.

Proprietary Technology Platforms Supporting TIL Therapy Development

Leveraging our proprietary DeepTIL™ (Dual-Free Platform for TIL) cell enrichment and expansion platform and NovaGMP™ (Non-Viral Gene-Modification Platform), we have developed a pipeline of natural and gene-modified TIL product candidates and supported their advancement across different stages of development. Together, these integrated platforms represent innovations that enable us to deliver TIL therapies that are robust, potent, affordable, and accessible — as evidenced by their reproducibility across multiple tumor types, high-yield expansion of ~20 billion cells, a feeder-free and non-viral manufacturing process, and a time-segmented delivery model.

Our R&D strategy follows a principle of incremental development. GC101 was initially developed using the DeepTIL™ platform. Building on its clinical data, GC203 was developed through a single-gene modification using the NovaGMP™ platform to enhance anti-tumor activity. Following clinical evaluation of GC203, we advanced to GC301 and GC304, which are dual-gene modified successors to GC203, designed to address challenges and clinical needs in cancer immunotherapy.

In addition, based on the time-segmented process, we are developing the RiverTIL™ (Rapid *In Vivo* Expansion and Reaction TIL) platform, which is designed to enable pre-manufactured seed TILs to expand *in vivo*. This approach is intended to reduce manufacturing time and cost, shorten patient waiting time, and improve accessibility of TIL therapies.

Optimizing Manufacturing Cost and Scalability of Cell Therapy Products

We have taken steps to address certain technical and operational challenges associated with the manufacturing and scalability of TIL therapies:

- ***We have developed a standardized TIL cell culture system*** designed to accommodate the heterogeneous nature of pan-solid tumor tissues, which contributes to a more consistent culture process. The reduced reliance on certain non-standard materials, such as feeder cells, helps simplify production and reduce contamination risks and associated costs.

- ***We have established a commercial-scale TIL manufacturing facility in China***, supported by digital management systems to facilitate production and delivery, and have participated as one of the drafting institutions in the development of the *Guidelines for Preparation and Quality Control of Tumor-Infiltrating Lymphocyte (TIL) Products*, which may contribute to industry standardization.

- ***We utilize commercially available AI tools in certain aspects of R&D and manufacturing*** to support process optimization and automation, and have taken steps to integrate certain upstream and downstream supply chain functions to improve operational efficiency and manage material costs.

- ***We adopt non-viral vector approaches*** in the development of certain gene-modified TIL therapies, which are generally less costly than viral vector systems and offer a different safety profile.
- ***Our in vivo TIL pipeline is designed to utilize transient gene modification of pre-manufactured TIL cells*** to support *in vivo* expansion, which is intended to reduce the need for extensive *ex vivo* expansion.

We Are Advancing a New Commercialization Model for Cell Therapy

Compared with predefined targeted therapies, TIL therapy is not constrained by fixed tumor targets and may be applied across a range of solid tumors, including those with high incidence or limited treatment options. It may also be used across different stages of disease, from postoperative adjuvant settings to later-line treatment, and may address clinical needs across tumor types and disease stages.

Leveraging our time-segmented production process, tumor tissue can be collected when surgery is feasible, and seed TILs can be generated, stored, and subsequently used for infusion. This approach provides greater flexibility compared to conventional TIL manufacturing timelines and may support earlier treatment. It may also facilitate collaboration between enterprises and hospitals, as well as between enterprises and patients, and support broader patient access.

Based on available data to date, our TIL therapies have shown a favorable safety profile, which may support use in a broader patient population. Early-stage or early-line patients may receive treatment with fewer treatment-related constraints, while late-stage or heavily pretreated patients may tolerate it more readily. The treatment may also be administered across a wider range of medical institutions, as it does not require IL-2 administration or high-intensity lymphodepletion and may reduce hospitalization requirements.

Our TIL therapies may also be combined with other treatment modalities, including small-molecule targeted therapies, monoclonal antibodies, ADCs, and immune checkpoint inhibitors. Such combinations may provide additional treatment options and may support potential collaboration with other pharmaceutical companies.

OUR COMPETITIVE STRENGTHS

We Are Advancing the Clinical Development of TIL Therapies as a potentially foundational treatment for pan solid tumors

Restoring the immune system's function is crucial for curing cancer, and TILs are a core component of this anti-tumor immunity. We focus on advancing the clinical development of innovative TIL cell therapies, which offer several advantages over other therapeutic modalities:

The TILs we manufacture contain tumor-reactive T cells capable of recognizing a range of tumor-associated and tumor-specific antigens through their T-cell receptors (TCRs). As a heterogeneous cell population, different TIL clones recognize different antigens, which helps address the heterogeneous nature of solid tumors. These TILs also express chemokine receptors that respond to signals within the tumor microenvironment and, following infusion, would migrate toward tumor sites and exert localized effects, including in certain cases tumors located in more difficult-to-access areas. In addition, the TILs we manufacture include rich memory T cell populations that could contribute to persistence *in vivo*, whereby upon interaction with tumor cells, these cells may become activated and exert cytotoxic effects, with a subset potentially remaining to provide ongoing immune surveillance.

Our TIL therapy is a personalized treatment approach that utilizes a patient's own tumor tissue and does not rely on predefined molecular targets, and therefore could be applied across a range of tumor types, disease stages and patient subgroups. The development and manufacturing of TIL therapies involve technical challenges, including variability in tumor tissue, differences in TIL

infiltration and suppression of tumor-reactive T cells, which make enrichment, functional restoration and large-scale expansion complex. Our manufacturing process is designed to support restoration of T cell function and enable expansion without reliance on high-concentration IL-2 or feeder cells, and incorporates non-viral gene modification methods. These processes require the accumulation of technical know-how and would support product consistency and ongoing development. We also consider our TIL capabilities to form a platform that supports the development of additional product candidates.

TIL therapies could be used in combination with other treatment modalities and may complement existing therapies by enhancing immune responses. In particular, TILs are the primary effector cells targeted by immune checkpoint inhibitors (ICIs), and the two approaches are synergistic, as TIL therapy introduces tumor-reactive T cells while ICIs help sustain their activity by modulating the tumor microenvironment. In addition, certain therapies, such as antibody-drug conjugates (ADCs) and targeted therapies, could enhance antigen release and potentially improve TIL activity. Our TIL therapies are designed to be administered without the need for IL-2 injections or high-intensity lymphodepletion, which would facilitate their use in combination with a range of therapeutic modalities while maintaining a manageable safety profile.

We Have Developed Proprietary Capabilities to Address Key Challenges in TIL Development and Manufacturing

We have improved the safety profile of TIL therapy by addressing limitations associated with conventional treatment approaches. Our cell enrichment and expansion platform is designed to maintain TIL viability, activity and yield while reducing reliance on IL-2. In clinical use, IL-2 administration is not required for our TIL therapy and the intensity of lymphodepletion is reduced compared with conventional regimens. As a result, patients could be treated in standard hospital settings without the need for intensive care resources, and certain pretreatment-related adverse events could resolve without significant medical intervention, which would support shorter recovery periods. These features would also facilitate broader clinical adoption by improving tolerability for patients, including those in earlier lines of therapy or with advanced disease, and by enabling a wider range of medical institutions to administer the therapy with less intensive facility and monitoring requirements.

In addition, our manufacturing and clinical approaches are designed to improve cost efficiency. Our feeder cell-free culture process reduces the complexity and cost associated with traditional methods, and for gene-modified TIL products, we utilize non-viral vector systems to avoid the costs associated with viral vector production and testing. The clinical regimen, which does not require IL-2 administration and involves reduced pretreatment intensity, would also lower overall treatment-related costs by reducing hospitalization, monitoring and supportive care requirements. Our *in vivo* TIL approach, which utilizes transient gene modification of pre-manufactured seed TILs, would further reduce the costs for extensive *ex vivo* expansion.

We have also developed processes to improve the accessibility of TIL therapy. Tumor tissue procurement can be challenging, particularly for patients with advanced disease or limited surgical options. To address this, we have developed a time-segmented manufacturing process that allows tumor tissue obtained during earlier surgical procedures to be used to prepare and preserve seed TILs for potential future use. This approach would help mitigate challenges associated with tissue availability and variability in TIL quality, support more timely treatment, and has been reviewed by the CDE and applied in clinical trial settings.

Our Advanced TIL Products Are Designed to Deliver Clinical Benefits to Patients

Our core product, GC101, is the world's first TIL therapy that does not require high-intensity lymphodepletion or the use of IL-2 injections, according to Frost & Sullivan. In clinical studies, GC101 has demonstrated a manageable safety profile, with no treatment-related deaths reported, and patients were generally treated in standard hospital settings without the need for intensive care resources. The reduced lymphodepletion intensity has also supported shorter recovery periods.

These characteristics differentiate GC101 from conventional TIL approaches and may support broader clinical adoption. GC101 has demonstrated remarkable objective responses in many types of advanced solid tumors including NSCLC, melanoma, gynecologic cancers, glioma, pancreatic cancer, etc. Multiple patients achieved complete response with the longest tumor-free survival exceeding four years. For detailed clinical data, see "— Our Product Pipeline — Core Product GC101: An Autologous Natural TIL Therapy for the Treatment of Solid Tumors."

We have established capabilities in developing gene-modified TIL therapies. Our key product candidate, GC203, is the world's first non-viral vector gene-modified TIL therapy, according to Frost & Sullivan, and is at Phase I clinical trial for the treatment of advanced pancreatic cancer and advanced gynecological cancers that have failed standard therapies. The development of GC203 reflects our ability to apply gene-modification strategies to enhance TIL activity and adaptability within the tumor microenvironment, while maintaining a safety profile generally comparable to GC101.

In addition, we have developed a portfolio of next-generation TIL candidates, including GC301 and GC304, which incorporate chimeric switch-receptor and membrane-bound cytokine-based designs to address immunosuppressive signals in the tumor microenvironment, as well as iGC101, an *in vivo* TIL candidate designed to support more efficient treatment delivery. Together, these assets demonstrate our ability to iterate on and expand our core technology platform.

We Have an Experienced Management and R&D Team with Extensive Industry and Scientific Experience

Under the leadership of an experienced team of scientific and industry professionals, we have developed capabilities across the full value chain of TIL therapy, from research and clinical development to manufacturing and commercialization. Our R&D and management teams combine scientific expertise, industry experience and operational capabilities, which support the execution of our development and commercialization strategies.

Dr. Huajun Jin, our Founder, CEO and CTO, has over 20 years of experience spanning academia, research and industry. He holds a Ph.D. in Genetics from Wuhan University and has received various professional recognitions, including the State Council Special Allowance. Dr. Jin has led the development of multiple cell therapy programs and has accumulated experience in research, clinical translation and manufacturing. Under his leadership, we have established our core technology platforms, including DeepTIL™ and NovaGMP™, and are developing additional platform capabilities aimed at addressing key challenges in TIL therapy.

Our broader team includes professionals with experience at international and domestic pharmaceutical and biotechnology companies, including Bayer, Bristol-Myers Squibb, Innovent Biologics and JW Therapeutics. They possess experience in TIL and cell therapy and have led or contributed to projects such as China's first non-viral vector gene-modified CAR-T therapy, the world's first antibody-expressing CAR-T therapy, the process development of China's first domestically marketed CAR-T therapy, and the clinical development and commercialization of China's first marketed CAR-T therapy.

Our management team has diverse academic and professional backgrounds and brings experience across R&D, manufacturing, regulatory affairs, intellectual property and commercialization. Together, our team supports an integrated approach to product development and execution, which we believe positions us to advance our TIL therapy programs and support long-term development.

OUR GROWTH STRATEGIES

Accelerate the Commercialization of GC101 to Establish Our First-Mover Advantage in TIL Therapy in China

We intend to leverage our clinical development progress and manufacturing capabilities to support the regulatory approval and commercialization of GC101. Subject to successful clinical development and regulatory approval, GC101 may become the first domestically approved TIL therapy in China. Our strategy centers on three key pillars: product registration and indication expansion, clinical advancement, and commercialization execution.

- ***Product Approval and Indication-Expansion Strategy.*** For indications with significant unmet medical needs and clearly defined clinical endpoints, we aim to pursue accelerated approval based on superior efficacy, allowing us to complete registrational trials and early commercialization more efficiently. At the same time, we are broadening GC101's indication portfolio across additional tumor types and wider patient populations to enhance its clinical and commercial impact.

- ***Clinical Development Strategy***. With no dependence on predefined molecular targets, GC101 has the potential to address both high-incidence and hard-to-treat cancers across multiple disease stages. We will continue advancing clinical development through indication expansion, combination-therapy studies (e.g., TIL plus checkpoint inhibitors), and development in front-line and adjuvant treatment settings to fully unlock GC101's therapeutic potential. For advanced NSCLC that has failed standard treatments, we are executing a clinical development plan targeting the enrollment of approximately 350 patients in total, comprising a Phase II trial commencing in 2026 and a Phase III trial spanning 2027 to 2029. For combination therapy with a PD-1 antibody as an early-line treatment for pan-solid tumors, we plan to conduct a Phase II trial and a Phase III trial from 2026 to 2030, targeting approximately 45 and 180 patient enrollments, respectively. For postoperative adjuvant therapy, our roadmap includes an IND application in 2026, followed by a Phase II trial and a Phase III trial spanning 2026 to 2030, targeting approximately 60 and 280 patient enrollments, respectively. Additionally, we are evaluating GC101 in combination with a PD-1 antibody for advanced melanoma, and plan to conduct a Phase II trial from 2026 to 2027, targeting approximately 30 patient enrollments. Through indication expansion, combination-therapy studies and development across different treatment settings, we seek to broaden the potential clinical applications of GC101 in solid tumors.

- ***Commercialization Strategy***. We plan to establish an integrated commercialization framework that combines direct collaboration with hospitals and oncology centers with patient-centered service pathways. This includes setting up regional treatment centers to support tissue collection, processing, and TIL infusion, ensuring nationwide accessibility. We also plan to work with contract sales organizations (CSOs) to accelerate market penetration and strengthen brand awareness among clinicians and patients through evidence-based engagement and data-driven outreach. In parallel, we intend to expand reimbursement coverage through commercial insurance and government subsidized insurance to improve affordability and access.

Please refer to "Future Plan and Use of [**REDACTED**]" for the detailed discussion on how we plan to use the [**REDACTED**] from the [**REDACTED**] to commercialize our Core Product.

Advance the Clinical Development of Our Next-Generation Products to Strengthen Our Technological Leadership

Building on our strong scientific foundation and R&D capabilities, we are accelerating the clinical development of our gene-modified TIL therapies to further reinforce our leadership in solid tumor cell therapy.

Beyond GC101, we are advancing GC203, our first gene-modified TIL candidate, which incorporates a membrane-bound IL-7 construct designed to enhance TIL potency and persistence. Following its entry into Phase I clinical trials in April 2024 to evaluate dose escalation and safety, we plan to execute a comprehensive clinical development roadmap. This includes a Phase I trial spanning 2026 to 2027 targeting approximately 60 patient enrollments, a Phase II trial in 2028 targeting approximately 100 patient enrollments, and a Phase II trial for an additional indication in 2030 targeting approximately 40 patient enrollments. We intend to prioritize indications with significant unmet medical needs, including gynecological cancers and pancreatic cancer.

In parallel, we are developing additional gene-modified TIL programs — including GC301 and GC304 — which leverage our proprietary technology platforms. For GC301, our dual-gene-modified TIL therapy targeting TGF-β in solid tumors with liver metastases, we plan to submit an IND application in 2026 to 2027, and commence a Phase I trial spanning 2027 to 2028 for 20 new enrollments. For GC304, our dual-gene-modified TIL therapy targeting HLA-peptide for sarcomas, colorectal cancer, and breast cancer, our clinical development plan includes advancing preclinical research in 2026, supporting IITs in 2027 to 2028, and initiating a Phase I trial in 2028 targeting approximately 20 patient enrollments. These programs are designed to further enhance potency, persistence, and adaptability, expanding both the clinical and commercial potential of our product pipeline. Please refer to "Future Plan and Use of [**REDACTED**]" for the detailed discussion on how we plan to use the [**REDACTED**] from the [**REDACTED**] to advance our TIL product pipeline.

Redefining the Affordability of High-Value Cell Therapy Products Through Technological Breakthroughs and Innovation

We advance our product candidates through successive stages of clinical and technological development. GC101, our natural TIL therapy, provides the clinical proof-of-concept that underpins the development of GC203, our single-gene-modified TIL product candidate. Building on GC203, we are advancing dual-gene-modified candidates GC301 and GC304, steadily strengthening our technological moat while maintaining scientific rigor and regulatory continuity.

At the same time, we are developing technologies intended to improve the manufacturing efficiency and accessibility of personalized cell therapies and support the broader application of TIL therapies. Over the next three to five years, we focus on the continuous upgrade and iteration of our core technology platforms.

For our DeepTIL™ platform upgrade, we plan to continuously improve processing methods for tumor tissues and increase automation in cleaning and cutting. We will also update TIL culture components to boost activation levels and tumor cell-killing capability, alongside optimizing culture conditions such as temperature, cell density, and duration. For our NovaGMP™ platform upgrade, we intend to refine electroporation methods to improve TIL survival rates and positive cell counts, screen small molecules to enhance electroporation tolerance, and explore a broader range of non-viral vector systems for gene delivery. For our RiverTIL™ platform development, we are exploring the introduction of CAR mRNAs targeting different molecular targets on peripheral blood cells into seed TILs, enabling CAR-expressing seed TILs to achieve transient and efficient *in vivo* expansion without the need for *ex vivo* expansion. This project includes testing different mRNA forms and structures, optimizing the specific parameters of mRNA introduction, and improving modification efficiency and expression in TILs.

As part of this innovative platform, iGC101 represents one of our key *in vivo* TIL programs. We are advancing its clinical trajectory through a defined implementation plan, which includes preclinical research in 2026, IITs in 2026 to 2027, a Phase I trial in 2028-2029 for 70 new enrollments, and a Phase II trial in 2030-2031 for 100 new enrollments. By enabling transient genetic modification of pre-manufactured seed TILs, followed by direct infusion and *in vivo* expansion, this approach supports rapid treatment initiation and is expected to meaningfully reduce costs and substantially improve accessibility compared with conventional TIL therapies. Our long-term objective is to make TIL therapy affordable and scalable on a global scale, enabling broad patient access and adoption. Please refer to "Future Plan and Use of [**REDACTED**]" for the detailed discussion on how we plan to use the [**REDACTED**] from the [**REDACTED**] to achieve the continued upgrade and iteration of our technology platforms.

Further Improving Efficiency through Operational Optimization

As a personalized treatment, TIL therapy faces a fundamental industry challenge: complex manufacturing processes limit scalability. To address this, we are committed to continuously improving operational efficiency through technological innovation, process optimization, and intelligent, lean manufacturing.

At the process level, we have adopted a novel technological framework that removes multiple resource-intensive steps — eliminating the need for high-concentration IL-2 during enrichment and rejuvenation, viral vectors during gene modification, and feeder cells during expansion. Compared with traditional methods, this streamlining significantly increases manufacturing efficiency and lowers production costs. Our *in vivo* TIL pipeline further streamlines manufacturing by avoiding large-scale *ex vivo* expansion, potentially achieving additional reductions in production time and cost.

On the intelligent manufacturing front, we are developing GMP-compliant automated and closed production systems to increase efficiency and equipment utilization. To ensure long-term commercial readiness and capacity matched with our clinical roadmap, we have established a ten-year facility and equipment investment plan spanning 2026 to 2036.

To meet our commercial capacity demands for GC101 and GC203, we plan to initiate an expansion project at our existing manufacturing facility in 2027 to build out an additional cell therapy manufacturing workshop. This expansion will be equipped with automated instruments, including seed cell and final-product cell incubators, final-product cell preparation workstations, and dispensing center distribution isolators. The implementation timeline spans from conceptual design in the first quarter of 2027 through purification renovation, equipment installation, facility validation, and government inspections, targeting commercial production approval by the end of 2028. To support further commercial scale, we will launch a subsequent expansion at this facility in 2029 to address our 2030 commercial demands, adding further seed cell incubators and final-product cell preparation workstations.

To support our broader commercial channels and downstream supply chain, we plan to initiate the construction of a dedicated seed cryopreservation production base in 2027 by leasing a new facility. This base will feature a dedicated production zone, a quality control zone, a warehouse, and supporting office space. Equipment procurement will include biosafety cabinets, CO_2 incubators, cell counters, and microscopes. Following conceptual planning and machine installations, this base is scheduled to enter operations in the fourth quarter of 2027. We intend to expand this capacity sequentially by constructing an additional seed cryopreservation workshop in 2030, followed by subsequent expansions in 2033 and 2035 to secure advanced cryopreservation equipment.

For our broader pipeline expansion, we plan to build an *in vivo* TIL product manufacturing workshop at our existing facility in 2027 to support pipeline diversification. Looking further ahead to meet our 2032 commercial projections, we plan to construct an entirely new, large-scale TIL cell therapy manufacturing base in 2030, which will incorporate advanced seed cell incubators and cell preparation workstations. We plan to build an identical manufacturing base starting in 2033 to capture maturing market demand.

In terms of digitalization, we have established a fully electronic end-to-end chain of identity and chain of custody (COI/COC) system, from tissue procurement to infusion, ensuring robust identity, monitoring, and compliance tracking throughout the entire workflow. In parallel, we have custom-built a TIL-specific MES production execution system and other digital tools to improve staff productivity, reduce human error, and further lower overall manufacturing costs.

Across the supply chain, we will use AI tools to facilitate development of raw material optimization for TIL culture, reducing upstream material costs. We will also integrate AI-driven optimization into our production and quality management systems, enabling faster, more reliable processes and minimizing resource waste.

Together, these initiatives reinforce our cost advantage and meaningfully expand the affordability of our TIL therapies to a broader patient population. Please refer to "Future Plan and Use of [**REDACTED**]" for the detailed discussion on how we plan to use the [**REDACTED**] from the [**REDACTED**] to improve efficiency and strengthen our production management and manufacturing capabilities.

Actively Pursue Strategic Partnerships to Accelerate Globalization

To fully leverage our technological advantages and accelerate internationalization, we plan to actively seek strategic collaborations with global pharmaceutical companies.

We intend to work with established multinational partners that have mature commercial infrastructures, enabling us to jointly advance product commercialization and broaden international market coverage. Through such collaborations, we can integrate our R&D and manufacturing expertise with our partners' development capabilities and commercial networks, creating mutually beneficial outcomes and expanding patient access worldwide.

Given the differentiated safety profile and pan-tumor potential of our therapies, our products offer extensive opportunities for combination with standard treatments, laying a solid foundation for cross-company partnerships. We are seeking potential collaborations with multinational pharmaceutical companies in areas such as clinical development, co-development, licensing, and commercialization. Once established, these partnerships are expected to accelerate global market entry, enhance international visibility, and support our long-term strategy to build a globally competitive TIL therapy portfolio.

Attract, Retain and Motivate High-Caliber Talents Across Our Business Functions

We believe our talents are the foundation of our innovation and long-term success. As a biotechnology company focused on developing and commercializing TIL therapies, we recognize that attracting, developing, and retaining exceptional talents is critical to sustaining our growth and competitiveness.

We plan to continue strengthening our teams across discovery, R&D, manufacturing, and commercialization by recruiting and retaining individuals with strong scientific, technical, and commercial capabilities. At the same time, we are committed to fostering a collaborative, performance-driven culture that encourages initiative, accountability, and a pursuit of excellence.

We will continue to invest in talent development and leadership training, promote cross-functional learning, and refine our organizational structure to enhance efficiency and agility. By cultivating a culture of continuous learning and innovation, we aim to build a dynamic team that advances our mission and reinforces our leadership in TIL and cell therapy development.

OUR PRODUCT PIPELINE

We are advancing a broad and differentiated pipeline of TIL-based cell therapies for solid tumors, enabled by our proprietary DeepTIL™ cell enrichment and expansion platform and NovaGMP™ non-viral gene-modification platform, and our emerging RiverTIL™ *in vivo* expansion platform. Our portfolio integrates clinically validated efficacy, safety, and durability with scalable and cost-efficient manufacturing, aiming to deliver potent and accessible TIL therapies across high-incidence and/or refractory cancers, including lung, breast, colorectal, ovarian, and melanoma. Anchored by GC101, the differentiated TIL therapy that does not require high-intensity lymphodepletion chemotherapy or IL-2 administration and is currently in registrational Phase II development for advanced melanoma with a planned BLA submission in 2026, and GC203, differentiated non-viral gene-modified TIL therapy demonstrating promising efficacy, our pipeline extends to innovative TIL therapies GC301 and GC304 that employ dual-gene modifications to

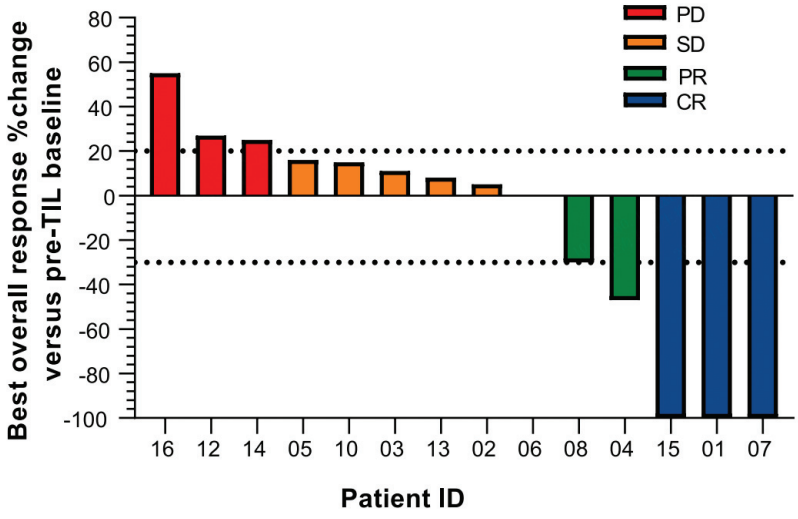
potentially overcome tumor immunosuppression and enhance therapeutic durability. In parallel, iGC101 represents a disruptive innovation in TIL therapy, enabling transient gene modification and *in vivo* expansion of pre-manufactured seed TILs to substantially reduce manufacturing cost and treatment waiting time.

Core Product GC101: An Autologous Natural TIL Therapy for the Treatment of Solid Tumors

Overview

GC101, our core product, is a TIL therapy designed to deliver safer, more effective, and durable treatment for patients with solid tumors, including advanced melanoma, advanced non-small cell lung cancer (NSCLC), and other high-incidence and refractory cancers. Unlike conventional TIL therapies that rely on high-intensity lymphodepletion chemotherapy and high-dose IL-2 administrations, GC101 avoids these intensive interventions, addressing critical safety and tolerability limitations that have historically restricted broader adoption of TIL therapy. It is suitable for both heavily pretreated patients and earlier-line patients, expanding its potential clinical impact. This is particularly important for patients whose disease progresses after immune checkpoint inhibitors, such as PD-1 antibodies, who face extremely poor prognoses. The addressable market for GC101 spans multiple solid tumor types, including melanoma, NSCLC, and other high-incidence and refractory cancers, representing a substantial unmet medical need.

In investigator-initiated trials (IITs), GC101 has shown objective responses across more than 10 types of solid tumors, including NSCLC, head and neck cancer, pancreatic cancer, glioma, melanoma, cervical cancer, ovarian cancer, endometrial cancer, bile duct cancer and esophageal squamous cell carcinoma. Multiple patients achieved complete responses (CR), and the most sustained tumor-free survival has exceeded four years. In 14 heavily pretreated patients with advanced gynecologic cancers (average number of prior lines of therapy: 3.4) and poor physical condition (ECOG PS 1-3), GC101 achieved a disease control rate of 71.4%, an ORR of 35.7% and a CRR of 21.4%. These results suggest that GC101 may have pan-tumor therapeutic potential with curative opportunities.



Source: Company data

In Phase I clinical study, GC101 has demonstrated robust anti-tumor activity across multiple tumor types, achieving an ORR of 38.5% in advanced metastatic solid tumors while maintaining a favorable safety profile. GC101 is currently undergoing a registrational Phase II trial in PD-1

antibody failed melanoma, and a BLA submission is anticipated in 2026. Beyond melanoma, GC101 is being evaluated in additional indications, including NSCLC, with early-line combination therapy and postoperative adjuvant therapy also being explored.

Supported by our proprietary DeepTIL™ technology platform, GC101 exemplifies the clinical application of our TIL innovations and serves as a cornerstone for the development of innovative TIL therapies, including gene-modified and *in vivo* approaches, enabling broader accessibility and application across the full spectrum of solid tumors.

Mechanism of Action

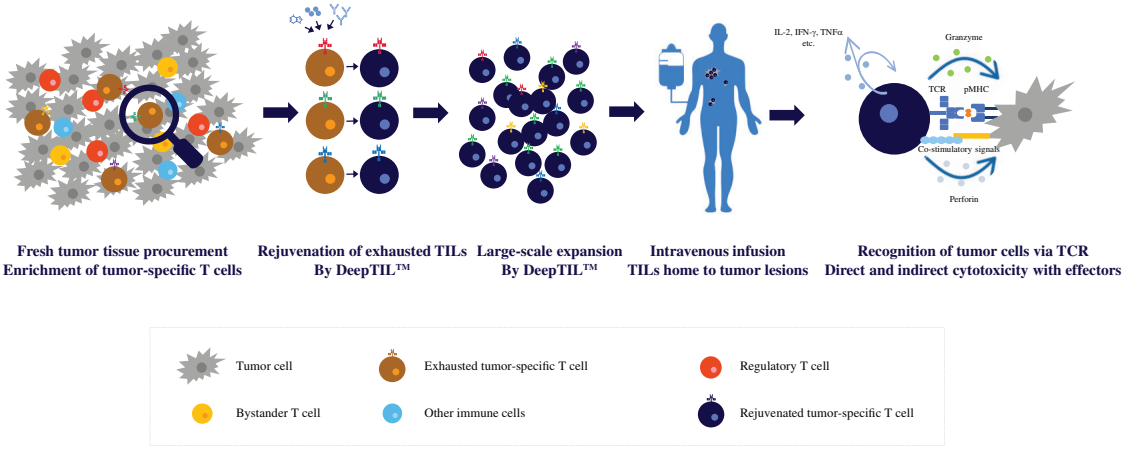
TILs are naturally occurring immune cells found inside tumors. These cells possess specialized surface proteins called T cell receptors that allow them to recognize a wide variety of abnormal proteins, known as antigens, displayed by tumor cells. Because tumors are complex and made up of diverse cells, the varied nature of a TIL population allows it to target many different parts of a solid tumor simultaneously. In the early stages of cancer, the body naturally sends TILs to attack these abnormal cells. However, as solid tumors grow, they create a hostile local environment that protects them. This immunosuppressive tumor microenvironment uses chemical signals and inhibitory pathways to shut down the TILs, exhausting them and stopping their natural ability to destroy the cancer.

Conventional TIL therapies attempt to overcome this hostile environment through intensive patient preparation and post-infusion support. Before receiving conventional TIL therapies, patients must undergo high-intensity lymphodepletion, which is a powerful regimen of chemotherapy designed to wipe out existing immune cells. This clearing is necessary because conventional TIL manufacturing relies on high concentrations of a growth factor called interleukin-2 (IL-2). This reliance makes the manufactured cells dependent on IL-2 to survive. Furthermore, high concentrations of IL-2 accidentally stimulate regulatory T cells, which are cells that actually protect the tumor and promote its growth. High-intensity chemotherapy is therefore required to eliminate these regulatory cells and clear space for the infused TILs. Following the cell infusion, patients must also receive multiple rounds of high-dose IL-2 to keep the conventional TILs active. This combination of intensive chemotherapy and high-dose IL-2 causes severe medical complications. Published clinical data for conventional TIL therapies shows that 100% of patients experience high-grade adverse events, representing a significant safety burden.

We designed GC101 to directly address these safety and efficacy limitations without relying on toxic patient conditioning or high-dose growth factors. GC101 is manufactured using our proprietary DeepTIL™ platform, which eliminates the use of high-concentration IL-2 during production. Instead, our process uses a specific combination of antibodies, signaling proteins, and small-molecule compounds to repair, rejuvenate, and multiply functional TILs outside the body. Because GC101 TILs are engineered to be functional and self-sustaining without an ongoing dependence on IL-2, they do not require high-dose IL-2 support after infusion. Consequently, patients do not need to undergo high-intensity lymphodepletion chemotherapy to clear out IL-2-sensitive regulatory T cells.

Once we infuse GC101 back into the patient at therapeutic doses, these rejuvenated TILs naturally travel to tumor sites and bind to cancer cells to destroy them directly using cytotoxic molecules such as perforin and granzymes. At the same time, GC101 TILs release inflammatory proteins, including interferon-gamma (IFN-γ), which act as distress signals to recruit and activate the patient's own remaining immune cells, such as natural killer cells and macrophages. To ensure these cells remain active inside the hostile tumor environment, we protect GC101 *in vivo* using a concurrent low-dose PD-1 antibody treatment. This antibody shields the infused TILs from the tumor's shutdown signals. By combining direct cell-killing capabilities with a production method that bypasses the need for high-intensity chemotherapy and high-dose IL-2, GC101 achieves potent and durable tumor control while significantly reducing treatment-related toxicities. This improved safety profile broadens the potential applicability of GC101 to both early-line patients and heavily pretreated individuals who cannot tolerate conventional TIL regimens.

The diagram below illustrates the mechanism of action of GC101.



Source: Company data

Market Opportunity and Competition

TIL therapy is an emerging immunotherapy for patients with advanced solid tumors who have limited treatment options. By harnessing a patient's own tumor-reactive T cells, TIL therapy has the potential to deliver durable anti-tumor responses beyond those achievable with standard-of-care therapies.

The global TIL therapy market was valued at RMB1.6 billion in 2025 and is projected to reach RMB14.1 billion by 2030 and RMB39.8 billion by 2035, representing a CAGR of 54.5% from 2025 to 2030 and 23.1% from 2030 to 2035. The China TIL therapy market is expected to launch in 2027, reaching RMB1.5 billion by 2030 and RMB8.1 billion by 2035, growing at a CAGR of 40.1% from 2030 to 2035.

Melanoma and NSCLC represent key initial indications driving TIL adoption. Globally, melanoma cases are projected to increase from 399.5 thousand in 2025 to 492.8 thousand by 2035, while NSCLC cases are expected to grow from 2.3 million in 2025 to 2.9 million by 2035. In China, melanoma patients are projected to reach 39.1 thousand and NSCLC patients 1.3 million by 2035. The growing prevalence of these cancers underscores a significant and expanding patient population for TIL therapy, alongside potential applications in other advanced solid tumors.

For details, see "Industry Overview — Overview of Major Therapeutic Areas in Solid Tumor Treatment."

Competitive Advantages

We believe that GC101 has the following competitive advantages.

- Clinically validated mechanism across tumors with high unmet need. GC101 is a TIL therapy that selectively target and eliminate tumor cells across a broad range of solid tumors. Patients whose disease progresses following standard therapies, including immune checkpoint inhibitors, have limited treatment options and poor prognoses. In Phase I clinical trials, GC101 demonstrated robust anti-tumor activity, achieving an ORR of 38.5% across advanced metastatic solid tumors. In a cohort of heavily pretreated NSCLC patients (median of three prior lines of therapy), GC101 achieved an ORR of 41.7%. In a cohort of patients with metastatic advanced melanoma (median of 3.5 prior

lines of therapy), GC101 achieved an ORR of 30% and a median progression-free survival of 5.5 months. The addressable market encompasses high-incidence cancers such as lung, breast, and colorectal, as well as refractory tumors including ovarian, melanoma, and glioma.

- Innovative natural TIL design with curative potential. GC101 rejuvenates and expands functional TILs *ex vivo* to therapeutic doses without the need for feeder cells or high-concentration IL-2. Its dual mechanism, direct cytotoxicity and modulation of the tumor microenvironment, amplifies systemic anti-tumor immunity and enables multi-targeted, durable tumor control. IITs have also reported multiple CRs, with the longest tumor-free survival exceeding four years. The process is compatible with pre-manufacturing of seed TILs, allowing early collection and time-segmented expansion to maintain cell functionality and optimize therapeutic efficacy, supporting use in both earlier-line and heavily pretreated patients.

- Favorable safety profile and operational simplicity. By avoiding high-intensity lymphodepletion and IL-2 administrations, GC101 markedly reduces the duration of severe adverse events compared to conventional TIL therapies. Treatment can be delivered in less demanding hospital wards without the mandatory requirement of ICU resources, and the time to achieve discharge criteria is significantly reduced. The simplified administration facilitates broader clinical adoption and reduces operational complexity for healthcare providers.

- Cost-effective and commercially scalable manufacturing model. GC101 enables collection of tumor tissue for pre-manufacturing of seed TIL products when surgery is feasible, enhancing therapeutic efficacy while avoiding additional invasive procedures. Our seed TIL process provides flexibility and efficiency. Pre-manufactured seed TILs with transient gene-modification support *in vivo* expansion strategies, significantly reducing production costs to a commercially competitive level. The time-segmented manufacturing process allows greater flexibility in production time, and further enhances operational efficiency and cost-effectiveness. GC101 is expected to be priced within an accessible range, supporting broad patient affordability.

- Registrational-stage readiness and foundation for pan-tumor therapy. GC101 is a registrational-stage candidate with registrational Phase II trials in PD-1 antibody failed melanoma, positioning it to potentially become the first marketed TIL therapy in China. As a foundational product in a broad TIL pipeline, GC101 complements the development of gene-modified and *in vivo* TIL programs designed to enhance efficacy, persistence, and applicability across multiple solid tumors, supporting both first- and best-in-class potential.

Summary of Clinical Trials

The following table sets forth an overview of major clinical studies of GC101.

Protocol Number	Phase	Study Design	Sites	Subjects	Trial Status	Actual Patient Enrollment
GC101 TIL-ST-I . . .	I	Open-label, single-arm trial to evaluate the safety and efficacy of GC101	China	Patients with advanced malignant solid tumors	Completed	43
GC101 TIL-NSCLC-Ib/II . . .	Ib/II	Open-label, single-arm trial to evaluate the safety and efficacy of GC101	China	Patients with advanced NSCLC	Ongoing	7

Protocol Number	Phase	Study Design	Sites	Subjects	Trial Status	Actual Patient Enrollment
GC101 TIL-MM-II . .	II (registrational)	Open-label, randomized, controlled, multicenter trial for the treatment of advanced melanoma	China	Patients with advanced melanoma	Ongoing	99
GC101 TIL&PD-1Ab-ST-II	II	Open-label, single-arm trial to evaluate the safety and efficacy of GC101 combined with PD-1 antibody	China	Patients with advanced solid tumors	Planned	N/A

GC101 TIL-ST-I: An Open-Label, Single-Arm, Phase I Clinical Trial of GC101 TIL Cell Injection for the Treatment of Patients with Advanced Malignant Solid Tumors

This Phase I clinical trial of GC101 is an open-label, single-arm, dose-escalation and dose-expansion study designed to evaluate its safety, tolerability, and preliminary efficacy in patients with advanced solid tumors. The primary endpoints are (i) to determine the maximum tolerated dose (MTD) and dose-limiting toxicities (DLT) of GC101, and (ii) to evaluate the incidence and frequency of adverse events (AE) and serious adverse events (SAE).

Trial design.

- Enrollment: Planned enrollment of 38 to 96 patients.
- Key inclusion criteria: (i) Cytologically or histopathologically confirmed malignant solid tumors; (ii) unresectable advanced solid tumors progressed/recurred after standard therapy or for which no effective options are available; (iii) tumor region amenable to resection or needle biopsy for TIL isolation; and (iv) at least one measurable lesion present at pre-conditioning assessment.
- Key exclusion criteria: (i) Participation in other clinical trials within four weeks prior to enrollment; (ii) prior receipt of allogeneic T-cell therapy, or gene-modified/edited autologous cell therapy within one year; (iii) receipt of systemic anti-tumor therapy within four weeks prior to enrollment; and (iv) history of other malignancies within five years prior to screening.

A total of 43 patients were enrolled. The study comprises a dose-escalation stage using a standard "3+3" design, followed by a dose-expansion stage across multiple tumor types, including melanoma and NSCLC. Eligible patients undergo tumor tissue collection for TIL manufacturing, receive low-dose lymphodepletion with cyclophosphamide and hydroxychloroquine, and are administered GC101 TILs with a low-dose PD-1 antibody to protect TIL from immunosuppression. Safety and efficacy are evaluated through 12 months of follow-up, with long-term survival assessment conducted every six months thereafter.

Status.

The trial was initiated in October 2022.

In October 2023, we completed the safety evaluation of dose-escalation part of Phase I clinical trial of GC101, based on a total of 11 enrolled patients with advanced malignant solid tumors. The safety review committee (SRC) concluded that no DLT was observed, and the expansion study could be initiated. On this basis, we initiated the expansion study and intentionally enrolled additional melanoma patients to obtain sufficient efficacy data.

In July 2024, based on data from a total of 19 enrolled patients with advanced malignant solid tumors, including 10 advanced melanoma patients included in the efficacy-evaluable set, the clinical study report (CSR) concluded that GC101 demonstrated a manageable safety profile in patients with advanced solid tumors and showed certain efficacy, manageable tolerability, and safety in patients with melanoma, supporting further development. Accordingly, we completed the Phase I clinical trial for the purpose of applying to initiate a registrational Phase II clinical trial of GC101 in advanced melanoma.

In August 2024, we requested an End-of-Phase I (EOP1) communication with the CDE. Following our EOP1 meeting with the CDE in November 2024, during which we reached consensus on the registrational Phase II trial protocol for the treatment of advanced melanoma, the CDE issued the meeting minutes in December 2024. With the support of EOP1 meeting minutes, we are considered to have completed a conventional Phase I clinical trial and could proceed to the registrational Phase II trial in advanced melanoma, which were based on results of the completed Phase I clinical trial.

Separately, for the purpose of evaluating the overall Phase I clinical trial across a total of 43 patients with multiple tumor types, we completed data cleaning[3] and statistical analyses of AE and SAE and achieved the corresponding primary endpoints in November 2025. The analyses covered safety and early efficacy in other solid tumor types, and did not affect the completion of Phase I trial to support the initiation of the registrational Phase II trial in advanced melanoma.

Safety Data.

A total of 42 patients received GC101 treatment and were included in the safety set (SS). One patient was excluded from the SS because the TIL product intended for his/her administration did not meet the predefined dose escalation level. Among the 42 patients, treatment-emergent adverse events (TEAEs) related to the investigational drug occurred in 37 subjects (88.1%). No DLT was observed and the MTD was not reached. No subjects experienced investigational drug-related TEAEs that resulted in death, discontinuation of investigational drug infusion, or were classified as immune-related adverse events (irAEs). The top three most frequent System Organ Classes (SOCs) for investigational drug-related TEAEs were: General Disorders and Administration Site Conditions (30 subjects, 71.4%), Investigations (26 subjects, 61.9%), Metabolism and Nutrition Disorders (11 subjects, 26.2%).

Investigational drug-related TEAEs with an incidence >25%, presented by Preferred Terms (PTs, per CTCAE), were as follows:

- Pyrexia (29 subjects, 69.0%); and
- Leukopenia (11 subjects, 26.2%)

One subject (2.4%) experienced one investigational drug-related TEAE classified as a SAE. Twelve subjects (28.6%) experienced investigational drug-related TEAEs of CTCAE Grade ≥3.

3 Data cleaning is a standard operational procedure for statistical analysis in all clinical trials and is a mandatory requirement by regulatory authorities globally to ensure the quality and integrity of clinical trial data. In China, according to the Technical Guidelines for Computerized Systems and Electronic Data in Clinical Trials (Draft for Comments) issued by the CDE, sponsors must establish clear milestones and quality requirements for data cleaning, complete all data collection, review, medical coding, and external data consistency checks, and correct errors in a timely manner before fulfilling the predetermined pre-lock data quality requirements to achieve database lock. Regulatory authorities provide comprehensive guiding principles for data collection, verification, correction, and transmission, and we conduct our data cleaning strictly in accordance with these applicable guidelines.

The material results relating to primary and secondary endpoints are summarized below.

	Dose Escalation											
	Dose Level 1 (N= 3)		Dose Level 2 (N= 4)		Dose Level 3 (N= 3)		Dose Escalation Total (N= 10)		Dose Expansion Total (N= 32)		Total (N= 42)	
	N	Incidence (%)	N	Incidence (%)	N	Incidence (%)	N	Incidence (%)	N	Incidence (%)	N	Incidence (%)
TEAE Associated with GC101 TIL	0	0	4	100.0	3	100.0	7	70.0	30	93.8	37	88.1
CTCAE≥3 TEAE	3	100.0	3	75.0	3	100.0	9	90.0	28	87.5	37	88.1
CTCAE≥3 TEAE Associated with GC101 TIL	0	0	1	25.0	1	33.3	2	20.0	10	31.3	12	28.6
Serious TEAE	2	66.7	1	25.0	1	33.3	4	40.0	5	15.6	9	21.4
Serious TEAE Associated with GC101 TIL	0	0	0	0	1	33.3	1	10.0	0	0	1	2.4
TEAE Resulted in Death Associated with GC101 TIL	0	0	0	0	0	0	0	0	0	0	0	0
TEAE Led to GC101 TIL Discontinuation	0	0	0	0	0	0	0	0	0	0	0	0
TEAE Classified as irAE Associated with GC101 TIL	0	0	0	0	0	0	0	0	0	0	0	0

Overall, GC101 TIL was well tolerated across advanced solid tumors, with adverse events consistent with expectations for TIL therapy, supporting its continued clinical development. The recommended phase II dose (RP2D) was determined as 5×10^9 - 45×10^9 ± 20%.

Efficacy Data.

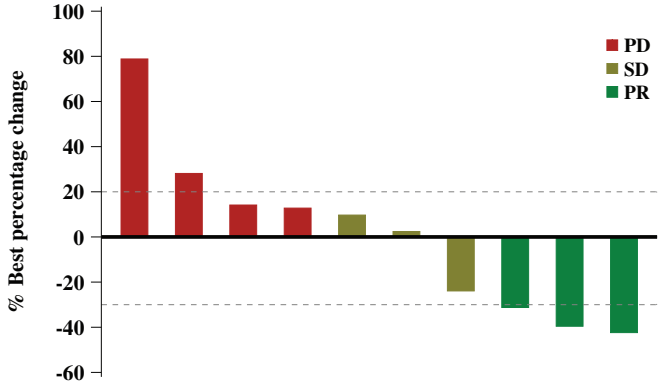
All patients had received prior treatment, including surgery, chemotherapy, immunotherapy, and targeted therapy, underscoring the activity of GC101 TIL in a heavily pretreated population.

As of July 2024, in the evaluable set of 10 patients with advanced melanoma, GC101 TIL demonstrated preliminary anti-tumor activity with a manageable safety profile. With a median follow-up of 8.2 months (range: 3.2-20.2 months), according to RECIST 1.1 criteria, three patients achieved partial responses (PR), resulting in an ORR of 30.0% (95% CI: 6.67%, 65.25%). Three additional patients achieved stable disease, yielding a disease control rate (DCR) of 60.0% (95% CI: 26.24%, 87.84%). mOS was not reached, with a 6-month OS rate of 83.3% (95% CI: 27.3%, 97.5%).

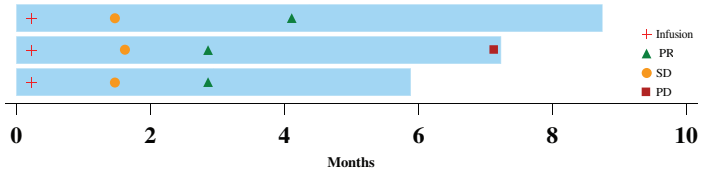
Objective Responses — Advanced Melanoma

Items	Total (N= 10)
PR n (%)	3 (30.0)
SD n (%)	3 (30.0)
PD n (%)	4 (40.0)
ORR n (%) (95% CI)	3 (30.0) (6.67~65.25)
DCR n (%) (95% CI)	6 (60.0) (26.24~87.84)

Best Percentage Change From Baseline in Target Lesion SOD



Time to Response and Time on Efficacy Assessment for Responders



Source: Company data

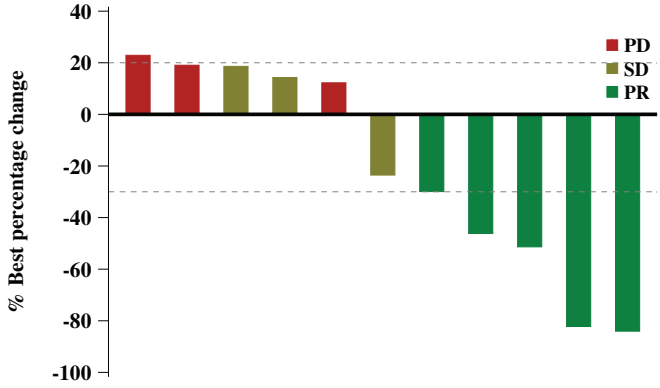
Between August 2022 and September 2025, 12 patients with advanced NSCLC received GC101 treatment. The median number of prior lines of therapy was three. With a median follow-up of 13.0 months (range: 1.5-31.0), the ORR was 41.7% (95% CI: 15.2%, 72.3%), median duration of response (DoR) was not reached[4]. The DCR of 66.7% (95% CI: 34.9%, 90.1%). mOS was not reached, with a 12-month OS rate of 66.7% (95% CI: 33.7%, 86.0%).

4 "DoR" (duration of response) refers to the length of time from the first documented tumor response until disease progression or death and is commonly used to assess the durability of anti-tumor responses. "Not reached" means that, at the time of data cut-off, the median value could not be calculated because more than half of the relevant patients had not yet experienced the event being measured.

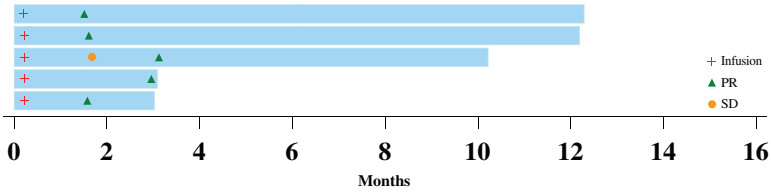
Objective Responses — Advanced NSCLC

Items	Total (N= 12)
PR n (%)	5 (41.7)
SD n (%)	3 (25.0)
PD n (%)	4 (33.3)
ORR n (%) (95% CI)	5 (41.7) (15.2~72.3)
DCR n (%) (95% CI)	8 (66.7) (34.9~90.1)

Best Percentage Change From Baseline in Target Lesion SOD



Time to Response and Time on Efficacy Assessment for Responders



Source: Company data

GC101 TIL-NSCLC-Ib/II: An Open-Label, Single-Arm, Phase Ib/II Clinical Trial Evaluating the Safety and Efficacy of GC101 TIL Cell Injection in Patients with Advanced Non-Small Cell Lung Cancer

This Phase Ib/II clinical trial of GC101 is an open-label, single-arm study. The purpose of conducting this Phase Ib/II clinical trial is to evaluate its safety, tolerability, and preliminary efficacy in patients with advanced NSCLC. We initiated this clinical trial voluntarily, and it was not requested or mandated by the NMPA or any other regulatory authority in light of the results of earlier trials or as a condition for further development of GC101. The trial consists of a Phase Ib part and a Phase II part. The primary endpoint for the Phase Ib part is to assess the incidence and frequency of AE and SAE from tumor tissue collection through the observation period. The primary endpoint for the Phase II part is to evaluate the ORR and progression-free survival (PFS) assessed by investigators according to RECIST v1.1 criteria. Secondary endpoints include evaluating the DCR and DoR per RECIST criteria, and ORR, DCR, DoR and PFS per iRECIST v1.1 criteria, as well as tracking OS and AEs.

Trial design.

- Enrollment: Planned enrollment of 34 to 44 patients, with 6 to 12 patients planned for the Phase Ib part and 28 to 32 patients planned for the Phase II part.
- Key inclusion criteria: (i) Advanced NSCLC confirmed by cytology or histopathology; (ii) tumor region amenable to resection for TIL isolation; and (iii) at least one measurable lesion present prior to pre-conditioning. Eligible patients under the Phase Ib part must fall under Cohort A (driver gene-positive patients failing targeted therapies and platinum-based chemotherapy) or Cohort B (driver gene-negative or unknown patients progressing after PD-(L)1 inhibitor and platinum-based chemotherapy). Eligible patients under the Phase II part must be negative for EGFR, ALK, and ROS-1 mutations and have failed either approved targeted therapies and platinum-based chemotherapy for other actionable mutations, or platinum-based combination therapy and PD-(L)1 antibody therapy.
- Key exclusion criteria: (i) Receipt of systemic anti-tumor therapy within 28 days prior to TIL infusion; and (ii) history of other malignancies within five years.

Eligible patients undergo tumor tissue collection for GC101 TIL manufacturing and sign a pre-collection informed consent. Patients may undergo repeat tissue collection if initial manufacturing is unsuccessful, with assessments repeated as required. Optimized pre-treatment is administered prior to TIL infusion, with three potential regimens.

GC101 TILs are administered intravenously on Day 0. One hour prior to each infusion, patients receive 100 mg of a PD-1 antibody injection. Patients receive additional maintenance doses of 100 mg of the PD-1 antibody injection every six weeks for up to two years until disease progression, intolerance, withdrawal, or study completion. Tumor assessments are conducted every six weeks for the first 24 weeks and every 12 weeks thereafter, continuing until early withdrawal or study completion. Long-term follow-up contacts are conducted every six months to record survival status and subsequent therapies.

Status.

The trial, which was originally designed as a Phase Ib clinical trial, was initiated in November 2024 based on the IND approval received from the NMPA (broad in scope and not restricted to any specific solid tumor indication) in April 2022. In December 2025, we amended the clinical trial protocol to expand the trial into a Phase Ib/II clinical trial. We subsequently submitted a written consultation to the CDE through its online portal regarding the regulatory requirements for transitioning from the Phase Ib part to the Phase II part of the trial. In January 2026, the CDE confirmed that no formal communication meeting with or pre-approval from the CDE would be required following completion of the Phase Ib part and before proceeding to the Phase II part of the trial. The primary endpoint of the Phase Ib part was achieved in May 2026. Following the evaluation of Phase Ib data, the SRC formally concluded in June 2026 that the ongoing trial is permitted to proceed to the Phase II stage.

We completed the Phase Ib part in June 2026 and expect to complete the entire Phase Ib/II clinical trial in June 2027.

GC101 TIL-MM-II: An Open-Label, Randomized, Controlled, Multicenter Phase II Clinical Trial of GC101 TIL Cell Injection in Patients with Advanced Melanoma

This registrational Phase II clinical trial of GC101 is an open-label, randomized, controlled, multicenter study designed to evaluate the efficacy and safety of GC101 TIL therapy compared with investigator-selected chemotherapy in patients with advanced melanoma. The primary endpoint is PFS as assessed by an independent radiology review committee (IRC) according to RECIST 1.1. Secondary endpoints include OS, PFS by investigator, ORR, DCR, DoR and safety.

Trial design.

- Enrollment: Planned enrollment of 98 patients.
- Key inclusion criteria: (i) Documented failure or intolerance to at least one PD-1 antibody therapy; (ii) unresectable advanced, recurrent, or metastatic melanoma with failure or intolerance to at least two prior systemic regimens; and (iii) tumor region amenable to resection or biopsy for TIL isolation, with at least one measurable lesion remaining after sampling.
- Key exclusion criteria: (i) Receipt of any other investigational drug within 28 days prior to randomization; and (ii) presence of other malignancies.

Eligible patients are randomized 1:1 to the GC101 TIL treatment group or the control group receiving investigator-selected chemotherapy. Patients in the GC101 TIL treatment group undergo tumor tissue collection for TIL manufacturing, followed by preconditioning with cyclophosphamide and hydroxychloroquine. GC101 TILs are subsequently administered intravenously with low-dose PD-1 antibody every six weeks for up to five doses. Patients in the control group receive single-agent or combination chemotherapy according to applicable treatment guidelines. Efficacy assessments are conducted every six weeks during the treatment period. Patients in the control group who experience IRC-confirmed disease progression may be eligible to cross over and receive GC101 TIL therapy. Patients who experience disease progression or initiate new anti-tumor therapy enter a long-term follow-up period, with survival status, subsequent therapy, and treatment-related adverse events recorded every 12 weeks.

Baseline characteristics.

A total of 99 patients were enrolled and randomized to the GC101 TIL treatment group (50 patients) or the control group (49 patients). All enrolled patients had advanced melanoma that had failed prior PD-1 antibody therapy. The median number of prior systemic therapy lines was two. Acral and mucosal melanoma accounted for 72.8% of patients. The median sum of diameters (SOD) of target lesions was 68.4 mm. The vast majority of patients had distant metastases. Most of them had metastases to vital organs, including the liver, lungs and bones. Baseline characteristics were balanced between the two treatment groups.

Status.

The trial was initiated in December 2024. The primary endpoint was achieved in May 2026. We expect to complete the registrational Phase II clinical trial and submit a BLA in September 2026.

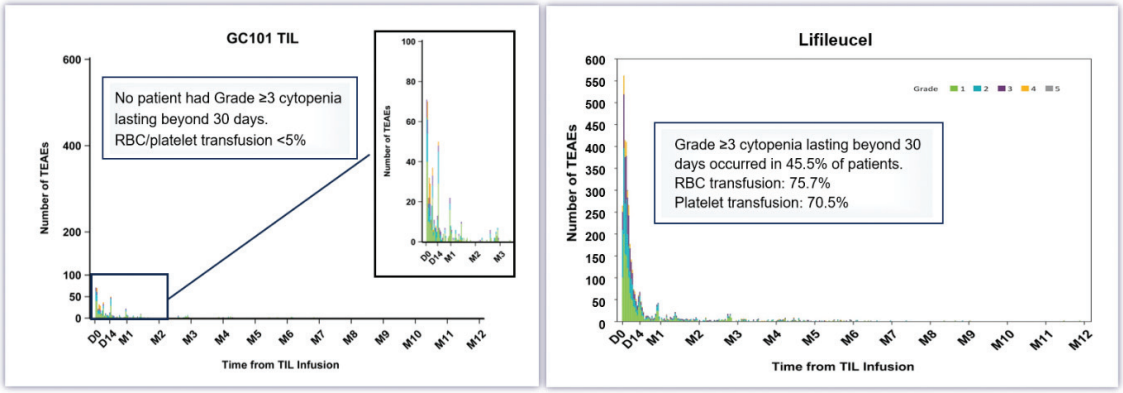
Safety data.

In the GC101 TIL treatment group, the safety profile was consistent with prior studies. The most common TEAEs were primarily hematologic toxicities attributed to the low-intensity preconditioning regimen. The median duration of adverse events was shorter than that in the control group (8 days versus 13 days).

Compared with published data for conventional TIL therapy, lifileucel[5], although no head-to-head comparison has been conducted, GC101 demonstrated a favorable safety profile. No patients experienced Grade 3 or higher cytopenia lasting beyond 30 days, compared with 45.5% reported in published lifileucel studies. The red blood cell and platelet transfusion rates were also substantially lower, at less than 5%, compared with more than 70% reported in published lifileucel studies.

5 Chesney, J., Lewis, K. D., Kluger, H., Hamid, O., Whitman, E., Thomas, S., Wermke, M., Cusnir, M., Domingo-Musibay, E., Phan, G. Q., Kirkwood, J. M., Hassel, J. C., Orloff, M., Larkin, J., Weber, J., Furness, A. J. S., Khushalani, N. I., Medina, T., Egger, M. E., Graf Finckenstein, F., … Sarnaik, A. (2022). Efficacy and safety of lifileucel, a one-time autologous tumor-infiltrating lymphocyte (TIL) cell therapy, in patients with advanced melanoma after progression on immune checkpoint inhibitors and targeted therapies: pooled analysis of consecutive cohorts of the C-144-01 study. *Journal for immunotherapy of cancer*, *10*(12), e005755.

Safety Profile Comparison Between GC101 TIL and Lifileucel



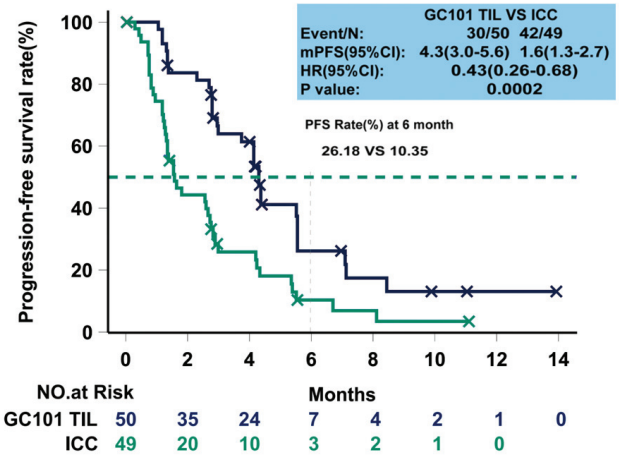
No IL-2-related toxicities, such as capillary leak syndrome, hypotension or febrile neutropenia, were observed in the GC101 TIL treatment group. No patients required intensive care unit admission, and patients generally experienced shorter hospitalization and rapid recovery following treatment.

Efficacy data.

As the first registrational randomized controlled trial of a TIL therapy in patients with late-line anti-PD-1 refractory advanced melanoma globally, the study met its primary endpoint. According to IRC assessment, median PFS in the GC101 TIL treatment group was 4.3 months, significantly longer than 1.6 months in the control group (HR=0.43; 95% CI: 0.26—0.68; p=0.0002), representing a 57% reduction in the risk of disease progression or death.

As of the data cutoff date of May 12, 2026, mOS was 12.2 months in the control group and had not yet been reached in the GC101 TIL treatment group. Despite a 57% cross-over rate from the control group to GC101 TIL therapy following disease progression, a trend toward improved OS was observed in the GC101 TIL treatment group.

PFS Comparison Between the GC101 TIL Treatment Group and the Control Group

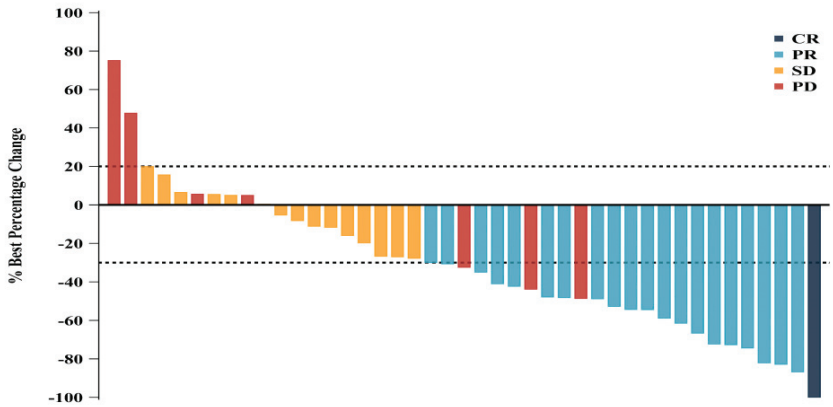


GC101 TIL = GC101 TIL treatment group; ICC = Control group

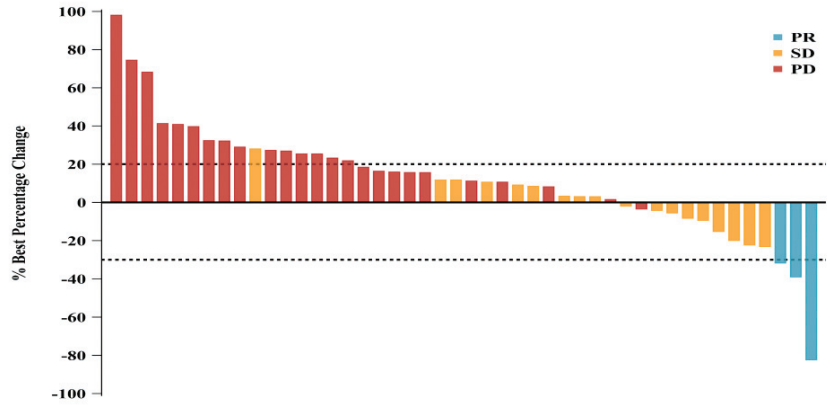
The ORR in the GC101 TIL treatment group was 42.0%, compared with 6.1% in the control group. In addition, certain patients in the GC101 TIL treatment group experienced complete response.

Best Percentage Change From Baseline in Target Lesion SOD

GC101 TIL treatment group



Control group



GC101 TIL&PD-1Ab-ST-II: An Open-Label, Single-Arm, Phase II Clinical Trial of GC101 TIL Cell Injection Combined with PD-1 Antibody for the Treatment of Patients with Advanced Solid Tumors

This Phase II clinical trial of GC101 is an open-label, single-arm study designed to evaluate the safety, tolerability, and preliminary efficacy of GC101 combined with PD-1 antibody in patients with advanced solid tumors, including malignant melanoma, head and neck squamous cell carcinoma, non-small cell lung cancer, and MSI-H/dMMR tumors. The study is divided into Phase IIa and Phase IIb. The primary endpoints for Phase IIa are the incidence of AEs, SAEs, and DLTs. The primary endpoints for Phase IIb are ORR, CR, and PFS according to RECIST v1.1 criteria.

Trial design.

- Enrollment: Planned enrollment of 6-12 patients in Phase IIa and 30 patients in Phase IIb.
- Key inclusion criteria: (i) Histologically or cytologically confirmed advanced solid tumors; and (ii) at least one measurable lesion prior to pre-conditioning.
- Key exclusion criteria: (i) Receipt of other investigational drugs within the past four weeks; (ii) prior receipt of allogeneic or gene-modified/edited autologous cell therapy within one year; (iii) prior receipt of systemic anti-tumor therapy; and (iv) history of other malignancies within five years.

The study comprises two sequential phases. Phase IIa is a dose-escalation stage intended to assess the safety and tolerability of GC101 TIL in combination with PD-1 antibody. Dose escalation follows a "3+3" design with two planned dose levels of TIL infusion: $5\text{-}20\times10^9$ cells and $20\text{-}45\times10^9$ cells. DLTs are monitored over 28 days, and the recommended Phase IIb dose is determined by the SRC based on safety and preliminary efficacy data.

Phase IIb is a dose-expansion stage designed to further evaluate efficacy and safety in approximately 30 patients. Patients receive a single GC101 TIL infusion in combination with PD-1 antibody administered at 200 mg starting 1-4 hours before TIL infusion, then every 3 weeks until disease progression, unacceptable toxicity, or six months after TIL infusion, whichever occurs first. Patients deriving continued benefit may continue PD-1 antibody for up to two years.

Eligible patients undergo tumor tissue collection for TIL manufacturing, receive low-dose lymphodepletion and are administered single-dose GC101 TILs with a low-dose PD-1 antibody. Safety and efficacy are evaluated every 6 weeks for the first 24 weeks post-infusion, thereafter, every 12 weeks until the patient enters long-term follow-up, with long-term survival assessment conducted every twelve weeks thereafter.

Status.

We received the IND approval in August 2025. We expect to initiate this trial in the third quarter of 2026.

Clinical Development Plan

Our clinical development plan is aligned with the Technical Guidelines for Clinical Trials of Anti-tumor Drugs issued by the CDE, which serves as one of the key guiding principles for oncology drug development. These guidelines provide that Phase I clinical trials typically enroll patients across various tumor types, and that early exploratory clinical trials should select multiple tumor types based on preclinical research results to obtain preliminary data on drug sensitivity across different cancers. Consistent with these principles, we obtained IND approval for GC101 under a clinical development framework that was not restricted to any specific tumor type and initiated a Phase I clinical trial of GC101 in patients with advanced solid tumors (GC101 TIL-ST-I). The GC101 TIL-ST-I trial generated safety, tolerability and preliminary efficacy data across multiple tumor types.

Based on the available clinical data from the GC101 TIL-ST-I trial, including preliminary efficacy results observed in patients with advanced melanoma and following the EOP1 meeting in November 2024, we initiated a registrational Phase II trial for advanced melanoma (GC101 TIL-MM-II) in December 2024. The trial reached its primary endpoint in May 2026. Based on the trial results, we plan to submit a BLA in September 2026 and aim for commercial launch following BLA approval.

For advanced NSCLC, we initiated a Phase Ib/II trial in November 2024 and expect to complete the trial in June 2027. Upon completion of the trial, we intend to hold an End-of-Phase II (EOP2) meeting with the CDE to discuss the clinical data package and the proposed design of a registrational Phase III trial. Subject to positive clinical results and regulatory feedback from the CDE, we anticipate initiating a Phase III trial in the second half of 2027.

We are also actively exploring the use of GC101 in combination with standard therapies in earlier-line tumor treatment settings. In August 2025, we received IND approval for a Phase II trial of GC101 combined with a PD-1 antibody as early-line therapy for pan-solid tumors. This clinical trial is expected to commence in the first half of 2026.

We intend to develop GC101 as postoperative adjuvant therapy for pancreatic cancer and glioma. We filed an IND application in December 2025 for GC101 as postoperative adjuvant therapy in patients with pancreatic cancer, and expect to initiate a clinical trial in the second half of 2026. We also filed an IND application in May 2026 for GC101 as postoperative adjuvant therapy in patients with glioma.

We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

Material Communications with Regulatory Authorities

The following table sets forth a summary of our material communications with regulatory authorities regarding GC101.

Timeline	Milestone/Stage
Phase I clinical trial in patients with advanced malignant solid tumors (CDE clinical trial registration number CTR20221207)	
January 2022	Submission of IND application to the NMPA
April 2022	IND approval received from the NMPA (broad in scope and not restricted to any specific solid tumor indication)
October 2022	Commencement of Phase I clinical trial in patients with advanced malignant solid tumors
November 2023	Submission of supplementary clinical trial application for manufacturing process modification (introducing new seed cell cryopreservation process)
January 2024	NMPA approval of manufacturing process modification (with no impact on the trial design approved under the 2022 IND)
July 2024	Completion of Phase I trial for purposes of the application for registrational Phase II clinical trial in patients with advanced melanoma (supported by CSR)
August 2024	Request for EOP1 communication and submission of CSR to the CDE
November 2024	EOP1 meeting with the CDE to review and discuss Phase I trial data
November 2025	Completion of trial across all tumor types (all primary endpoints achieved)
Registrational Phase II clinical trial in patients with advanced melanoma (CDE clinical trial registration number CTR20244769)	
November 2024	EOP1 meeting: CDE no-objection to proceeding with registrational Phase II trial in patients with advanced melanoma
December 2024	EOP1 meeting minutes issued by the CDE
December 2024	Commencement of the registrational Phase II clinical trial
May 2026	Primary endpoint met in the registrational Phase II clinical trial
September 2026 (Expected)	Submission of BLA
Phase Ib/II clinical trial in patients with advanced NSCLC (CDE clinical trial registration number CTR20243489)	
April 2022	IND approval received from the NMPA (broad in scope and not restricted to any specific solid tumor indication)
November 2024	Commencement of trial (originally designed as a Phase Ib clinical trial)
December 2025	Amendment to trial protocol to expand the ongoing trial into a combined Phase Ib/II clinical trial
January 2026	Receipt of CDE clarification confirming that a formal communication meeting is not required upon completion of the Phase Ib part before initiating the Phase II part of the trial
Phase II clinical trial in combination with PD-1 antibody in patients with advanced solid tumors	
May 2025	Submission of IND application to the NMPA
August 2025	IND approval received from the NMPA
November 2026 (Expected)	Commencement of trial
Phase II clinical trial for postoperative adjuvant therapy in treating pancreatic cancer	
December 2025	Submission of IND application to the NMPA
Phase II clinical trial for postoperative adjuvant therapy in treating glioma	
May 2026	Submission of IND application to the NMPA

For the Phase I clinical trial of GC101 in patients with advanced malignant solid tumors, we submitted an IND application to the NMPA in January 2022 and subsequently received IND approval in April 2022. Consistent with standard NMPA regulatory requirements for the transition to late-stage development, the IND approval requires that a meeting application be submitted to the CDE before initiating any confirmatory or registrational clinical trials. According to relevant regulations, subsequent exploratory clinical trials do not require NMPA review and instead only need approval of the clinical trial protocol by the relevant ethics committee.

In November 2023, we voluntarily submitted a supplementary clinical trial application for GC101 to upgrade our manufacturing capabilities by introducing a new seed cell cryopreservation process. This optimization enables the collection of tumor tissue and generation of seed TILs during an earlier stage of a patient's treatment journey, followed by cryopreservation for subsequent expansion and manufacturing when treatment is needed. By separating these manufacturing steps over time, this approach addresses a key challenge in TIL therapy, where the quality and quantity of TILs obtained from heavily pretreated late-line patients may be diminished, while also improving manufacturing flexibility. This supplementary application was approved by the NMPA in January 2024. In the official approval notice, the NMPA confirmed that we may continue to conduct the clinical trials in accordance with the original April 2022 IND approval, and therefore did not affect the commencement, conduct or completion of the Phase I clinical trial for GC101. This supplementary approval related solely to manufacturing process modifications; it did not modify any clinical trial design elements approved under the 2022 IND approval (including patient enrollment criteria, primary or secondary endpoints, dose-escalation scheme, or overall study structure).

For the registrational Phase II clinical trial of GC101 in patients with advanced melanoma, we held an EOP1 meeting with the CDE in November 2024, and the CDE issued the corresponding EOP1 meeting minutes in December 2024. At the EOP1 meeting, the CDE confirmed that (i) the Phase II clinical trial would be a registrational trial, serving as the confirmatory study for registration, and (ii) the PFS, as assessed by an IRC in accordance with RECIST 1.1, would be accepted as the primary endpoint for the registrational Phase II clinical trial to support a BLA for conditional marketing approval. Details of the EOP1 meeting with the CDE evidenced by the EOP1 meeting minutes are as follows:

- *Date of the meeting*: November 1, 2024.
- *Purpose of the meeting*: to discuss on the trial design of the registrational Phase II clinical trial of GC101 proposed for an application for conditional marketing approval.
- *Meeting background*: the Company conducted a single-arm Phase I clinical trial of GC101 in patients with advanced malignant solid tumors. The following are the clinical trial results based on the data cutoff date as of April 23, 2024 (safety data) and July 28, 2024 (efficacy data).
    - *Safety data:* Among the 19 patients with advanced malignant solid tumors enrolled, no investigational drug related death occured. Only one case of Grade 3 decreased platelet count was considered as investigational drug related SAE and subsequently resolved. The most commonly observed TEAEs included hematologic abnormalities and inflammatory responses. Grade ≥3 adverse events were primarily controllable and reversible hematologic toxicities. Overall, GC101 demonstrated a favorable and manageable safety profile. Among these patients, 10 subjects had advanced melanoma. In this subgroup (N = 10), GC101 was similarly well tolerated and demonstrated preliminary signs of efficacy.
    - *Efficacy data:* In the advanced melanoma subgroup (N = 10), three subjects (30.0%) achieved a partial response, resulting in an ORR of 30.0% (95% CI: 6.67% to 65.25%) under RECIST 1.1 criteria. The median follow-up duration was 8.2 months (range: 3.2 to 20.2 months). The median PFS was 5.5 months (95% CI: 1.45 to 7.13 months). The median DoR had not yet been reached. mOS had not yet been reached. The 6-month OS rate was 83.3% (95% CI: 27.3% to 97.5%). Based on patient follow-up and analysis, the Phase I clinical trial of GC101 has generated sufficient efficacy data to support the initiation of a registrational Phase II clinical trial in advanced melanoma.

- *Meeting agenda*: During the meeting, three key issues in relation to the registrational Phase II clinical trial of GC101 in advanced melanoma were discussed with the CDE:

  (i) Clinical trial design — the conduct of a randomized, controlled, open-label registrational Phase II clinical trial comparing GC101 with chemotherapy in patients with unresectable advanced, recurrent or metastatic melanoma who have failed or are intolerant to PD-1 antibody therapy, with median PFS assessed by an independent radiology review committee (IRC) as the primary endpoint to support an application for conditional marketing approval;

  (ii) Selection of the control arm — the use of chemotherapy as the control arm; and

  (iii) Sample size and statistical design — the proposed sample size, event number, analysis plan for the registrational Phase II clinical trial.

Consensus was reached with the CDE on all three issues.

As evidenced by the EOP1 meeting minutes issued in December 2024, the CDE had no objection to us conducting the proposed registrational Phase II clinical trial of GC101 in advanced melanoma to support a potential conditional marketing approval. We thereafter registered the registrational Phase II clinical trial on the CDE's Drug Clinical Trial Registration and Information Disclosure Platform in December 2024. In December 2024, CDE designated a registration ID of CTR20244769 to the registrational Phase II clinical trial.

For the Phase II clinical trial of GC101 in combination with PD-1 antibody in patients with advanced solid tumors, we submitted an IND application to the NMPA in May 2025 and obtained IND approval in August 2025. The IND approval allows the initiation of a Phase II open-label, single-arm clinical trial evaluating GC101 in combination with PD-1 antibody in advanced solid tumors.

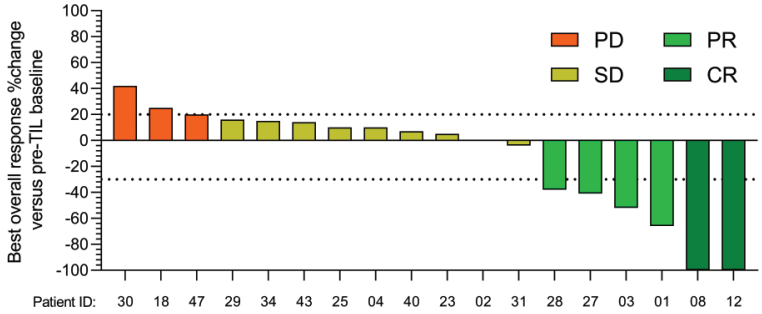
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GC101 SUCCESSFULLY.

Key Product Candidate GC203: A Non-Viral Gene-Modified TIL Therapy for Refractory Solid Tumors

Overview

GC203, our key product candidate, is a differentiated non-viral gene-modified TIL therapy designed to enhance the potency and persistence of autologous T cells for patients with advanced solid tumors. Leveraging the inherent tumor specificity of GC101, GC203 incorporates a self-associating, membrane-bound IL-7 construct to boost T cell activity, durability, and adaptability, while remodeling the tumor microenvironment to activate endogenous immune cells and amplify anti-tumor responses.

In an IIT involving heavily pretreated patients with advanced ovarian cancer, GC203 demonstrated an ORR of 33.3% and complete remissions in 11.1% of patients. Median progression-free survival reached 5.1 months, and the 12-month OS rate was 68.8%. No long-term complications were observed following GC203 infusion, and no unexpected or novel safety concerns emerged during follow-up. The most common grade 3 or higher AEs were hematologic toxicities associated with preconditioning, including leukopenia (50%), lymphopenia (38.9%) and neutropenia (33.3%). Importantly, no grade 5 events were reported.



Source: Company data

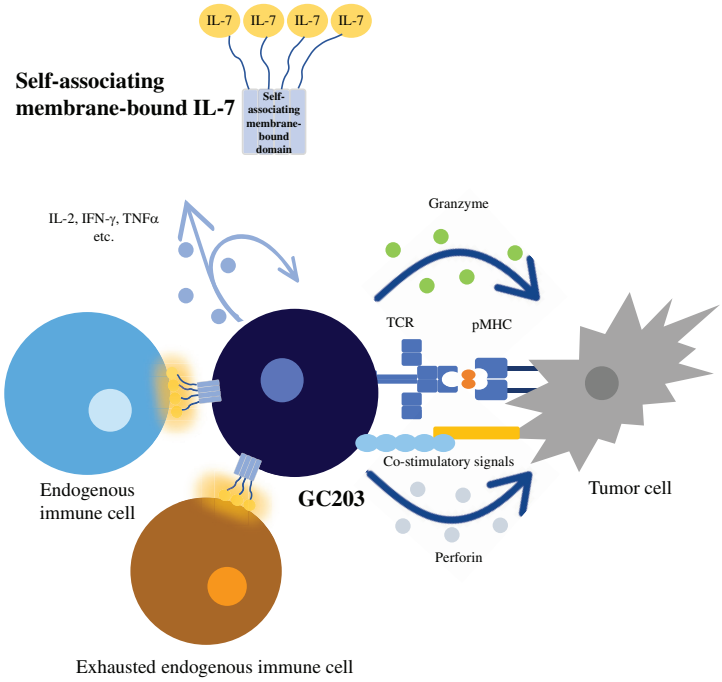
GC203 has also received IND approvals for advanced pancreatic cancer, supporting its expansion into additional solid tumor indications. As a differentiataed non-viral vector gene-modified TIL therapy, GC203 represents a promising, broadly applicable approach for patients with refractory solid tumors.

Mechanism of Action

GC203 is a gene-modified TIL therapy in which autologous T cells are modified using a non-viral vector platform to stably express a self-associating, membrane-bound IL-7 construct. GC203 retains the tumor-specific cytotoxicity of GC101 through TCR-mediated recognition of heterogeneous tumor cells.

The membrane-bound IL-7 enhances the stemness and persistence of TILs *in vivo*, supporting long-term anti-tumor activity. Because regulatory T cells (Tregs) do not express the IL-7 receptor, this modification selectively avoids activating pro-tumor Tregs. Compared with secreted IL-7, the membrane-bound, self-associating IL-7 minimizes systemic exposure and toxicity, while leveraging TILs' natural tumor-homing ability to remodel the tumor microenvironment. This local activity stimulates endogenous immune cells, generating a synergistic anti-tumor response. The self-associating IL-7 exhibits higher functional activity than monomeric IL-7, further enhancing the therapeutic potency of GC203.

The diagram below illustrates the mechanism of action of GC203.



Source: Company data

Market Opportunity and Competition

The rising global and China incidence of pancreatic and gynecologic highlights sizeable and expanding patient populations that could benefit from TIL-based treatments.

Globally, new pancreatic cancer cases increased from 495.8 thousand in 2020 to 549.0 thousand in 2025, representing a CAGR of 2.1%. Incidence is projected to reach 634.3 thousand by 2030 and 726.7 thousand by 2035. In China, cases are expected to grow from 127.7 thousand in 2025 to 148.9 thousand in 2030 and 170.2 thousand by 2035. Pancreatic cancer remains one of the most lethal malignancies, and the absence of effective immunotherapy options highlights a sizeable unmet need for next-generation TIL approaches.

Cervical, uterine, and ovarian cancers collectively represent a major global cancer burden. Worldwide, new cases of cervical cancer grew from 604.1 thousand in 2020 to 702.6 thousand in 2025 and are projected to reach 814.5 thousand by 2035. Uterine cancer cases increased from 417.4 thousand in 2020 to 452.9 thousand in 2025, with incidence expected to exceed 551.4 thousand by 2035. Ovarian cancer cases rose from 314.0 thousand in 2020 to 347.0 thousand in 2025 and are projected to reach 415.6 thousand by 2035. In China, incidence across these gynecologic cancers continues to rise steadily, with cervical, uterine, and ovarian cancers projected to reach 168.6 thousand, 87.4 thousand, and 72.3 thousand cases respectively by 2035. Given the limited efficacy of existing systemic therapies in advanced or recurrent disease, TIL therapy offers a highly relevant immunotherapy alternative for these patient populations.

For details, see "Industry Overview — Overview of Major Therapeutic Areas in Solid Tumor Treatment."

Competitive Advantages

We believe that GC203 has the following competitive advantages.

- High efficacy profile. GC203 achieves gene-modification efficiency comparable to viral-vector approaches. In heavily pretreated ovarian cancer patients, GC203 demonstrated an objective response rate twice that of natural TIL therapy, with over 10% of patients achieving complete remission. Promising responses have also been observed in cervical and pancreatic cancers, underscoring its broad potential across refractory solid tumors. Its membrane-bound, self-associating IL-7 construct enhances TIL persistence and tumor adaptability while activating endogenous immune cells to generate synergistic anti-tumor responses.

- Favorable safety profile. By leveraging a non-viral vector, GC203 avoids the risks associated with replicating viral vectors. Patients do not require high-intensity lymphodepletion or IL-2 administrations, and all treatments have been safely administered in less demanding hospital wards with a significantly shortened hospitalization duration. The therapy's design ensures potent anti-tumor activity without increasing systemic toxicity.

- Cost-effective and scalable. The non-viral manufacturing platform significantly reduces vector costs with viral-based approaches, supporting broader accessibility and the potential for large-scale production. Additionally, GC203's gene-modified design provides a foundation for future TIL product pipelines, offering a versatile platform for expanding gene-modified TIL therapies.

Summary of Clinical Trials

The following table sets forth an overview of the clinical studies of GC203.

Study Number	Phase	Study Design	Sites	Subjects	Status	Actual Patient Enrollment
GC203 TIL-ST-I	I	Open-label, single-arm trial for the treatment of advanced malignant solid tumors	China	Patients with advanced malignant solid tumors	Ongoing	16

GC203 TIL-ST-I: An Open-Label, Single-Arm, Phase I Clinical Trial of GC203 TIL Cell Injection for the Treatment of Patients with Advanced Malignant Solid Tumors

This Phase I clinical trial of GC203 is an open-label, single-arm study designed to evaluate the safety, tolerability, and preliminary efficacy of GC203 TIL therapy in patients with advanced solid tumors, and to explore potential biomarkers associated with response. The primary endpoint is the incidence and frequency of AE and SAE within 24 weeks post-infusion.

Trial design.

- Enrollment: Planned enrollment of 58 patients.
- Key inclusion criteria: (i) Advanced malignant solid tumors confirmed by cytology or histopathology with failure of standard therapy; (ii) tumor region amenable to resection or biopsy for TIL isolation; and (iii) at least one measurable lesion present at pre-conditioning assessment.
- Key exclusion criteria: (i) Participation in other clinical trials within four weeks prior to enrollment; (ii) prior receipt of allogeneic or gene-modified/edited autologous cell therapy within one year; (iii) receipt of systemic anti-tumor therapy within four weeks prior to enrollment; and (iv) history of other malignancies within five years prior to screening.

Eligible patients undergo tumor tissue collection for TIL manufacturing, followed by low-dose preconditioning with cyclophosphamide and hydroxychloroquine. Patients then receive intravenous GC203 TIL infusion with low-dose PD-1 antibody to protect from immunosuppression. Safety and efficacy are evaluated over a 360-day follow-up period, with tumor assessments every six weeks for the first 24 weeks and every 12 weeks thereafter until disease progression, initiation of other therapy, withdrawal, death, or study completion.

Status.

The trial was initiated in May 2024. We expect to complete the Phase I clinical trial in September 2027.

Clinical Development Plan

We initiated a Phase I trial in April 2024 to evaluate the efficacy and safety of GC203 in multiple solid tumors. Enrollment for the dose-escalation phase is expected to complete in the second quarter of 2026. Based on the trial results, we plan to proceed with dose-expansion cohorts in ovarian and pancreatic cancers.

We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

Material Communications with Competent Authorities

The following table sets forth a summary of our material communications with regulatory authorities regarding GC203.

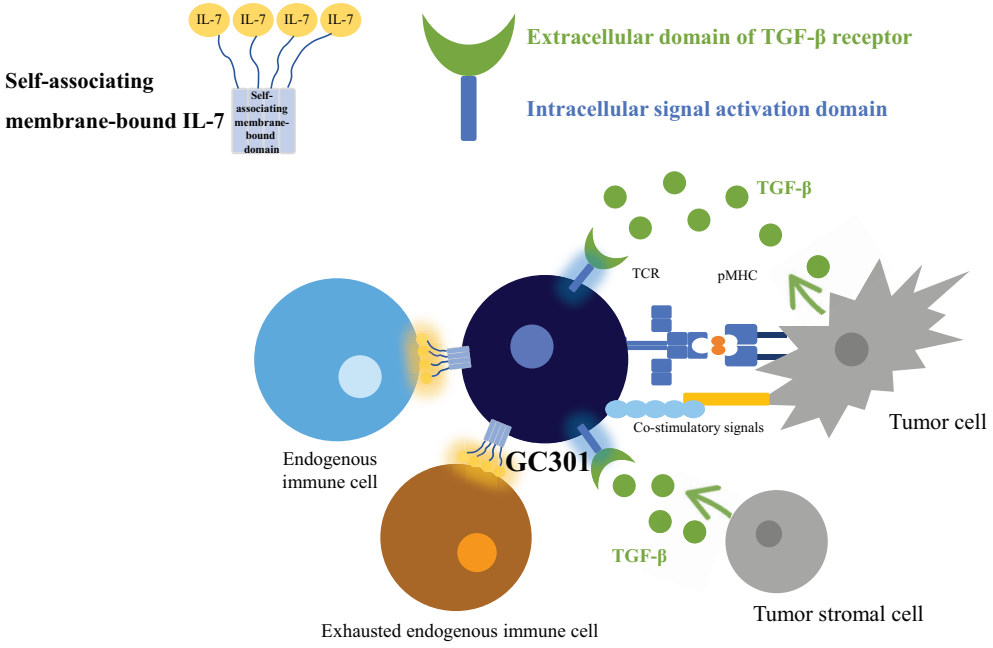
Study	Milestone/Stage	Timeline
Phase I clinical trial of GC203 in patients with advanced malignant solid tumors	Submission of IND application to the NMPA	Jan 2024
	IND approval from the NMPA	April 2024

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GC203 SUCCESSFULLY.

GC301: A Dual-Gene-Modified TIL Therapy for Solid Tumors with Liver Metastases

Building on the self-associating membrane-bound IL-7 expressed in GC203, GC301 further incorporates a chimeric switch receptor directed at the inhibitory TGF-β. This design directly addresses clinical needs: the immune microenvironment of many solid tumors with liver metastases presents abnormally high levels of TGF-β, a key driver of TIL exhaustion, impaired proliferation, and suppressed antitumor activity, which together form a major bottleneck for traditional TIL therapy in this setting.

GC301 retains the core attributes of GC203. Sustained expression of membrane-bound IL-7 supports TIL survival within the tumor microenvironment and activates surrounding immune cells to mount a coordinated antitumor response. The added chimeric switch receptor further elevates TIL activation. Its extracellular domain binds specifically to TGF-β, while its intracellular domain is replaced with a potent activation motif.



Source: Company data

Upon TGF-β binding through the engineered receptor, GC301 TILs no longer receive suppressive signals. Instead, the receptor converts this interaction into a strong activating signal. This not only neutralizes TGF-β-mediated inhibition but also creates a dual stimulatory effect — baseline activation through IL-7 plus switch-receptor-mediated activation. The result is enhanced TIL activation, cytotoxicity, and cytokine production, effectively conferring "resistance" to TGF-β-driven immunosuppression.

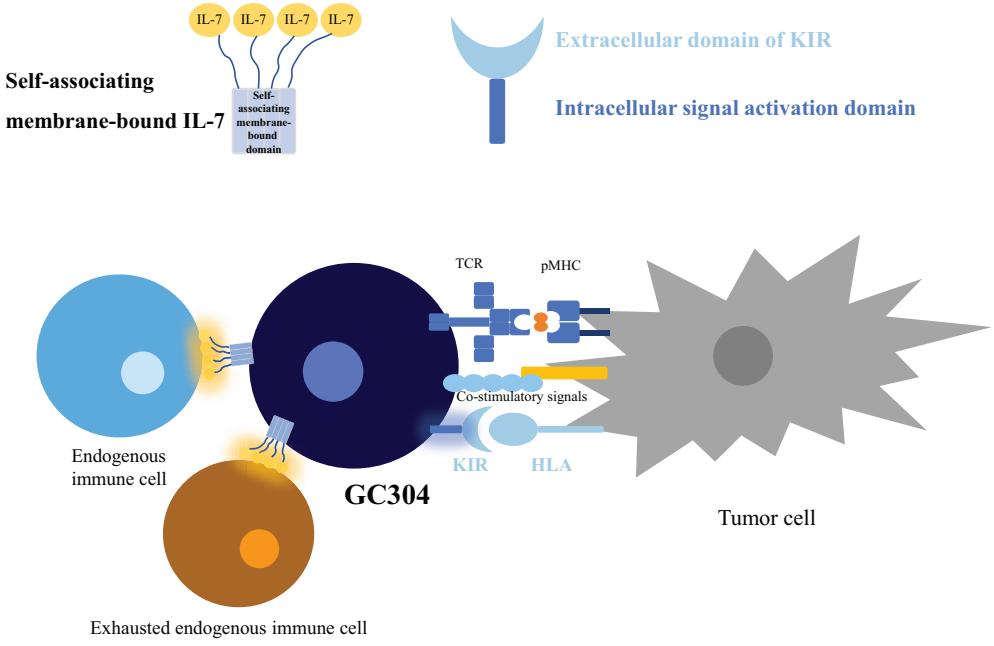
GC301 has the potential to overcome long-standing efficacy limitations of TIL therapy in solid tumors with liver metastases, offering a new immunotherapy strategy for patients with poor prognosis and few effective treatment options. GC301 is currently in IIT, and we plan to submit an IND application in the second half of 2027.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GC301 SUCCESSFULLY.

GC304: A Dual-Gene-Modified TIL Therapy for Sarcomas, Colorectal, and Breast Cancer

GC304 follows the same design principles as GC301 and builds upon the established technology of GC203, namely the stable expression of membrane-bound self-associating IL-7. The key distinction is its chimeric switch receptor was constructed with the extracellular domain of KIR (Killer cell immunoglobulin-like receptor) to bind one of the HLA family proteins on tumor cell membrane, thereby enhancing tumor-specific recognition and activation. The targeted HLA-peptide is commonly expressed across hard-to-treat tumors such as sarcomas, colorectal cancer, and breast cancer, offering GC304 a natural tumor-specific entry point.

Mechanistically, the GC304 switch receptor functions dually. Its extracellular domain is optimized for precise binding to HLA, enhancing TIL-tumor cell contact and addressing the challenge of insufficient recognition in low-immunogenic tumors. Engagement with HLA triggers activation of the intracellular stimulatory domain, rapidly initiating strong intracellular signaling and boosting cytotoxic effector molecules secretion as well as proliferative capacity.



Source: Company data

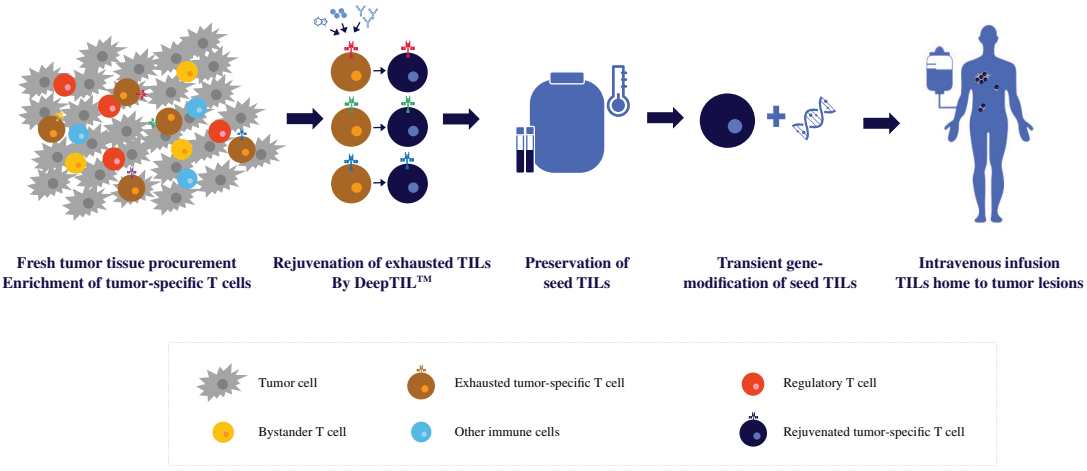
Clinically, GC304's tumor-specific targeting combined with its dual activation mechanism may overcome efficacy plateaus in refractory sarcoma, colorectal cancer, and breast cancer. It offers a more targeted, safe, and potentially effective immunotherapy option, further expanding the clinical reach of gene-modified TIL therapy. GC304 is in preclinical development, with an IIT planned for the second half of 2027.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GC304 SUCCESSFULLY.

iGC101: An *In Vivo* Expanding TIL Therapy for Pan-Solid Tumors

iGC101 aims to redefine the traditional TIL manufacturing paradigm with a focus on simplifying and accelerating production while reducing cost. Using pre-manufactured seed TILs, the clinical workflow will employ transient, efficient, non-viral gene modification, eliminating risks associated with replication-competent viruses and avoiding the high production and testing costs of viral vectors. Through this modification step, TILs transiently express a CAR directed at an endogenous protein.

Once infused, iGC101 could expand rapidly upon recognition of a group of endogenous target cells, enabling a nearly off-the-shelf TIL approach that could significantly lower costs and shorten patient waiting times.



Source: Company data

iGC101 will be initially explored in indications already validated by GC101, aiming to transform personalized TIL therapy into a streamlined, widely accessible cell therapy. iGC101 is in preclinical development, and we plan to initiate an IIT in the second half of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET iGC101 SUCCESSFULLY.

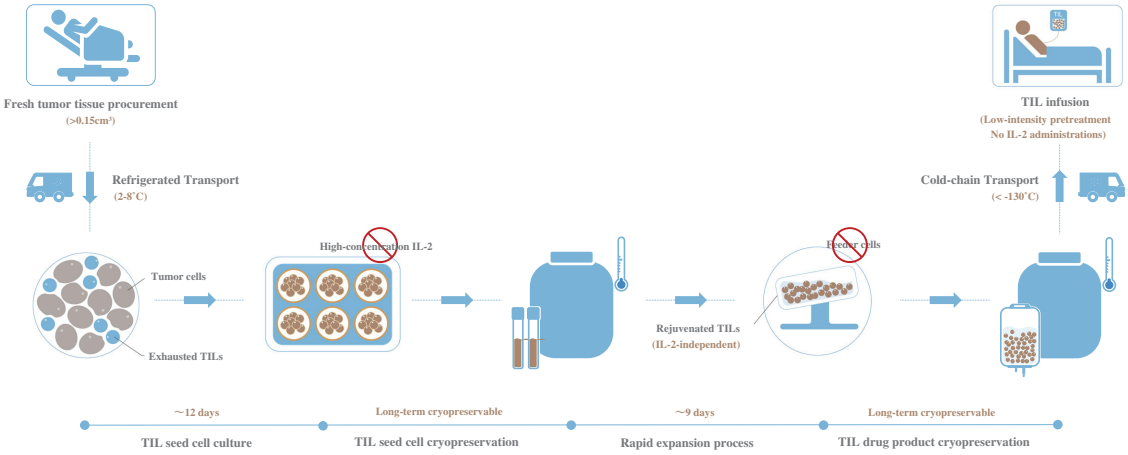
OUR TECHNOLOGY PLATFORMS

Our proprietary technology platforms serve as the foundation of our TIL therapy development. TIL therapy is a form of immunotherapy that uses a patient's own immune cells, harvested directly from their tumor, to recognize and attack cancer cells. By integrating innovations in cell selection, growth, and genetic enhancement, we have established a standardized and cost-efficient framework for developing both natural and genetically modified TIL therapies.

DeepTIL™: Cell Enrichment and Expansion Platform

The DeepTIL™ (Dual-Free Platform for TIL) platform represents a technical advancement over traditional TIL manufacturing. Standard methods typically require "feeder cells" (blood cells from healthy donors) and high concentrations of growth-stimulating proteins (IL-2) to grow enough cells for treatment. The DeepTIL™ platform is "Dual-Free" because it eliminates the need for both donor feeder cells and high-concentration IL-2 supplementation, simplifying the manufacturing process.

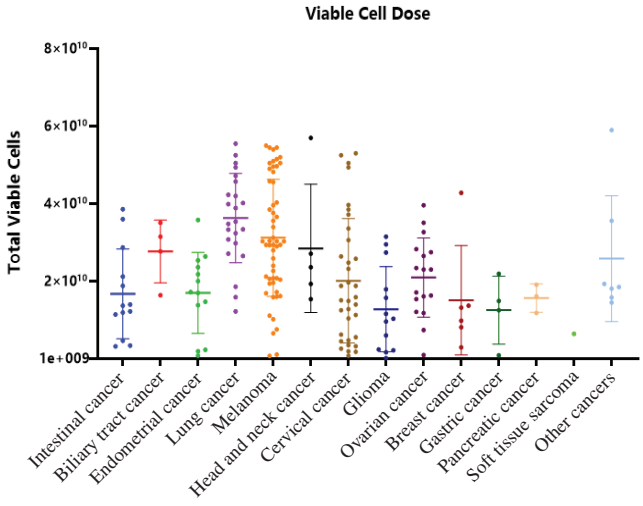
DeepTIL™ Cell Expansion Platform



Key features include:

- ***Broad Applicability:*** We can successfully extract and grow immune cells from over 30 different tumor types, achieving a culture success rate exceeding 95% and an average yield of approximately 20 billion cells.
- ***Simplified manufacturing:*** By removing the need for donor "feeder cells," we reduce the risks associated with sourcing external biological materials and simplify regulatory compliance.
- ***Improved safety profile:*** Our platform produces TILs that remain active without the need for high-dose IL-2 injections. In a clinical setting, this would allow for milder pre-treatment and fewer side effects for the patient.
- ***Functional rejuvenation:*** The platform uses a specialized process to "reprogram" the cells, restoring their natural potency and ability to fight tumors.

Robust process across tumor types



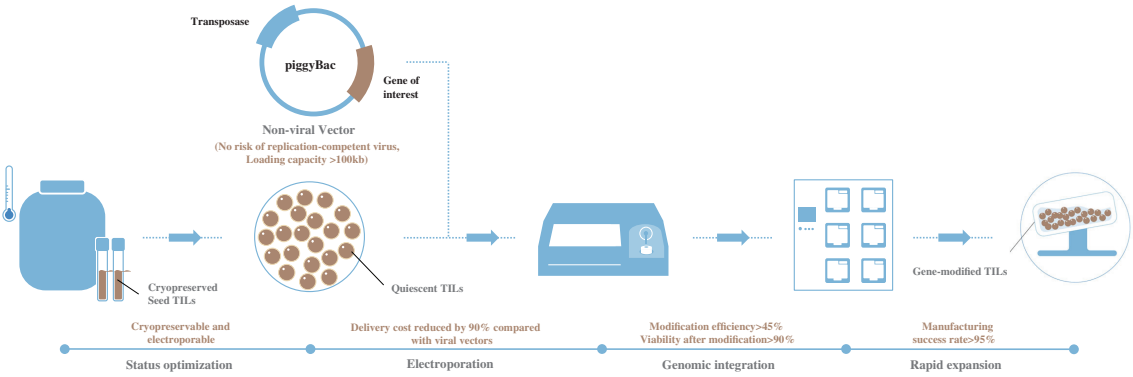
Source: Company data

Our Core Product, GC101, was developed using this platform and has demonstrated a collective response rate exceeding 40% in patients with advanced solid tumors who had previously failed other treatments.

NovaGMP™: Non-Viral Gene-Modification Platform

The NovaGMP™ (Non-Viral Gene-Modification Platform) platform uses a non-viral system (known as PiggyBac transposon system) to insert new genetic instructions into immune cells. While many companies use modified viruses to deliver genes, our platform uses an electrical pulse (electroporation) to transfer genetic material.

NovaGMP™ Gene-modification platform



Key features include:

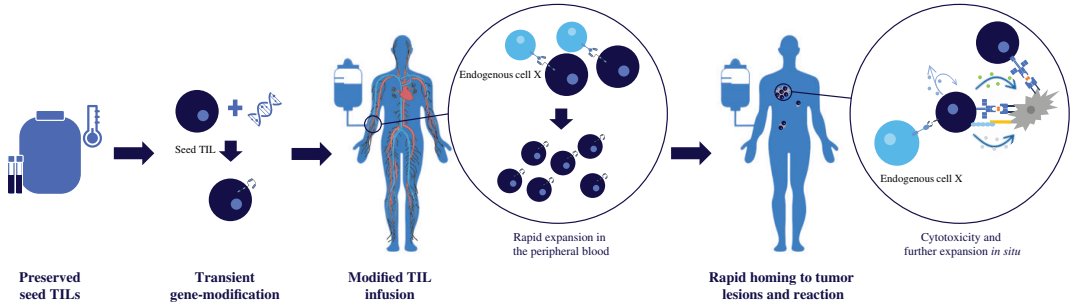
- ***Efficiency and cost:*** It achieves genetic modification rates similar to viral methods but at a significantly lower production cost.
- ***High payload capacity:*** This system can carry 20 times more genetic information than traditional viral delivery, allowing us to create more complex and precisely engineered therapies.
- ***Enhanced safety:*** Because no viruses are used, there is no risk of accidental viral replication, which streamlines the safety testing and regulatory approval process.
- ***Integration:*** This platform allows us to add specific "anti-tumor" features to the rejuvenated cells produced by our DeepTIL™ platform.

NovaGMP™ platform has been applied in the development of our key product candidate GC203 (single-gene modification) and GC301/GC304 (dual-gene modifications), which build upon our Core Product GC101 to enhance anti-tumor activity and address key challenges in tumor immunotherapy.

RiverTIL™: *In Vivo* TIL Expansion Platform

Building on our time-segmented process, we are developing the RiverTIL™ (Rapid *In Vivo* Expansion and Reaction TIL) platform to move part of the cell-growing process from the laboratory directly into the patient's body (known as *in vivo* expansion).

RiverTIL™ Platform



Key features include:

- ***Internal growth***: Instead of growing billions of cells in a lab, we produce modified TILs that are designed to multiply rapidly within the patient's own body.
- ***Reduced timelines***: By reducing the time cells spend in the laboratory, we can deliver the therapy to the patient much faster.
- ***Lower costs***: This approach minimizes the need for large-scale, expensive laboratory facilities, making personalized TIL therapy more accessible and affordable.

Our preclinical candidate, iGC101, is the first product to utilize this platform, aiming to streamline the delivery of personalized cancer treatment.

RESEARCH AND DEVELOPMENT

R&D Strategy

Our research and development strategy focuses on advancing TIL therapies for patients with advanced solid tumors, prioritizing indications with significant unmet medical needs, including PD-1-antibody resistant or refractory melanoma, gynecologic cancers, and other hard-to-treat malignancies. In addition to later-line settings, we pursue first-line and adjuvant combination approaches with the objective of establishing TIL-based early-line or post-surgical treatment options, thereby enabling deeper and more durable clinical benefit across a broad spectrum of solid tumors.

GC101 provided the foundational clinical validation of the DeepTIL™ platform, upon which GC203 was advanced through a single-gene modification enabled by NovaGMP™. Building on these, we are progressing dual-gene-modified candidates such as GC301 and GC304, applying a stepwise approach to strengthen therapeutic potency while maintaining regulatory continuity and development efficiency.

We integrate our proprietary DeepTIL™ cell enrichment and expansion platform with the NovaGMP™ non-viral gene-modification platform to enhance the quality, consistency, and scalability of TIL products. DeepTIL™ is compatible with a range of gene-modification modalities, allowing the development of natural and gene-modified TIL therapies with tailored anti-tumor functions. Through iterative optimization of cell expansion and gene-modification processes, we aim to further improve TIL viability, functionality, and persistence, including exploration of exogenous elements such as signal-converting receptors and membrane-bound cytokines.

We also maintain translational flexibility through the development of innovative *in vivo* TIL approaches, which leverage transient non-viral gene modification of pre-manufactured seed TILs to facilitate rapid in-patient expansion. This approach is designed to shorten production timelines, reduce costs, and substantially increase accessibility, supporting the long-term evolution of TIL therapies toward broader clinical use.

Guided by these principles, we prioritize programs with the greatest potential for clinical impact. This includes GC101 and GC203 in clinical development, as well as preclinical candidates GC301, GC304, and iGC101 enabling us to systematically address unmet needs across multiple tumor types. Through this platform- and pipeline-driven strategy, we aim to maintain a TIL research program capable of delivering natural, gene-modified, and *in vivo*-expanded therapies with enhanced potency, persistence, and safety, while retaining the flexibility to integrate emerging innovations in cell therapy.

R&D Team

Our R&D team possesses extensive expertise and development experience in cellular therapies. As of the Latest Practicable Date, a majority of our R&D team members held advanced degrees, including 15.6% with doctoral degrees and 37.8% with master's degrees. The advanced degrees of our core R&D personnel are in relevant life science disciplines, including genetics, biochemistry and molecular biology, cell biology and biochemistry. The following table sets forth a breakdown of our R&D team by function as of the Latest Practicable Date:

Functions	Number of employees by function
Non-clinical Research and Development	17
Clinical Development	28
Total	45

Our core R&D personnel consist of five members with multidisciplinary expertise in chemistry, biology, pharmacology, and medicine. Their collective track records at leading global and domestic biopharmaceutical companies, including Bayer, Bristol-Myers Squibb, Innovent Biologics, Fosun Kite, and JW Therapeutics, demonstrate a proven ability to move complex cellular therapies from early-stage discovery through to commercialization.

- **Dr. Jin Huajun (CEO & CTO):** Dr. Jin received a doctorate degree in genetics from Wuhan University and has been engaged in cell and gene therapy research and development since 2009. Prior to joining our Group, he held research and development positions at the Gene Virus Treatment Laboratory of the Eastern Hepatobiliary Surgery Hospital, the Tumour Biotherapy Diagnosis and Treatment Centre of the Second Military Medical University, etc. Dr. Jin is responsible for the overall strategy, management and coordination of the development of the Core Product, including product research, clinical development, manufacturing and regulatory planning.

- **Dr. Huang Chen (Deputy General Manager):** Dr. Huang received a doctorate degree in biochemistry and molecular biology from Wuhan University and has been engaged in cell and gene therapy-related research and intellectual property activities from 2011 to 2014 and since 2017. Prior to joining our Group, he was responsible for intellectual property planning supporting cell therapy product development at Shanghai Cell Therapy Group Co., Ltd. Dr. Huang is responsible for the pre-clinical research activities of the Core Product and the preparation, filing and management of patent applications and other intellectual property matters relating to the Core Product.

- **Ms. He Zhou (Deputy General Manager):** Ms. He received a master's degree in cell biology from Zhejiang University and has been engaged in cell therapy process development and manufacturing since 2015. Prior to joining our Group, she participated

in the development of CAR-T and TIL products at Shanghai Cell Therapy Research Institute and CAR-T process development at JW Therapeutics (Shanghai) Co., Ltd. Ms. He is responsible for the process development, technology transfer, manufacturing process optimization and production activities of the Core Product.

- **Ms. Tang Mengmeng (Deputy General Manager):** Ms. Tang received a master's degree in biochemistry from Indiana University Bloomington and has accumulated extensive experience in cell therapy-related research, project management, registration and compliance activities since 2012. Prior to joining our Group, she worked on cell therapy-related research and development project management, process development and drug registration activities. Ms. Tang is responsible for regulatory affairs, registration submissions and clinical compliance matters relating to the Core Product.

- **Mr. Lin Shuwei (Deputy General Manager):** Mr. Lin received a bachelor's degree in biological science from Wuhan University and a master's degree in business administration from Nanyang Technological University. He has been engaged in cell therapy-related clinical operations since 2019. Prior to joining our Group, he worked at Fosun Kite Biotechnology Co., Ltd., where he was involved in activities relating to CAR-T products. Mr. Lin is responsible for the clinical development and operational management of the Core Product, including clinical trial execution and investigator site coordination.

All key R&D personnel involved in the development of the Core Product remained employed by our Group during the Track Record Period and as of the Latest Practicable Date.

R&D Costs

In 2024 and 2025, we incurred research and development costs of RMB91.0 million and RMB114.9 million, respectively. Of these amounts, RMB60.5 million and RMB83.4 million were attributable to our Core Product, respectively, representing 66.5% and 72.6% of our total research and development costs, and 52.3% and 50.8% of our total operating expenses, in the corresponding periods. We anticipate to continue to significantly invest in our R&D efforts, since we plan to expand the indications and continue the clinical development of our Core Product, advance more pipeline candidates along clinical trials and conduct additional preclinical studies.

Clinical Development

Relationship with CROs and SMOs

We collaborate with contract research organizations (CROs) and site management organizations (SMOs) to conduct and support our preclinical and clinical trials in accordance with industry practice. Selection of CROs and SMOs is based on multiple factors, including their business focus, capabilities, overall market recognition, prior compliance record, and adherence to regulatory standards such as GLP for nonclinical safety studies and CNAS accreditation for third-party or central laboratories. We also consider the R&D capabilities of their teams and the management skills of their leaders, based on experience and prior track record. Overall, we aim to select CROs and SMOs that are optimally compatible with our preclinical and clinical development programs.

When collaborating on a specific project, our project leader takes a comprehensive approach to management, closely monitoring progress, maintaining regular communication with CRO and SMO teams, and tracking project milestones to identify potential risks. Simultaneously, the project leader maintains close contact with the financial departments of both our Company and the CRO/SMO organization, implementing stringent financial controls at various stages to ensure timely and high-quality completion. Upon project completion, a thorough review is conducted to provide feedback and enhance the efficiency of future collaborations.

In terms of involvement and contributions, preclinical CROs primarily provide services related to toxicity and safety evaluations, including animal studies, in accordance with agreed study designs and under our supervision. Clinical CROs provide the range of services necessary for the execution of complex clinical trials, while SMOs assist in implementing and managing clinical trials, including trial preparation, clinical safety management, data management, and report preparation. Engagement decisions are based on the complexity and workload of each trial. We closely monitor the work of our CROs and SMOs, providing specific guidance to ensure quality and efficiency, while allowing our in-house team to focus on critical clinical trial elements such as trial design, data analysis, and strategic decision-making. All human studies are conducted in compliance with applicable laws and regulations, following industry standards and Good Clinical Practice (GCP) guidelines.

Service fees paid to CROs and SMOs are determined primarily based on prevailing market rates for similar services, the number of enrolled patients, the duration of clinical trials, and the quality and scope of services provided. We believe that our ability to collaborate closely with CROs and SMOs enables us to conduct preclinical studies and clinical trials efficiently, generate reliable data, and shorten the overall time required for product development.

In 2024 and 2025, we engaged three and four CROs, respectively, incurring total expenses of RMB9.8 million and RMB7.6 million. During the same years, we engaged six and nine SMOs, respectively, with associated expenses of RMB2.1 million and RMB2.9 million. See "— Our Suppliers" for the details of our major CROs and SMOs engaged during the Track Record Period.

Regulatory Affairs

Our regulatory affairs team is responsible for managing the regulatory approval process for our product candidates. This includes preparing and assembling application dossiers for IND and BLA submissions, addressing inquiries from relevant regulatory authorities, and monitoring our R&D projects to ensure ongoing compliance with applicable regulations.

The team oversees the full regulatory submission process, ensuring that filings are completed and approved by the appropriate authorities prior to the initiation of clinical trials or commercialization. Key responsibilities include drafting and managing submission dossiers, responding to regulatory questions, and conducting assessments of chemistry, manufacturing, and controls (CMC) and good manufacturing practice (GMP) readiness for our product candidates.

CHEMISTRY, MANUFACTURING & CONTROLS

CMC Team

As of the Latest Practicable Date, our CMC team consisted of professionals with extensive experience in process development, analytical development, cell therapy manufacturing, and quality management from leading biopharmaceutical companies. The team specializes in supporting preclinical and clinical development as well as commercial supply throughout the lifecycle of TIL therapies.

The CMC team function plays a critical role in our TIL programs. It is responsible for developing safe, robust, and economically efficient manufacturing processes for our TIL products, ensuring cell quality is controllable and stable, and meeting regulatory requirements.

Process Development

Our process development platform covers process development and optimization for TIL cell products, process scale-up and transfer, and process characterization studies. Our TIL cell culture process boasts core technological advantages, including no use of feeder cells, no use of high-concentration IL-2, and no use of viral vectors. The process is fully closed to minimize contamination and cross-contamination and employs a modular design to achieve commercial-scale production, which could reduce operating costs.

Our Core Product, GC101, has completed extensive process characterization studies, defined process control strategies, and qualified process performance. Based on this, we have established a robust process and accumulated substantial production experience during clinical trials.

Analytical Development

The analytical development platform includes PCR/qPCR laboratories, flow cytometry laboratories, physicochemical laboratories, and a cell analysis platform. It supports Quality Control testing and product characterization for TIL therapies and develops novel characterization methods to enhance understanding of both process and product.

Our analytical development and optimization aim to improve process robustness, enhance understanding of product mechanisms of action, provide quality research data beyond release criteria, and support the establishment of material and product specifications.

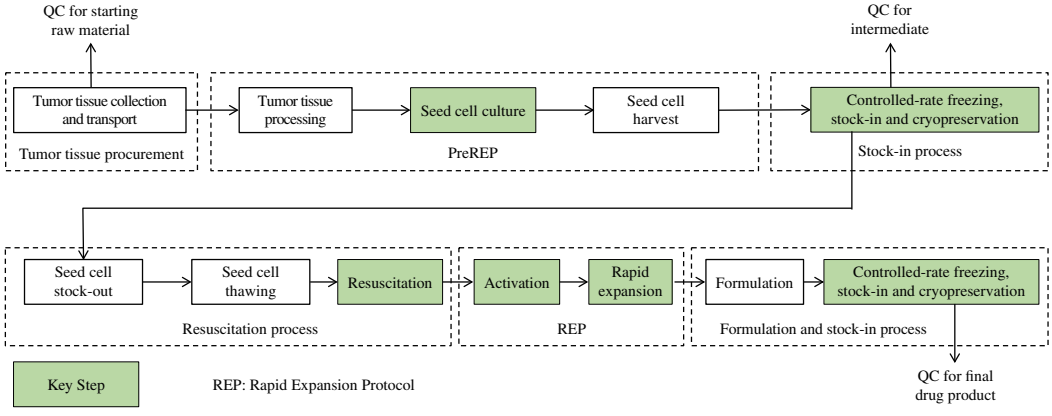
Quality Control and Assurance

We have established, updated, and implemented a rigorous internal quality management system for candidate product manufacturing in accordance with GMP requirements. Our quality management system complies with GMP standards.

We implement a comprehensive quality control strategy, including release testing of raw materials, excipients, process intermediates, and finished products, designed to address the high heterogeneity of TIL starting materials and strict sterility requirements. We have established, transferred, and validated methods from our analytical development platform, including flow cytometry for TIL cell immunophenotypes; cell biology assays (viability, counting); ELISA-based impurity testing; and a range of microbial tests, including rapid sterility assays.

Manufacturing Process

Our commercial-scale manufacturing capacity is demonstrated by the standardized production processes used for our Core Product. The manufacturing process chart below outlines the comprehensive steps involved in the production of our TIL therapy, which spans from initial tumor tissue procurement through to final formulation and cryopreservation. This chart highlights the critical phases of our manufacturing infrastructure, including the PreREP, stock-in, resuscitation, and Rapid Expansion Protocol (REP) processes, alongside our quality control checkpoints for starting raw materials, intermediates, and final drug products.



We utilize separate, independent manufacturing lines for our different product candidates to ensure product segregation and maintain operational integrity. We operate on the foundational principle of Quality by Design (QbD) to guarantee the consistency and quality of patient-specific, autologous products. Based on the distinct characteristics of our cellular manufacturing processes, we have established standardized, modular, and fully traceable production processes under strict GMP conditions.

Manufacturing Facility

During the Track Record Period and as of the Latest Practicable Date, we operated a manufacturing site exceeding 16,000 m^2 for TIL therapies in Shanghai, China. The site obtained a Drug Production License in February 2026 and is operated in accordance with applicable GMP requirements. This site enables scalable production of both natural and gene-modified TIL products, supporting clinical development and prospective commercialization of our TIL therapy pipeline. We currently intend to rely primarily on this facility to support the anticipated commercialization of our TIL product candidates. The facility was designed to support future clinical and commercial demand, and we may further expand our manufacturing capabilities as our pipeline advances and market demand increases.

The manufacturing processes for cell therapy products are characterized by high technical complexity and lengthy lead times for capacity scaling. In line with industry practice, where commercial-scale capacity is established during late-stage clinical trials to prevent supply disruptions upon market launch, our Shanghai facility officially commenced operations in December 2024 to support the increasing demand of our registrational clinical trial and future commercial requirements.

During the Track Record Period, we adopted a staged commencement model to optimize resource allocation and capacity planning. Under this model, production capacity is activated progressively in accordance with clinical development progress and anticipated commercial demand, rather than commissioning the entire facility at inception. Of the total site area of over 16,000 m^2, approximately 8,000 m^2 has been fully commissioned and is currently in active use, comprising production workshops, quality control laboratories, material warehouses, and administrative zones. The remaining facility footprint has been reserved for future expansion and may be activated progressively as our clinical programs progress and anticipated demand increases.

The table below sets forth the annual manufacturing capacity and utilization rates of our commissioned manufacturing facilities during the Track Record Period:

Product Candidate	Maximum Designed Annual Capacity (treatments)	Current Operational Annual Capacity (treatments)	Utilization Rate[(1)]
GC101	Approximately 5,400	Approximately 1,300	25%
GC203	Approximately 1,900	Approximately 500	25%

Note:

(1) Utilization rate is calculated based on the ratio of operational annual capacity to maximum designed annual capacity.

As our pipeline advances, we intend to progressively activate the remaining facility footprint and expand manufacturing capacity in accordance with projected clinical and commercial demand. In particular, prior to the commencement of potential registrational clinical trials for future indications, including NSCLC, we expect to further increase manufacturing capacity to support anticipated clinical and commercial supply requirements. To support future scale-up, we will continue to maintain GMP compliance through routine internal audits, personnel training, facility and equipment qualification and maintenance, and quality controls covering raw material

inspection, in-process monitoring and product release testing. We also maintain procedures for change control, deviation management and corrective and preventive actions (CAPA), together with contingency plans designed to mitigate operational and supply chain risks.

The facility employs a fully enclosed culture system (isolator and incubator) coupled with a strict GMP management system for seed TIL culture, ensuring that each patient's cells are cultured independently to avoid contamination, mixing, or cross-contamination. Similarly, under strict GMP management, a closed culture system is used for cell expansion, and a fully automated harvesting system is used for cell collection, minimizing contamination and cross-contamination while improving production capacity.

The facility is equipped with a real-time online EMS system to monitor temperature, humidity, and air pressure in sterile areas. It also features a real-time online BMS system to monitor process gas pipeline pressure, equipment temperature, and gas concentrations, with alarms set to ensure safe and stable production. We plan to achieve fully automated TIL cell production in the future and have preliminarily implemented unmanned operation for disinfection, sterilization, and material handling through robots.

We have a dedicated supply chain team to ensure timely supply of materials and oversee cold chain logistics for TIL cell products and starting materials (patient tumor tissue). We collaborate with qualified external logistics providers, managing point-to-point transportation — including planning, monitoring, and transport — in accordance with government guidelines. Providers are selected based on distribution network, cold chain experience, and cost, and transportation is initiated only after validation. As of the Latest Practicable Date, we have not experienced production or infusion failures due to logistics during clinical trials.

To ensure patient safety, product quality, and data integrity, we have deployed computer-validated systems including COI, ERP, and COC. The COI system ensures consistency from patient material receipt through logistics, manufacturing, release, and use. The ERP system manages production-related materials, and the COC system oversees production execution, ensuring accurate patient information, traceability, and reliable TIL product delivery.

As of the Latest Practicable Date, the facility had successfully prepared clinical trial TIL products for GC101, with all batches meeting rigorous quality standards.

COMMERCIALIZATION AND BUSINESS DEVELOPMENT

Our commercialization strategy is strategically phased to align with the development of our Core Product GC101. We plan to submit a BLA for GC101 in 2026, with anticipated market launch in 2027 following regulatory approval. We intend to adopt a pricing strategy that balances clinical value, patient affordability, manufacturing costs, production capacity utilization and long-term profitability. Given the individualized manufacturing process associated with TIL therapies, we expect the pricing of GC101 to reflect its clinical benefits, manufacturing complexity and treatment economics relative to available therapeutic alternatives.

To enhance patient affordability and access, we plan to pursue multiple reimbursement channels, including seeking inclusion in the Commercial Health Insurance Innovative Drug Catalog (商業健康保險創新藥品目錄), commonly referred to in the industry as the "Category C Catalog," and collaborating with commercial health insurers and government-guided supplemental medical insurance programs, such as Huiminbao. The Category C Catalog serves as a supplementary reimbursement mechanism to China's basic medical insurance system and is intended to facilitate access to innovative therapies that may not be suitable for inclusion in the basic medical insurance reimbursement catalog. There can be no assurance that GC101 will ultimately be included in the Category C Catalog or obtain favorable reimbursement coverage from commercial insurers or Huiminbao programs.

As of the Latest Practicable Date, we had established cooperative relationships with 50 hospitals and institutions across 21 cities, primarily through our clinical development activities, academic conferences, and medical education programs. These hospitals and institutions currently serve as clinical trial sites or clinical research collaborators rather than commercial customers. While most of our product candidates remain in early-stage development, our Core Product GC101 is approaching the commercialization stage. We believe that clinical development and commercialization are closely interconnected in advanced cell therapies. Physicians and key opinion leaders participating in our clinical trials develop familiarity with our products' characteristics, safety profiles and clinical performance, which may position these institutions as part of our initial target customer base following regulatory approval. We believe that establishing professional relationships with these institutions during the clinical development stage will facilitate future commercialization efforts and support patient access following launch. None of these hospitals and institutions are located within free trade zones.

We believe GC101 may potentially become the first domestically approved TIL therapy, although there can be no assurance that such approval will be obtained or that competing products will not obtain approval earlier. Based on publicly available information, we are not aware of any overseas TIL therapy developer currently conducting registrational clinical trials in China. Nevertheless, overseas competitors may seek to enter the China market in the future through independent development, licensing arrangements, strategic collaborations or other commercial arrangements. To strengthen our competitive position, we continue to advance the clinical development of GC101, expand our network of clinical collaborators and treatment centers, enhance our manufacturing capabilities and leverage our proprietary technologies and operational experience in TIL therapy development and manufacturing.

During the Track Record Period, our activities within this network were primarily focused on investigator training, medical education, and clinical trial coordination. The costs associated with these activities were primarily incurred in connection with our clinical development efforts and were included in our research and development expenses and administrative expenses. We leveraged our existing technical and medical affairs teams to manage these institutional relationships, thereby optimizing our cost structure and ensuring a seamless transition from clinical development to commercial launch.

As advised by our PRC Legal Advisor, neither GC101 nor GC203 is currently restricted to being supplied or used only within the relevant free trade zones. Both products are being developed through the NMPA drug registration pathway and, if approved and compliant with applicable laws and regulations, may be supplied to qualified medical institutions nationwide.

We continue to evaluate strategic partnerships and licensing arrangements that may accelerate the development and commercialization of our TIL platform. We typically identify and engage with potential partners through academic conferences, industry conferences, professional referrals and other business development activities. We assess potential collaborators based on factors such as their research and development capabilities, commercial networks, operational resources and financial strength.

As of the Latest Practicable Date, we had not entered into any definitive partnership or licensing arrangement and had not identified any specific partner with whom material terms had been agreed. We will continue to evaluate collaboration opportunities that may support the development of our broader pipeline and enhance the overall value of our proprietary TIL platform.

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we held 27 granted patents and 64 patent applications, including one granted patent and 13 patent applications (which included three patent applications in the Chinese Mainland) in respect of our Core Product. Our Group owns all intellectual property rights relating to product candidates, including the Core Product. As of the Latest Practicable Date,

we have not received any material concerns or inquiries from relevant intellectual property authorities, and we are not aware of any legal or substantive impediments that would reasonably be expected to prevent us from obtaining the patents for our pending applications.

The following table sets forth an overview of our material granted patents and filed patent applications in connection with our clinical and preclinical product candidates as of the Latest Practicable Date:

Product(s)	Name of Patent[(1)]	Owner	Jurisdiction	Status	Patent Expiration[(2)]
GC101	Seed cell medium of tumor-infiltrating lymphocyte and application thereof	Our Group	JP	Granted	May 2041
			CN, US, EP, KR, HK	Pending	N/A
NovaGMP™ platform	Novel piggybac transposon system and use thereof	Our Group	JP	Granted	October 2041
			CN, HK, US, EP, KR	Pending	N/A
GC101	Pharmaceutical composition for enhancing cell killing, and use thereof	Our Group	CN, US, EP	Pending	N/A
GC101	Tumor infiltration lymphocyte culture medium and application thereof	Our Group	CN, US, EP, JP, KR	Pending	N/A
GC203	Membrane surface protein containing GPI anchor region	Our Group	CN	Granted	November 2042
			EP, JP, US, SA, AE	Pending	N/A
GC203	Tumor infiltrating lymphocyte expressing membrane-bound cytokine	Our Group	JP, SG, EP, CN, HK	Pending	N/A

Abbreviations: AE= United Arab Emirates; CN = China; EP = European Patent Office; HK = The Hong Kong Special Administrative Region of The People's Republic of China; JP = Japan; KR = Republic of Korea; PCT = Patent Cooperation Treaty; SA = Saudi Arabia; SG = Singapore; US = United States of America

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.

The term of an individual patent may vary based on the countries/regions in which it is granted. The scope and protection afforded by a patent also vary on a claim-by-claim and country-by-country basis and depend on factors such as the type of patent, the breadth of its claims, the availability of patent term extension or adjustment, the availability of legal remedies in a particular jurisdiction and the validity and enforceability of the patent. We cannot assure you that

any of our pending or future patent applications will result in issued patents, or that any of our owned or in-licensed patents will provide commercially meaningful protection for our product candidates or their manufacturing methods.

In addition to patents, we also rely on trade secrets and tech know-hows to protect our product candidates, utilizing confidentiality agreements with employees and third parties, as well as invention assignment clauses to secure ownership of developed technology. Our standard employment contract, which we used 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.

Additionally, we maintain physical and electronic security systems to protect our data. Despite these measures, agreements may be breached or prove insufficient, trade secrets may be independently developed by third parties, and unauthorized parties may gain access to our proprietary information. Please see "Risk Factors — Risks Relating to Our Intellectual Property Rights" in this Document for a description of risks related to our intellectual property.

We conduct our business under the brand name of "Juncell Therapeutics" and/or "君賽生物." As of the Latest Practicable Date, we held 82 registered trademarks in Chinese Mainland, two registered trademarks in Hong Kong, and three pending trademark applications in Chinese Mainland. We are also the owner of six registered copyrights, including three registered software copyrights, and one domain name.

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

A freedom-to-operate searches and analyses ("FTO Analysis") has been conducted in China and the U.S. in relation to our Core Product and key product candidate. The FTO Analysis covered searches conducted for the period up to the Latest Practicable Date. Based on the FTO Analysis, our Directors are of the view that there are no substantial risk of infringement of valid and enforceable issued patents of any third party in China and the U.S. covering TIL-related technologies that may impact the commercialization of our Core Product and key product candidate in China and the U.S. as strategized by the Company.

OUR SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of CROs, SMOs, CDMOs, landlords of our leased property and providers of other services. We did not experience any material disputes with our suppliers. In addition, we believe that adequate alternative sources exist for these services and supplies, and we have developed alternative sourcing strategies based on supply continuity risk assessments. We generally maintain credit periods of 60-90 days.

Below is a summary of the key terms of a typical agreement with our CROs, SMOs, and CDMOs:

- *Services.* The CRO, SMO, or CDMO provides services such as implementing preclinical or clinical research projects, manufacturing or handling production materials, and performing materials supply or other ad-hoc work as specified in the master agreement or work orders.

- *Term.* The CRO, SMO, or CDMO is required to perform services according to the prescribed time frame set out in the master agreement or applicable work order.

- *Payment.* We make payments to the CRO, SMO, or CDMO according to the agreed payment schedule. Typically, we provide an upfront payment ranging from 10% to 20% of the total contract value upon execution of the agreement or work order. The remaining balance is generally paid in installments based on the progress of patient enrollment, with a final payment of approximately 5% to 10% withheld until the completion of final deliverables, such as the closure of all clinical sites or the successful completion of on-site inspections.
- *Confidentiality.* Both parties agree to maintain the confidentiality of all information related to the performance of the master agreement.
- *Credit terms.* Payments are generally arranged within 60-90 days of invoice receipt. Installments are made according to milestone payment arrangements specified in the agreement.
- *Intellectual property.* We retain ownership of all intellectual property arising from the clinical research or related projects and are entitled to apply for patents for such intellectual property.
- *Liabilities and termination*. The liability of a CRO, SMO, or CDMO arises if they fail to provide services in accordance with the agreed schedule. Our liability arises if we fail to make timely payments under the credit terms. Either party may terminate the agreement immediately by written notice if a breach is not remedied within 15-30 days after notice by the non-breaching party.

In 2024 and 2025, our purchases from our five largest suppliers in each year in aggregate amounted to RMB47.3 million and RMB56.3 million, representing 46.5% and 37.9% of our total corresponding purchases in such year, respectively, and our purchases from the largest supplier in each year accounted for 27.3% and 25.1% of our total corresponding purchases, respectively. Our material increase in the expenses attributable to the five largest suppliers in each year during the Track Record Period is in line with the advancement of clinical trials of our product candidates.

The following table sets forth details of our five largest suppliers during the Track Record Period.

Supplier	Year of Commencement of Business Relationship	Major Purchases	Credit Terms	Settlement Method	Purchase Amount	% of Total Purchases for the Period
					(RMB in thousand)	
For the year ended December 31, 2024						
Supplier A	2022	Equipment	Before delivery	Bank transfer	27,728	27.3%
Supplier B	2020	Consumables	60 days	Bank transfer	7,999	7.9%
Supplier C	2023	R&D services	30 business days	Bank transfer	4,384	4.3%
Supplier D	2023	Clinical trial services	Initial prepayment, then milestone-based payments	Bank transfer	3,769	3.7%
Supplier E	2020	Property lease	Prepaid quarterly	Bank transfer	3,399	3.3%
Total					**47,279**	**46.5%**
For the year ended December 31, 2025						
Supplier A	2022	Equipment	Before delivery	Bank transfer	37,312	25.1%
Supplier B	2020	Consumables	60 days	Bank transfer	9,238	6.2%
Supplier F	2023	Clinical trials	Initial prepayment, then milestone-based payments	Bank transfer	4,048	2.7%
Supplier G	2021	Clinical trials	30 days	Bank transfer	2,909	2.0%
Supplier H	2021	Consumables	60 days	Bank transfer	2,833	1.9%
Total					**56,340**	**37.9%**

Notes:

Supplier A: Founded in 1993 and registered in Shanghai, the group is a global provider of automated pharmaceutical systems, specializing in freeze-drying, small-volume injection, and sterile API equipment and services.

Supplier B: Established in 2003 and registered in Beijing, the company is a technology-driven trading firm specializing in the distribution of imported biological reagents, scientific instrumentation, and pharmaceutical intermediates.

Supplier C: Founded in 2015 and registered in Shanghai, this high-tech biotechnology enterprise focuses on the research, development, and integrated service provision of innovative antibody therapeutics.

Supplier D: Established in 2014 and registered in Suzhou, the company is a comprehensive medical service provider specializing in clinical trial management, regulatory registration, biostatistics, and data management.

Supplier E: Founded in 2017 and registered in Shanghai, the company provides diversified technical services in medical and biotechnology, alongside business consultancy, exhibition planning, and specialized construction engineering.

Supplier F: Established in 1976, this Grade A Tertiary specialized oncology hospital, affiliated with Peking University, is a premier institution for cancer treatment, research, and prevention.

Supplier G: Established in 2011 and registered in Beijing, the company provides professional clinical research services to the pharmaceutical, medical device, and *In-Vitro* Diagnostic (IVD) sectors.

Supplier H: Founded in 2014 and registered in Wuhan, this integrated high-tech enterprise specializes in fundamental biomedical services, innovative product R&D, and the distribution of scientific research consumables.

All of our five largest suppliers in each year during the Track Record Period are Independent Third Parties. None of our Directors or any Shareholder 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 associates had any interest in any of our five largest suppliers in each year during the Track Record Period.

COMPETITION

The cell therapy industry, particularly in the field of tumor-infiltrating lymphocyte (TIL) therapies, is characterized by rapid technological advancement, evolving treatment paradigms, and intense global competition. We face potential competition from a wide range of industry participants. These include multinational pharmaceutical and biotechnology companies, as well as academic and research institutions that are developing TIL or other adoptive cell therapies for solid tumors. Any TIL therapies that we successfully develop and commercialize will compete with existing cancer treatments, including immune checkpoint inhibitors, CAR-T and TCR-T therapies, oncolytic viruses, bispecific antibodies, and targeted small molecules.

Our Core Product effectively competes within this landscape by addressing the fundamental clinical and economic barriers inherent in conventional TIL therapies through proprietary technical differentiators. From a manufacturing and clinical perspective, our proprietary expansion technology eliminates the requirement for feeder cells and high-concentration IL-2, a simplification applicable to over 30 tumor types. Because the TILs expanded via our process are IL-2 independent, patients do not require post-infusion IL-2 injections — which carry boxed warnings — or high-intensity lymphodepletion. This profile enables treatment administration in standard hospital settings rather than intensive care units, significantly reducing the risk of severe toxicities, shortening hospital stays, and lowering the total cost of care.

Furthermore, our strategic commercialization model utilizes a time-segmented production process to collect tumor tissue during earlier surgical intervention to produce and cryopreserve "seed TILs." This approach addresses a critical industry-wide challenge where TIL quality and quantity often decline in late-line patients, facilitating earlier patient engagement and transforming a highly personalized process into a more accessible, nearly off-the-shelf therapeutic approach. The competitive potential of this platform is evidenced by clinical outcomes in patients with advanced solid tumors, where multiple subjects have achieved complete tumor clearance, with the longest tumor-free survival exceeding four years as of the Latest Practicable Date.

AWARDS AND RECOGNITIONS

The following table sets out a summary of the major awards and recognitions we have received.

Year	Award/Recognition	Issuing Authority
2021 . .	National High-Tech Enterprise	Shanghai Municipal Science and Technology Commission, Shanghai Municipal Finance Bureau, and Shanghai Municipal Tax Service of the State Taxation Administration
2021 . .	10th China Innovation and Entrepreneurship Competition — National Finals	Organizing Committee of the China Innovation and Entrepreneurship Competition
2022 . .	Shanghai Innovative Small and Medium-sized Enterprise	Shanghai Municipal Commission of Economy and Informatization
2022 . .	Winner of the 2022 National Disruptive Technology Innovation Competition	Torch High Technology Industry Development Center, Ministry of Science and Technology of the PRC
2022 . .	Top 10 Most Promising Innovative Therapy Enterprises — 2022 China Biopharmaceutical Industry Value Ranking	Organizing Committee of the China Biopharmaceutical Innovation Cooperation Conference
2023 . .	Top 10 Most Promising Cell and Gene Therapy Enterprises — 2023 China Biopharmaceutical Science and Technology Innovation Value Ranking	National Biomedicine Enterprise Platform
2023 . .	Shanghai "Specialized, Refined, Differentiated, and Innovative" SME	Shanghai Municipal Commission of Economy and Informatization
2023 . .	Future Industry Excellence Award — 2023 Global "Future Industry Star" Competition	Organizing Committee of the 2023 Global "Future Industry Star" Competition
2023 . .	"Rising Star in Biomedicine" Excellence Award	Office of the Shanghai Biopharmaceutical Industry Development Leading Group
2024 . .	Shanghai May Day Labor Award	Shanghai Federation of Trade Unions and Shanghai Municipal Human Resources and Social Security Bureau
2025 . .	Shanghai Model Collective	Shanghai Municipal People's Government
2025 . .	National Disruptive Technology Entrepreneurship Star — Mercury Enterprise	Beijing-Tianjin-Hebei National Center for Technological Innovation and Guangzhou Industrial Investment Holding Group Co., Ltd.

INSURANCE

We maintain insurance policies that we consider consistent with industry practice and adequate for our operations. Our principal coverage includes insurance for adverse events occurring during clinical trials, providing protection for potential compensation arising from serious adverse events experienced by trial participants. Following commercialization of our TIL therapies, we plan to secure product liability insurance to address potential risks associated with their clinical use. 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" in this Document.

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 the Latest Practicable Date, we had 134 employees in total, and 130 employees were based in our headquarters in Shanghai. As of the same date, four employees were based in Guangzhou, Beijing, Chengdu, Zhengzhou, who were primarily responsible for clinical affairs. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Functions	Number of employees	Percentage
Non-Clinical Research and Development	17	12.7%
Clinical Development and Regulatory Affairs	28	20.9%
Manufacturing and Quality	70	52.2%
General and Administrative	19	14.2%
Total	**134**	**100.0%**

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.

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.

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.

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 the Latest Practicable Date, we leased three major properties in China with an aggregate GFA of approximately 20,100.0 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, none of our leased properties had a carrying amount equal to or exceeding 15% of our consolidated total assets. 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.

PERMITS, LICENSES AND OTHER APPROVALS

As confirmed by our legal advisors, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations in all jurisdictions that we had business operation during the Track Record Period and up to the Latest Practicable Date. For more details regarding the laws and regulations to which we are subject, see "Regulatory Overview" in this Document. 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 key permits, license and other approvals as of the Latest Practicable Date.

License/Permit	Issuing Authority	Grant Date	Expiration Date
Drug Production License . . .	Shanghai Municipal Medical Products Administration	February 6, 2026	February 5, 2031
Drug Clinical Trial Approval Notice (for GC101 in combination with PD-1 antibody)	NMPA	August 1, 2025	N/A
Drug Clinical Trial Approval Notice (for GC203)	NMPA	April 28, 2024	N/A
Drug Clinical Trial Approval Notice (for GC101)	NMPA	April 24, 2022	N/A

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

ESG Governance

ESG Governance Structure

We are committed to enhancing our ESG management capabilities and integrating ESG considerations into our strategic decision-making and daily operations. We have established a three-tier governance structure covering the decision-making, management, and execution levels to ensure the effective coordination and implementation of ESG-related initiatives.

- **Decision-making level:** The Board of Directors serves as the highest decision-making body for ESG matters and bears ultimate responsibility for our ESG management strategy, risk management, target setting and progress monitoring, as well as overall ESG performance.

- **Management level:** The Strategy Committee coordinates and oversees ESG-related work, provides recommendations on ESG strategies and material topics, and regularly monitors and reviews the progress of ESG targets and ESG performance. The Committee also maintains active communication and collaboration with various stakeholders on ESG issues.

- **Execution level:** The ESG Working Group, comprising ESG representatives from functional departments and subsidiaries, is responsible for identifying and managing ESG risks in daily operations, executing ESG initiatives, and implementing our ESG strategies, policies, and goals.

  Our Directors (including independent Directors) possess knowledge and skills covering industry experience, finance, risk management, and corporate management, and have sufficient ability to identify and evaluate important issues. To ensure the effectiveness of ESG management, Board members receive annual ESG training, including on climate change issues. In addition, we consult with external ESG expert teams when necessary.

  For more Board of Directors information, please refer to "— Directors and Senior Management — Board Of Directors."

Stakeholder Engagement and ESG Risk Identification and Assessment

We place great importance on maintaining continuous communication and strong relationships with internal and external stakeholders, including investors, regulators, employees, suppliers, business partners, communities, and the general public. To ensure effective communication, we have established transparent and efficient multi-channel mechanisms to proactively identify and respond to stakeholder expectations and concerns, thereby safeguarding stakeholder interests.

Based on a comprehensive analysis of our industry characteristics, business nature, regulatory requirements, and stakeholder expectations, we have identified and prioritized the following material ESG topics:

Environmental Topics	Emissions and Waste Management
	Resource Utilization
	Climate Change Response
	Environmental Compliance Management
Social Topics	Product Quality and Safety
	Product Research and Innovation
	Clinical Trials
	Intellectual Property Management
	Responsible Marketing
	Information Security
	Sustainable Supply Chain Management
	Employee Compliance Employment
	Employee Compensation and Benefits
	Employee Development and Training
	Occupational Health and Safety
	Social Contribution and Charity
Governance Topics	Corporate Governance
	Compliance Management
	Anti-corruption and Business Ethics

We consider environmental, social, economic, and company development factors into the assessment of ESG risks. We evaluate the impact possibility, scale, and scope of these factors, and refer to the evaluation results of our peers.

We have conducted a detailed analysis of ESG risks, and the impact analysis and management measures of our key ESG risk are as follows:

Issues	Specific risk	Impact analysis	Management measures
Climate Change Response . .	Physical Risk: Acute: Heavy rain, floods, typhoons; Chronic: Rising Average temperature	Possible damage to production facilities and operational disruption. May affect drug storage stability and transport safety.	Formulate and implement the Plant Emergency Management Procedures (《廠房應急管理規程》) to ensure rapid and orderly restoration of utilities such as water, electricity, and gas during extreme weather events, safeguarding both production continuity and the safety of employees and equipment. Optimize air-conditioning operation and cold-chain management, adopt high-efficiency refrigeration equipment, and strengthen operational standards
	Policy and Regulatory: Stricter global carbon emission regulations; Technological: Transition cost to low-emission technologies	Stricter emission regulations may increase corporate compliance costs. Transitioning to low-arbon technologies may result in significant upfront investment costs.	Introduce energy-efficient facilities, optimize energy-saving technologies and operations to improve efficiency and reduce emissions. Conduct technical assessments on energy-saving and emission-reduction technologies to ensure feasibility and cost-effectiveness.
Clinical Trials .	Compliance risks arising from non-adherence to regulatory requirements; Operational risks due to improper trial design or execution leading to delays or failures; Ethical risks related to subject safety and informed consent	Potential suspension or termination of clinical trials by regulators, affecting the development timeline of core products; Increased R&D costs and delayed commercialization; Reputational damage and reduced investor confidence.	Formulate internal management policies such as the Standard Operating Procedures for Subject Recruitment and the Screening (《受試者招募和篩選標準操作規程》) and Standard Operating Procedures for Site Monitoring (《研究中心監查標準操作規程》) to ensure compliance and safety throughout the clinical trial; All our clinical trials are subject to approval by an ethics committee composed of experts in medicine, pharmacy, and related fields; Protect subjects' rights to information, safety, and privacy through measures such as clinical trial insurance, ethical review, informed consent procedures, and confidentiality of personal information; Conduct continuous quality oversight and safety assessments throughout the entire clinic trial process to ensure the authenticity and reliability of research data.

Issues	Specific risk	Impact analysis	Management measures
Product Quality and Safety. .	Quality risks arising from insufficient process control leading to product deviations; Compliance risks related to non-fulfillment of GMP requirements; Safety risks where quality issues may result in patient safety incidents	Potential product recalls, regulatory penalties or production suspension; Adverse impact on patient safety and therapeutic outcomes; Negative effects on corporate reputation and long-term development.	Establish a comprehensive quality management system; Implement full-cycle management covering product collection, transportation, manufacturing, and reinfusion. Conduct regular external quality audits of critical materials and suppliers, and comprehensive annual internal quality audits; Organize periodic quality training programs to enhance staff awareness and competency in quality management.

ESG Management Initiatives

Environmental Management

We strictly comply with applicable environmental laws and regulations, standardize emissions and waste management, enhance resource utilization efficiency, and fulfill our environmental responsibilities. We are committed to the environmental principles of "preventing and controlling pollution, reducing pollutant emissions, operating in full compliance with laws and regulations, and continuously improving our environmental practices to enhance environmental quality."

Environmental Compliance Management

We strictly comply with the Environmental Protection Law of the People's Republic of China (《中華人民共和國環境保護法》) and other applicable regulations and have established the Environmental Protection Management Procedures (《環境保護管理規程》) to reduce and prevent potential environmental risks arising from our operations, ensuring compliance with environmental protection requirements. We have established an EHS[1] Management Committee responsible for developing environmental policies, strategies and targets, and supervising environmental compliance. In addition, we carry out training and publicity on environmental laws and regulations to strengthen employees' environmental awareness and conduct assessments for personnel in environmental management positions.

Emissions and Waste Management

We place strong emphasis on emissions and waste management, in full compliance with the Law of the People's Republic of China on the Prevention and Control of Environmental Pollution by Solid Waste (《中華人民共和國固體廢物污染環境防治法》) and the Pollution Discharge Permit Management Regulation (《排污許可管理條例》), and other applicable environmental laws and regulations. We have formulated the Environmental Pollution Control Management Procedures (《環境污染控制管理規程》), the General Solid Waste Management Procedures (《一般固廢管理規程》), and the Hazardous Waste Management Procedures (《危險廢物管理規程》) to ensure standardized and compliant management of general solid waste, hazardous waste, wastewater, exhaust gas, and noise. We have set management targets for emissions and waste: Achieving 100% compliant discharge of exhaust gas and wastewater, and 100% compliant disposal of solid waste across all production facilities, laboratories, and office areas.

1 EHS: Environment, Health, and Safety

- **General Solid Waste:** We actively categorize and recycle general solid waste through an established management process covering collection, storage, transport, and disposal, supported by detailed ledgers and inventory records to ensure proper handling and traceability.

- **Hazardous Waste:** In accordance with the National Hazardous Waste List (《國家危險廢物名錄》) and our environmental impact assessment report, hazardous waste generated include contaminated solid waste from experiments, medical waste, laboratory waste liquids, used activated carbon, and waste oil. All such waste is transferred to third-party entities with hazardous waste disposal qualification for harmless treatment. We have implemented standardized management procedures and conduct training and assessments for new employees on hazardous waste collection and transfer.

- **Wastewater:** Wastewater generated from production processes is treated to meet the Pollutant Discharge Standard for the Biopharmaceutical Industry (《生物製藥行業污染物排放標準》) before discharge through the main outlet into the municipal sewage network. Domestic wastewater is discharged through the park's sewage network in compliance with the Integrated Wastewater Discharge Standard (《污水綜合排放標準》). We also conduct regular wastewater monitoring and inspections of treatment facilities to ensure stable and compliant discharge.

- **Air Emissions:** We strictly control factory air emissions in accordance with the Emission Standard of Air Pollutants for Pharmaceutical Industry (《製藥工業大氣污染物排放標準》) and the Integrated Emission Standard of Air Pollutants (《大氣污染物綜合排放標準》). We scientifically manage the use of chemicals in relevant processes to reduce acid mist volatilization, replacing activated carbon and other adsorbents annually, and maintaining air emissions adsorption equipment to ensure their effective operation. We also conduct periodic testing of air emissions to ensure compliance.

- **Noise:** The main sources of noise are utilities and auxiliary equipment such as air conditioning units and air compressors. We manage noise in accordance with Category 3 and Category 4 limits under the Emission Standard for Industrial Enterprises Noise at Boundary (《工業企業廠界環境噪聲排放標準》), and promptly report and address any abnormalities detected in boundary noise monitoring.

Resource Utilization

We strictly comply with laws and regulations related to resource utilization, emphasize efficient and responsible use of resources, continuously optimize resource efficiency in production and operations, and integrate energy conservation and emission reduction into all aspects of daily management.

Energy Conservation

We follow the Energy Conservation Law of the People's Republic of China (《中華人民共和國節約能源法》) and have formulated the Energy Management Procedures (《能源管理規程》) to ensure a compliant energy management system. Our energy management targets include improving the energy management system, optimizing environmental parameter control, enhancing the application of energy-saving technologies and equipment, and improving overall energy efficiency.

We actively identify opportunities for energy conservation and emission reduction, gradually implement energy-saving initiative to enhance energy management performance and reduce greenhouse gas emissions. In our office areas, we use energy-efficient lighting systems, optimize the energy configuration of air-conditioning and water heating systems to improve energy use efficiency and reduce emissions. Meanwhile, we continuously optimize the energy structure and adopt renewable energy solutions such as installing rooftop photovoltaic systems to build a highly efficient, energy-saving, and low-carbon production and operation model.

Water Resource Management

We strictly comply with the Water Law of the People's Republic of China (《中華人民共和國水法》) and our internal policy such as the Environmental Protection Management Procedures (《環境保護管理規程》) and the Energy Management Procedures (《能源管理規程》) . We adhere to the principle of water conservation in both operations and offices by improving the water supply network, applying water-saving technologies, and providing employee training to enhance awareness. Our water conservation target is to "optimize water equipment parameters settings, strengthen the use of water-saving devices and technologies, and improve water utilization efficiency."

Packaging Material Management

We have established the Standard Procedures for Material Inspection, Storage, Issuance, and Distribution (《物料驗收入庫、貯存、領用及發放標準管理規程》), ensuring compliant, safe, and traceable management of packaging materials that directly contact products. Packaging waste generated during production is classified and disposed of as general solid waste in accordance with relevant regulations.

Climate Change Response

Climate change has had a profound impact on the global economy and industrial development, and green and low-carbon transition has become a key direction for promoting sustainable social development. As a responsible enterprise, we fully recognize the potential impacts of climate change on our operations and supply chain stability. We actively identify and respond to climate-related risks and opportunities, and continuously promote green production, renewable energy use, and low-carbon management practices. We have set a greenhouse gas reduction target to reduce Scope 1 and Scope 2 emission intensity by 5% by 2027, using 2025 as the baseline year, thereby contributing to global efforts to address climate change.

Climate-related Risks and Opportunities

We identify and assess climate-related risks and opportunities based on our business characteristics and with reference to international sustainability standards, formulating corresponding mitigation measures to enhance climate adaptability and resilience and thereby ensuring stable operations.

Risk/Opportunity Type	Description	Potential Impact	Mitigation Measures
Physical Risk . .	**Acute:** Heavy rain, floods, typhoons	Possible damage to production facilities and operational disruption.	Formulate and implement the Plant Emergency Management Procedures (《廠房應急管理規程》) to ensure rapid and orderly restoration of utilities such as water, electricity, and gas during extreme weather events, safeguarding both production continuity and the safety of employees and equipment.
	Chronic: Rising average temperature	May affect drug storage stability and transport safety.	Optimize air-conditioning operation and cold-chain management, adopt high-efficiency refrigeration equipment, and strengthen operational standards.

Risk/Opportunity Type	Description	Potential Impact	Mitigation Measures
Transition Risk	**Policy and Regulatory:** Stricter global carbon emission regulations	Stricter emission regulations may increase corporate compliance costs.	Introduce energy-efficient facilities, optimize energy-saving technologies and operations to improve efficiency and reduce emissions.
	Technological: Transition cost to low-emission technologies	Transitioning to low-carbon technologies may result in significant upfront investment costs.	Conduct technical assessments on energy-saving and emission-reduction technologies to ensure feasibility and cost-effectiveness.
Opportunity	**Resource Efficiency:** Application of energy-saving technologies	Application of such technologies can reduce energy consumption and operating costs, while cutting greenhouse gas emissions.	Introduce energy-efficient equipment and technologies and optimize energy management.
	Energy Source: Renewable energy adoption	Applying renewable energy can reduce electricity costs and greenhouse gas emissions.	Install rooftop photovoltaic systems and optimize energy structure.

Environmental and Climate Performance Targets and Indicators

We currently have no products approved for commercial sales, and based on our own stage of development, we have formulated and progressively advanced a number of environmental management targets, including targets relating to emissions and waste management, energy management, water conservation, and greenhouse gas reduction. With respect to the comparability of the greenhouse gas reduction target, we have set a target to reduce greenhouse gas emission intensity under Scope 1 and Scope 2, which is consistent with the common practice among listed peers of adopting emission intensity as a phase-based management objective. Taking into account our own stage of development, we have set a target to reduce Scope 1 and Scope 2 emission intensity by 5% by 2027, using 2025 as the baseline year, primarily reflecting that we are currently in a phase of gradual expansion of our operations and production capacity, during which emission levels and energy consumption may change as capacity expands, processes are further developed and facilities are invested; We currently have no products approved for commercial sales, therefore, we use the number of employees as denominator of intensity data.

Our other environmental targets include:

- We have set management targets for emissions and waste: Achieving 100% compliant discharge of exhaust gas and wastewater, and 100% compliant disposal of solid waste across all production facilities, laboratories, and office areas.
- Our energy management targets include improving the energy management system, optimizing environmental parameter control, enhancing the application of energy-saving technologies and equipment, and improving overall energy efficiency.

- Our water conservation target is to "optimize water equipment parameters settings, strengthen the use of water-saving devices and technologies, and improve water utilization efficiency."

Considering that some environmental data will continue to change with the expansion of production capacity at this stage, we have primarily adopted qualitative management targets for the time being and plan to gradually establish more specific and measurable quantitative targets.

Our environmental performance[2] from 2024 to 2025 is summarized below:

Indicator	Unit	2024[3]	2025
Greenhouse Gas Emissions[4]			
Scope 1 GHG Emissions	tons CO_2e	108.15	525.60
Scope 2 GHG Emissions	tons CO_2e	1,004.60	1,676.04
Scope 3 GHG Emissions[5]	tons CO_2e	5,630.46	4,479.24
Total GHG Emissions (Scope 1 & 2)	tons CO_2e	1,112.75	2,201.64
GHG Emission Intensity (Scope 1 & 2)	tons CO_2e/ person	9.27	15.61
Energy Use			
Direct Energy Consumption			
Natural Gas Consumption	m^3	50,020.00	243,086.00
Renewable Energy (Photovoltaic)	10,000 kWh	0	20.91
Indirect Energy Consumption			
Purchased Electricity	10,000 kWh	187.22	312.34
Comprehensive Energy Consumption			
Total Energy Consumption	kWh	2,366,658.03	5,735,698.16
Energy Intensity	kWh/person	19,722.15	40,678.71
Waste Generation			
Total Hazardous Waste	tons	7.20	18.00
Hazardous Waste Intensity	tons/person	0.06	0.13
Total Non-hazardous Waste	tons	3.40	11.00
Non-hazardous Waste Intensity	tons/person	0.03	0.08
Air Emissions			
SOx Emissions	tons	0.005	0.01
NOx Emissions	tons	0.07	0.14
NMHC Emissions	tons	0.02	0.03
Particulate Matter Emissions	tons	0.01	0.03
Water Resource Use			
Total Water Consumption	tons	5,100.00	31,791.03
Water Intensity	tons/person	42.50	225.47
Wastewater Discharge			
Total Wastewater Discharge	tons	4,590.00	28,611.90

2 Our environmental performance data include emissions, resource utilization, and other related indicators for the years ended December 31, 2024 and 2025.

3 Our plant in Anting, Shanghai commenced construction in 2024, with partial operations beginning the same year. Full operations started in 2025, leading to an expected upward trend in energy consumption and emissions data.

4 Scope 1 greenhouse gas (GHG) emissions arise from the direct combustion of natural gas. Scope 2 GHG emissions result from the use of purchased electricity. GHG accounting is conducted in accordance with the Guidelines for Accounting and Reporting of Greenhouse Gas Emissions by Industrial Enterprises (Trial) (《工業其他行業企業溫室氣體排放核算方法與報告指南(試行)》) issued by the National Development and Reform Commission. The emission factor for purchased electricity is based on the national average electricity emission factor from the Announcement on the Release of the 2022 Electricity Carbon Dioxide Emission Factor (《關於發佈2022年電力二氧化碳排放因子的公告》) published by the Ministry of Ecology and Environment in December 2024.

5 For Scope 3 GHG emissions, we have collected and calculated data for Category 1 (purchased goods and services, including external consulting and material procurement) and Category 2 (capital goods). Going forward, we plan to progressively expand data collection and calculation to other relevant Scope 3 GHG emission categories.

Indicator	Unit	2024[3]	2025
Wastewater Intensity	tons/person	38.25	202.92
Packaging Material Use			
Total Packaging Material	tons	0.25	0.53
Packaging Material Intensity	tons/person	0.002	0.004

Product Responsibility

We uphold the mission of "Rescue Cells, Rescue Lives," actively engaging in product research and innovation, building and continuously optimizing a robust quality management system, ensuring product quality and safety, and fulfilling our product responsibility.

Product Research and Innovation

We are professionally dedicated to the development of innovative therapies and novel drugs. Leveraging our proprietary DeepTIL™ cell expansion platform and NovaGMP™ gene modification platform, we have developed a series of world-leading natural TIL and gene-modified TIL therapies. These product candidates have demonstrated excellent clinical efficacy and safety across more than ten types of advanced solid tumors.

Product Quality and Safety

We regard product quality and patient safety as our highest priorities. We strictly comply with the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》), the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法實施條例》), the Measures for the Supervision and Administration of Drug Operations and Use Quality (《藥品經營和使用質量監督管理辦法》), and the Good Manufacturing Practice (GMP) standards and appendices (《藥品生產質量管理規範(GMP)》) as well as other relevant laws, regulations, and standards. We have established and continuously improved a comprehensive quality management system. Through well-defined process specifications, standard operating procedures (SOPs), and an online traceability system, we implement full-cycle management covering product collection, transportation, manufacturing, and reinfusion. We have systematically embedded risk management principles throughout the product life cycle.

Full-cycle management includes:

- **Material Control:** We impose stringent quality control on all raw materials, excipients, packaging materials, and consumables. Through supplier management, material risk assessment, quality standard formulation, and sampling inspection, we ensure that all materials originate from qualified suppliers and meet regulatory requirements to safeguard product safety and reliability.

- **Production Process Control:** We have formulated comprehensive process control strategies, including critical material control, intermediate and finished product release control, in-process control at critical control points, and management of critical and important process parameters. The cell production team strictly follows established process procedures and batch records to ensure process consistency.

- **Product Testing:** Based on pharmacopeial standards, current guidelines for cell therapy products, and accumulated product development data, we have established comprehensive quality standards and testing documentation for both products and intermediates, assessing critical quality attributes accordingly.

- **Product Quality Monitoring:** Our Quality Department is responsible for quality control and assurance functions and has implemented the Quality Monitoring Management Procedures (《質量監控管理規程》). The quality assurance (QA) team oversees the entire process from tissue receipt to product release, including pre-production, in-process, post-production, packaging, sample testing, product review, and release.

- **Product Release:** We enforce a strict multi-level review process. Production and quality control (QC) personnel must complete batch production and testing records in a timely, accurate, and standardized manner. After review, QA conducts a secondary review, and final approval is granted by the designated quality authorized person.

We also conduct regular external quality audits of critical materials and suppliers, and comprehensive annual internal quality audits. Any identified issues are promptly corrected and tracked to ensure effective resolution. In addition, we organize periodic quality training programs across various departments and positions to enhance staff awareness and competency in quality management.

Pharmacovigilance

We have established a pharmacovigilance system that covers both clinical development and post-marketing stages. A dedicated pharmacovigilance department has been set up, with defined quality objectives and control indicators. We evaluate performance across key areas including the compliance of individual case safety reports and aggregate reports, data integrity, risk management, system reliability, continuous improvement, and personnel competence. In addition, we cooperate with professional pharmacovigilance service providers to ensure the compliant collection and management of safety information through standardized procedures.

As of the Latest Practicable Date, although we have not yet commercialized any products, we have established recall management procedures that define recall decision-making, recall team formation, recall execution process, and reporting requirements, to ensure full preparedness for future post-marketing quality risk management.

Clinical Trials

We strictly comply with the Civil Code of the People's Republic of China (《中華人民共和國民法典》), the Good Clinical Practice (GCP) standards (《藥物臨床試驗質量管理規範》), and other relevant laws and regulations. We have formulated internal management policies such as the Standard Operating Procedures for Subject Recruitment and the Screening (《受試者招募和篩選標準操作規程》) and Standard Operating Procedures for Site Monitoring (《研究中心監查標準操作規程》) to ensure compliance and safety throughout the clinical trial process.

Before potential trial participants take part in our clinical trial, doctors will fully know them according to the requirements of the GCP and the ethical principles of the Declaration of Helsinki (《赫爾辛基宣言》). After the participants in the trial agree and sign the informed consent form, they can carry out the relevant tests and operations. Participants have the right to know, make their own decisions and privacy, and can unconditionally withdraw from the study at any stage.

Our business is not directly involved in animal experiments.

All our clinical trials are subject to approval by an ethics committee composed of experts in medicine, pharmacy, and related fields. The ethics committee independently reviews, approves, and monitors study protocols and related documents, as well as methods and materials used for obtaining informed consent, ensuring full protection of subjects' rights, safety, and welfare. We protect subjects' rights to information, safety, and privacy through measures such as clinical trial insurance, ethical review, informed consent procedures, and confidentiality of personal information. We also conduct continuous quality oversight and safety assessments throughout the entire clinic trial process to ensure the authenticity and reliability of research data.

Responsible Marketing

We place great emphasis on the compliance, accuracy, and truthfulness of information in marketing activities. We have implemented the Responsible Marketing Management Policy (《負責任營銷管理辦法》) to ensure that all marketing practices comply with applicable laws and regulations and protect patient privacy. We maintain an internal review mechanism whereby all external promotional materials and marketing content must be reviewed and approved by the medical, compliance, and legal departments before dissemination.

Intellectual Property Protection

Intellectual property protection is the foundation of our technology and business operations. We strictly adhere to the *Patent Law of the People's Republic of China*, the *Trademark Law of the People's Republic of China*, and the *Copyright Law of the People's Republic of China*, and have established the *Intellectual Property Management Policy* to establish a sound intellectual property protection mechanism. All documents are encrypted and access-controlled to prevent information leakage. We conduct trade secret protection training for new employees and organize annual company-wide intellectual property training sessions to enhance confidentiality awareness and risk prevention capabilities. For more information on our intellectual property, please refer to "— Intellectual Property."

Information Security

To strengthen our information security management, we have formulated and implemented the Information Security Management Policy (《信息安全管理制度》), the Data Security Management Policy (《數據安全管理制度》), and the System User Management Policy (《系統用戶管理制度》). We have established an Information Center with a three-tier management structure consisting of the Information Center Director, IT Manager, IT Supervisor, and IT Engineers. The center is comprehensively responsible for cybersecurity management and IT infrastructure management and maintenance to ensure the compliant, stable, and efficient operation of our systems.

We continuously enhance our cybersecurity protection system through improved internet usage management, system security management, data confidentiality management, and access authorization control, thereby providing strong support for business operations. The Information Center conducts regular and ad hoc inspections, spot checks, and backend reviews of employees' computer and network usage. In cases of policy violations, we take disciplinary measures commensurate with the severity of the incident, including but not limited to reminder and education, notice of criticism, downgrading of performance appraisal ratings, financial penalties, termination, and referral to judicial authorities when necessary.

Sustainable Supply Chain Management

We continuously strengthen sustainable supply chain management. We formulated the Procurement Management Policy (《採購管理制度》) and the Supplier Management Policy (《供應商管理制度》), which standardize procurement processes, codes of conduct, and full life-cycle management of suppliers, including onboarding, assessment, and elimination. Supplier evaluation comprehensively considers factors such as quality, risk, functionality, total supply cost, service, innovation, environmental health and safety, environmental protection, lawful employment, and business ethics, with the aim of building a stable, efficient, and sustainable supply chain that reliably supports our business operations.

During supplier onboarding, we conduct objective and fair qualification reviews for all candidate suppliers. For major or complex procurement projects, we establish a multi-dimensional evaluation system covering quality, technical capability, service, and collaboration risk, with clearly

defined weightings and scoring criteria. Final supplier selection is based on overall scores. When selecting suppliers for GMP-related materials or services, we take the supplier's sustainable performance into consideration and prioritize those with environmental management system certifications.

For supplier assessment, we have established a systematic performance evaluation framework. Suppliers are selected for special evaluation based on procurement volume or category, with annual or semi-annual assessment frequency. Evaluation criteria include quality, cost, delivery, service, financial and supply risk, and environmental health and safety. We use weighted average scoring, communicate results with suppliers, and, when necessary, track the implementation and effectiveness of supplier performance improvement plans to close the management loop.

In supplier elimination, suppliers with an assessment result of "unacceptable" are immediately removed. Suppliers not formally evaluated but deemed unsuitable based on daily performance by business units or category managers, or those involved in serious illegal, non-compliant, or unethical conduct during procurement or contract execution (classified as blacklisted suppliers), are prohibited from future engagement.

We conduct a series of measures on supplier quality management. Before the supplier service project starts, we will train all suppliers of the project to ensure that they understand and follow our testing requirements. We have established regular communication mechanisms with relevant suppliers: For CROs and SMOs, we will hold weekly/monthly meetings with communication with them according to the agreement and project progress to confirm the project progress and quality, etc. For testing suppliers, we communicate testing progress and sample management through monthly meetings; For supply chain suppliers, we will keep in touch with each other by email, hold meetings as needed, and communicate about medicines and other management-related matters. Besides, we conduct annual or on-demand supplier audits based on the importance of services undertaken by service providers and the risk management level of our Company.

For more supplier management information, please refer to "— Clinical Development — Relationship with CROs and SMOs" and "— Our Suppliers."

Employee Compliance Employment

We strictly comply with the Labor Law of the People's Republic of China (《中華人民共和國勞動法》), the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》), and the Provisions on the Prohibition of Using Child Labor (《禁止使用童工規定》). We always uphold the philosophy and values of "Concentration, Innovation, Inclusion, Collaboration", and actively attract and select outstanding talent. We have formulated the Employee Recruitment and Onboarding Management Policy (《員工招聘與入職管理制度》) to standard operating procedures for talent recruitment and onboarding management, and strictly prohibit child labor and forced labor. We have also formulated and implemented the Employee Diversity Policy (《員工多元化政策》) to advocate for diversity and inclusion. All employees, regardless of gender, age, family status, race, ethnicity, religion, sexual orientation, gender identity, disability, or any other legally protected characteristic, are respected, treated fairly, and provided with equal opportunities.

Our core idea is to respect differences and regard diversity as an innovative asset; Provide opportunities for competency-based development and strictly prohibit discrimination. Ensure the diversity level and equal opportunities of employees in talent attraction and access.

We set diversified recruitment targets and use diversified recruitment channels, and the heads of various departments and personnel departments jointly interview to ensure that the interview process is jointly evaluated by interviewers with different backgrounds, and the whole recruitment process is open and fair. Put an end to discrimination based on nationality, gender, age and region, and provide suitable jobs for the disabled.

We uphold the principle of diversity and tolerance, which is embodied as follows:

- Any form of ethnic discrimination is strictly prohibited. As of December 31, 2025, our employees are from Tujia, Zhuang, Bai, Hui and Han ethnic groups.
- Any form of gender discrimination is strictly prohibited to create equal employment opportunities for employees of different genders. As of December 31, 2025, our female employees accounted for about 56.03%.
- Any form of age discrimination is strictly prohibited. As of December 31, 2025, the age of our employees ranged from the minimum of 23 to the maximum of 62, with a large span.

In the Management System of Employee Renewal and Resignation (《員工續約與離職管理制度》), we clearly stipulate the details of dismissing employees, standardize the procedures for renewing and resigning employees, ensure that the renewal matters are handled according to the regulations, and ensure the normal handover of employees' work and ensure the continuity of work. Including but not limited to:

- Staff supervisors actively communicate with resigned employees, strive to retain employees with good performance, and explore the possibility of improving their working environment, conditions and treatment.
- Resigned employees fill in the Application Form for Resignation, and submit it to the Personnel Administration Center after being signed by department leaders for approval.

Employee Compensation and Benefits

We strive to provide employees with competitive compensation and benefits, constantly improve the compensation and benefits system, implement a standardized compensation management system, and formulate the Compensation and Performance Management Policy (《薪酬績效管理制度》), the Corporate Benefits Policy (《企業福利制度》), and the Attendance and Leave Management Policy (《員工考勤與休假管理制度》) to provide guidance and help for performance improvement and employee development. We have established a compensation scheme consisting of fixed salary, variable pay, and subsidy to protect the income rights and interests of every employee.

We conduct performance evaluations fairly, justly, and responsibly, and provides employees with equal opportunities for promotion and salary adjustment based on the results of performance evaluation. The following are some provisions in the Compensation and Performance Management Policy (《薪酬績效管理制度》):

- The person in charge of the department should pay close attention to the daily performance of employees in a timely manner, make a fair, serious and responsible performance evaluation of employees' monthly performance at the end of each month, arrange performance interviews, confirm the assessment results with employees, give improvement suggestions and goals, and pay close attention to the progress status of employees in a timely manner according to the improvement cycle.
- If the appraisee disagrees with the appraisal result, he can lodge a complaint with the Human Resources Center within 3 days after the performance interview, and the Human Resources Center will arrange reconsideration according to the objection.

We provide statutory social insurance and housing fund contributions, and offer additional benefits including meal and housing allowances, holiday and birthday gifts, marriage and maternity benefits, commercial insurance, anniversary gifts, team-building activities, and recreational

programs such as interest groups, social events, and sports competitions. Special benefits include vaccination programs, priority enrollment or cryopreservation for TIL therapies, and TIL cell cryopreservation services. We have carried out a series of employee care activities, including:

- Home visits and gift distribution for employees on leave due to childbirth, illness, or injury.
- Women's Day celebrations with flowers, fruits, and gift cards for female employees.

We clearly stipulate the details of employee benefits in the Corporate Benefits Policy (《企業福利制度》), including but not limited to:

- Meal and housing allowances: Employees can enjoy meal and housing allowance corresponding to their ranks, which will be paid together with their salary every month. Employees can apply for overtime meal allowance. The Company will regularly prepare overtime meals in various office areas so that employees can enjoy them during overtime.
- Holiday benefits: Employees on probation who have been employed for 3 months and all employees who have become full-time employees can enjoy the holiday benefits uniformly distributed by the Company on traditional festivals in China, such as Dragon Boat Festival and Mid-Autumn Festival.
- Birthday benefits: Employees who have been employed for 3 months can enjoy birthday gifts from the Company. All on-the-job employees can enjoy the employee birthday party organized by the Company regularly.
- Marriage and maternity benefits: Employees who have become full-time employees can apply for wedding gifts issued by the Company with their marriage certificates, and enjoy paid marriage leave, which needs to be taken off at one time. Employees who have become regular employees can apply to enjoy the birth gift issued by the Company. Employees can enjoy paid marriage leave or maternity leave (paternity leave) benefits, but they need to make work handover arrangements in advance.
- Insurance benefits: Employees who have become full-time employees can apply to the Company for reimbursement of relevant insurance expenses within the time limit specified by the Company after purchasing "Huhuibao" by themselves every year, and submit purchase evidence.
- Team-building activities: All full-time employees can participate in the quarterly departmental league building. Every year, the Company will organize large-scale group construction or free travel inside and outside the city of different scales, and all full-time employees can participate free of charge.

Employee Development and Training

We provide broad development opportunities and clear promotion pathways for every employee and have formulated the Management System of Training and Assessment Standards (《培訓及考核標準管理制度》) to systematically standardize personnel training. In terms of training planning, annual training plans are prepared every December based on comprehensive needs analysis, reviewed at the end of each month to finalize the detailed training schedule for the upcoming month to align with business needs and employee development.

We adopt a variety of online and offline training and implement targeted training for employees at different levels. Specifically including: 2-3 onboarding sessions annually for new employees; professional skills and management courses (e.g., Lean Management, Post-Mortem Analysis) for core employees; technical skills training (e.g., GMP compliance) for operational staff; external executive training for senior management.

In terms of career development mechanism, we have established a standardized and streamlined dual-channel promotion management system to provide employees with two parallel career development paths: technology and management. The technical route follows the promotion sequence of "Assistant Engineer → Engineer → Senior Engineer → Principal Engineer → Expert Engineer", and the management route is set as "Specialist → Supervisor → Manager → Senior Manager → Deputy Director → Director → Senior Director". This dual-channel promotion management system ensures that employees who focus on deep technology and those who go to management positions can receive equal career development and recognition.

Occupational Health and Safety

We attach great importance to the occupational health and safety of employees and strictly follow the working principle of the "prevention-first, combining prevention with control". According to the Law of the People's Republic of China on the Prevention and Control of Occupational Diseases (《中華人民共和國職業病防治法》) and the Provisions on the Administration of Occupational Health at Workplaces (《工作場所職業衛生管理規定》), we have formulated internal systems such as the Occupational Health Management Regulations (《職業衛生管理規程》), continuously improved the OHS management system, fully protected employees from occupational hazards in the production and labor process, and effectively prevented the occurrence of occupational diseases.

In order to ensure that every employee can obtain adequate occupational health and safety protection, we carry out occupational hazard factor detection at least once a year and evaluate the occupational hazard status at least once every three years to ensure that the working environment meets the national occupational health standards. Moreover, we strictly implement the management system of personal protective equipment, equip employees with protective equipment, and require proper work attire. We also organize employees to have occupational health check-ups every year and establish a comprehensive occupational health training system. In addition, we enhance employees' safety awareness and emergency response ability comprehensively by organizing special training on controlled chemicals knowledge sharing, environmental health and safety, and biological safety and liquid nitrogen safety and carrying out laboratory emergency drills and fire evacuation drills.

During the Track Record Period and up to the Latest Practicable Date, no work-related injuries or fatalities have occurred.

Anti-Corruption and Business Ethics

We strictly comply with laws and regulations such as the Anti-Unfair Competition Law of the People's Republic of China (《中華人民共和國反不正當競爭法》) and the Anti-Monopoly Law of the People's Republic of China (《中華人民共和國反壟斷法》), and are committed to establishing a fair and transparent operating environment. We have formulated the Integrity Management Policy (《廉潔從業管理制度》) and the Anti-Fraud, Anti-Money Laundering, Anti-Bribery and Anti-Corruption Policy (《反舞弊、反洗錢、反賄賂及反腐敗管理制度》), which clearly define improper conduct such as fraud, malpractice, money laundering, bribery, and corruption, delineate relevant responsibilities, and establish a comprehensive process mechanism covering reporting, investigation, follow-up, and reporting to ensure timely identification and effective handling of various violations. We have set up a dedicated reporting hotline and email address, through which whistleblowers can provide feedback to the President's Office.

We have established a regular anti-corruption training mechanism to ensure that anti-corruption training covering all employees is conducted at least once a year. Additionally, we emphasize integrity and ethical obligations during new employee onboarding, strengthen a culture of integrity, and enhance employees' awareness and ability to proactively avoid corruption risks in their daily work.

Social Contribution and Charity

We actively fulfill our corporate social responsibilities, strive to address issues of public concern, and give back to society through concrete actions. In 2023, we participated in the 30th "Love Under the Blue Sky" charity event in Jiading District, Shanghai and made donations. In 2025, we launched an educational science comic campaign on tumors to raise public awareness of tumor immunotherapy and TIL therapy, supported by the Shanghai Jiading District Association for Science and Technology.

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 legal or administrative proceedings that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operation. 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.

Legal Compliance

According to our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we had not been 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. We carry out all of our business activities exclusively in the Chinese Mainland. As confirmed by our PRC Legal Advisor during the Track Record Period and up to the Latest Practicable Date, we had complied with the applicable PRC laws and regulations in all material respects.

Non-Compliance

Social Insurance and Housing Provident Fund

During the Track Record Period, we did not make full social insurance and housing provident fund contributions based on the actual salaries of our employees. Under applicable PRC laws and regulations, if we fail to make full social insurance contributions, the relevant authorities may order us to pay the shortfall within a prescribed period and impose a daily late fee of 0.05%. Failure to pay within the deadline may result in a fine ranging from one to three times the overdue amount. For housing provident funds, if we fail to settle the shortfall within a mandated timeframe, the authorities may apply for compulsory enforcement by a PRC court.

During the Track Record Period and up to the Latest Practicable Date: (i) our contributions were not lower than the minimum contribution bases recognized by the local social insurance and housing provident fund regulatory authorities; (ii) pursuant to the "Notice on Supporting and Serving the Development of the Private Economy" (Shui Zong Fa [2018] No. 174), authorities are strictly prohibited from organizing centralized clearances of historical unpaid contributions; (iii) we have not received any notice from the relevant government authorities requiring supplementary contributions or imposing administrative penalties; (iv) as confirmed by credit reports, we have not been subject to any administrative penalties for violations of related laws and regulations relating to social insurance or housing provident funds; (v) based on interviews with the social insurance

authorities and housing provident fund management centers in our principal operating locations, it is not their common enforcement practice to proactively require enterprises to make retrospective contributions for all employees for historical underpayments; and (vi) we have confirmed that, should we receive any notice from the competent authorities requiring us to make contributions within a prescribed period or to make up any shortfall, we will promptly and fully pay the outstanding amounts and any applicable late payment charges. Based on the above, our PRC Legal Advisor is of the view that, provided there are no material adverse changes to current regulatory policies and environment, the risk of us being penalized or required to make supplementary contributions by the relevant competent authorities is remote, provided that we make full and timely payments if requested by the competent authorities.

We have taken and will continue to take the following remedial measures to comply with the regulatory requirements for social insurance and housing provident fund contributions: (i) we will make reasonable efforts to pay the contributions for all employees according to the relevant PRC laws and regulations going forward; (ii) our human resource department monitors our ongoing compliance with the social insurance and housing provident fund contribution regulations and oversees the implementation of any necessary measures; (iii) we will regularly review and monitor the reporting and contributions of social insurance and housing provident fund to keep us abreast of relevant regulatory developments; and (iv) we undertake to maintain close communication with relevant authorities on a regular basis to understand their requirements and interpretation of relevant rules and regulations, and make contributions to social insurance and housing provident fund in accordance with their specific guidance in a timely manner.

Registration of Leased Properties

As of the Latest Practicable Date, the lease agreements for two of our leased properties in China had not been registered with the relevant PRC authorities. One of these lease agreements had not been registered because the lessor had not provided a valid title certificate for the leased property, which is generally required for lease registration. The other lease agreement had not been registered because the lessor informed us that it was unable to complete the registration procedures and did not cooperate in the registration process. As advised by our PRC Legal Advisor, the non-registration of these lease agreements will not affect their validity. However, the relevant local housing administrative authorities may require us to complete the registrations within a specified timeframe. If we fail to rectify the non-compliance within such timeframe, we may be subject to a fine ranging from RMB1,000 to RMB10,000 per unregistered lease. During the Track Record Period and as of the Latest Practicable Date, we had not been subject to any administrative penalties imposed by the competent authorities for failing to complete lease registrations. We will take all practicable and reasonable steps to ensure that the unregistered leases are registered if required by the competent authorities, including requesting the relevant property owners to cooperate with us to complete the registrations under the existing, new, or renewed lease agreements.

As of the Latest Practicable Date, with respect to the first of these two unregistered leased properties, the lessor had not provided us with valid title certificates or relevant authorization documents evidencing their right to lease the property, as the underlying title certificate expired in 2014. As advised by our PRC Legal Advisor, it is the lessor's sole responsibility to obtain the necessary ownership certificates or authorizations; as a tenant, we are not subject to administrative penalties for leasing a property without a valid title certificate. Although the expired title certificate has prevented us from obtaining certain required permits (including construction permits, fire safety acceptance inspections, and completion acceptance for construction works) local authorities have confirmed during interviews that: (i) there are no plans for the repurposing or demolition of the property, and we will not be required to vacate the premises or halt our operations; (ii) this issue will not adversely affect our business stability; and (iii) we may continue using the property for our operations, as these circumstances do not constitute a material violation of PRC laws or regulations. Furthermore, as of the Latest Practicable Date, we had passed all mandatory annual fire safety inspections conducted by the property management company, and no safety incidents had occurred.

Our premises are equipped with necessary utilities, facilities, and fire safety measures, rendering them safe for occupation. In the event that the property becomes unavailable for use, we will promptly relocate our operations to an alternative site to ensure business continuity.

For further details, please see the sections headed "Risk Factors — Risks Relating to Our Operations — We may face certain risks related to our leased properties."

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. For more details, see "Risk Factors — Risks Relating to Our Operations" in this Document. Our Directors oversee and manage the overall risks associated with our operations. 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 but not limited to 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.

Internal Control

We have employed an independent internal control consultant to assess our internal control system in connection with the [**REDACTED**]. The internal control consultant has conducted certain agreed-upon review procedure on our internal control system in certain aspects, including financial reporting and disclosure controls, corporate level controls, information system control management and other procedures for our operations. 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 believe we will be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. 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. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. 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 relationships with suppliers and customers, hospitality and gifts, financial interests, and personnel matters. Employees, including but not limited to 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 such parties; have close relatives working for such parties; or serve as a consultant or director in an association or company in the same market or industry. Employees are also required to maintain the strict confidentiality of all proprietary information and agree to the definition of confidential information, the scope of protected content, the use of intellectual property — including but not limited to know-how, technology transfers, and potential breach liabilities.

Our employee agreements include non-competition clauses, which generally prohibit employees from engaging in or directly or indirectly assisting any third party in the same, similar, or competitive business activities as our Company for a period of two years following the termination of employment. The applicability of these non-competition obligations depends on the nature of the employee's role and the level of access to confidential information at the time of departure. Employees may not, without prior written approval from our Company, own, manage, operate, or control any entity that competes with our business where the non-competition clause is applicable.

Data Privacy Protection

During our clinical development and operations, we process and use personal information of the trial subjects enrolled in our clinical trials on a pseudonymized basis. This personal information includes trial subject identification codes, demographic information, medical treatment data, and clinical trial data. All such data are stored within Chinese Mainland, and there is no cross-border transfer of personal information regarding our trial subjects. We also process and use personal information of other subjects, mainly consisting of contact and credential information for our own employees, healthcare professionals at clinical research sites, and employees of our suppliers, in order to complete our respective clinical trials. Data are used only for the intended purposes as agreed by the subjects and consistent with the informed consent forms.

We have established internal control measures and strict policies to govern the collection, handling, storage, and retrieval of personal data to ensure the security of the aforementioned information. These measures include formulating and implementing a Data Security Management Policy and a Personal Information Protection Policy in accordance with GCP and other relevant regulations. We have designated dedicated personnel and database administrators responsible for daily maintenance, authority control, and security protection. Our technical safeguards include multiple layers of network protection and strict access controls for personnel involved in our clinical trials and daily operations. Furthermore, we enter into confidentiality agreements with our employees which remain binding after their employment ends, and we provide regular training on data security policies. We also include specific data protection clauses in our agreements with hospitals, CROs, and SMOs to clearly define the data processing roles and obligations of each party.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any incident of patient data or other personal data leakage, breach, or material losses. As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we have been in compliance with all applicable laws and regulations on data security and personal information protection in China in all material aspects and have not been subject to any material penalty in this regard.