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Application Proof of



TransThera Sciences (Nanjing), Inc. 藥捷安康(南京)科技股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

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TransThera Sciences (Nanjing), Inc. 藥捷安康(南京)科技股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

[REDACTED]

Number of [REDACTED] : [REDACTED] H Shares (subject to the
under the [REDACTED] [REDACTED])

Number of [REDACTED] : [REDACTED] H Shares (subject to
reallocation)

Number of [REDACTED] : [REDACTED] H Shares (subject to
reallocation and the [REDACTED])

Maximum [REDACTED] : HK\$[REDACTED] per H Share, plus
brokerage
of 1.0%, SFC transaction levy
of 0.0027%, AFRC transaction levy
of 0.00015% and Hong Kong Stock
Exchange trading fee of 0.00565%
(payable in full on application in
Hong Kong dollars and subject
to refund)

Nominal value : RMB1.00 per H Share

[REDACTED] : [REDACTED]

Joint Sponsors, [REDACTED], [REDACTED],
[REDACTED] and [REDACTED]

(In no particular order)



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The [REDACTED], on behalf of the [REDACTED], may, where considered appropriate and with the consent of our Company, reduce the number of [REDACTED] and/or the indicative [REDACTED] range below that is stated in this document at any time on or prior to the morning of the last day for lodging applications under the [REDACTED]. In such case, an announcement will be published on the website of our Company at www.transthera.com and the Hong Kong Stock Exchange at www.hkexnews.hk as soon as practicable following the decision to make such reduction, and in any event not later than the morning of the last day for lodging applications under the [REDACTED]. For further details, please see the sections headed "Structure of the [REDACTED]" and "How to Apply for [REDACTED]" in this document.

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[REDACTED]

IMPORTANT

[REDACTED]

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[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

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SUMMARY

This summary aims to give you an overview of the information contained in this document and is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial information appearing elsewhere in this document. As this is a summary, it does not contain all the information that may be important to you and we urge you to read the entire document carefully before making your [REDACTED] decision. There are risks associated with any investment. Some of the particular risks in [REDACTED] in the [REDACTED] are set out in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biopharmaceutical company seeking to [REDACTED] on the [REDACTED] of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules.

OVERVIEW

We are a clinical demand-oriented, registrational clinical-stage biopharmaceutical company focusing on discovering and developing innovative small molecule therapies for oncology, inflammatory and cardiometabolic diseases. Leveraging our fully-integrated in-house R&D system, we have built a pipeline of six clinical-stage product candidates and one preclinical stage product candidate. Our Core Product Tinengotinib (TT-00420) is a potential first-in-class, registrational stage, internally discovered and developed unique multi-targeted kinase (“MTK”) inhibitor primarily targeting three key pathways (namely, FGFR/VEGFR, JAK and Aurora kinases). It has the potential to address the unmet clinical needs in a variety of relapsed or refractory, drug-resistant solid tumors, including cholangiocarcinoma (“CCA”), prostate cancer, breast cancer, biliary tract carcinoma (“BTC”) and pan-FGFR solid tumors.

THERE IS NO ASSURANCE THAT WE WILL ULTIMATELY BE ABLE TO DEVELOP AND MARKET OUR CORE PRODUCTS OR ANY OF OUR PIPELINE PRODUCTS SUCCESSFULLY.

SUMMARY

The following chart illustrates our pipeline and summarizes the development status of our selected clinical-stage and preclinical-stage drug candidates as of the Latest Practicable Date:

Drug Candidate	Targets/ Mechanism	Indication	Mono/ Combo	Clinical Stage					Expected Upcoming Milestone	Rights Region
				Preclinical	IND Enabling	Phase I	Phase II	Pivotal Phase II/ Phase III		
★ Tinengotinib (TT-00420)	Unique MTK	CCA ¹	Mono	China	China	China	China	China	Complete the trial in 2H 2025	Global
				U.S. ¹ , China	Complete patient enrollment in 2H 2026					
	(FGFR/VEGFR/ JAK/Aurora)	mCRPC	Combo (NHT)	U.S. ¹ , China	Complete the trial in Q4 2024	Global				
				U.S. ¹ , China	Initiate the trial in 2H 2024 (US)/ 1H 2025 (China)					
	HER2– breast cancer	BTC	Combo (PD-L1)	U.S. ¹ , China ³	Complete the trial in Q4 2024	Global				
				U.S. ¹ , China ³	Clinical timeline TBD					
	Pan-FGFR solid tumor	Solid tumor	Mono	China	China	China	China	China	Complete the trial in Q4 2024	Global
				U.S., China	Complete the trial in 1H 2026					
	TT-00973	AXL/FLT3	CLL/MCL/WM	Mono	U.S., China	U.S., China	U.S., China	U.S., China	Obtain results from primary endpoint in 2H 2025	Global
	TT-01488	Reversible BTK	UC	Mono	China	China	China	China	Complete the trial in 2H 2024	Greater China ⁶
TT-01688	SIP1	AD	Mono	U.S., China	U.S., China	U.S., China	U.S., China	Complete the trial in 2H 2024	Global	
TT-00920	PDE9	HF	Mono	U.S., China	U.S., China	U.S., China	U.S., China	Clinical timeline TBD	Global	
TT-01025	VAP-1	NASH	Mono	U.S., China	U.S., China	U.S., China	U.S., China	Clinical timeline TBD	Global	
TT-02332	NLRP3	Metabolic/Inflammation	Mono	U.S., China	U.S., China	U.S., China	U.S., China	IND submission in the first half of 2025	Global	

★ Core Product

Abbreviations: CCA=cholangiocarcinoma; mCRPC=metastatic castration-resistant prostate cancer; HER2– breast cancer=human epidermal growth factor receptor 2 negative breast cancer; BTC=biliary tract carcinoma; CLL=chronic lymphocytic leukemia; NHT=novel hormone therapies; MCL=mantle-cell lymphoma; WM=waldenström’s macroglobulinemia; HF=heart failure, UC=ulcerative colitis; AD=atopic dermatitis; NASH=nonalcoholic steatohepatitis; MRCT=multi-regional clinical trial; TBD=to be determined; Q4=fourth quarter; 1H=first half; 2H=second half.

SUMMARY

Notes:

1. We received Breakthrough Therapy Designation for CCA from the NMPPA in July 2023, and received Fast-Track Designation for CCA from the FDA in August 2021.
2. We are exploring these indications under the same trial protocol of one clinical trial (NCT04742959) conducted in the U.S.
3. We are exploring these indications under the same trial protocol of one clinical trial (CTR20212760) conducted in China.
4. This trial is an investigator-initiated trial.
5. We are currently conducting a Phase III multi-regional clinical trial (NCT05948475) of Tinengotinib monotherapy for the treatment of CCA across the U.S., South Korea, United Kingdom, eight countries in the EU and Taiwan.
6. We in-licensed exclusive rights from LG Chem to use, develop, manufacture, commercialize and otherwise exploit TT-01688 in Greater China. For more information, see “Business – Collaboration and License Agreements – License-in Agreement with LG Chem.”

SUMMARY

Our Business Model

Our core business model involves internally discovering, developing and commercializing small molecule drugs that address the unmet medical needs in the fields of oncology, inflammatory and cardiometabolic diseases.

With our global vision and clinical practice, we have formed a strong engine for our continuous innovation of small molecule drug candidates. According to Frost & Sullivan, we are one of the first dedicated innovative small molecule drug developers in China to establish a global clinical development platform aiming to create novel therapies for the global market. We plan to continue executing our global clinical development and marketing strategy through our methodology platform, Adaptive Comprehensive Expandable (“ACE”) platform.

OUR CORE PRODUCT

Tinengotinib (TT-00420), our Core Product, is an internally discovered and developed, potential first-in-class, registrational stage, unique MTK inhibitor for the treatment of drug-resistant, relapsed or refractory cancers. Tinengotinib targets three key pathways including FGFR/VEGFR, JAK and Aurora. Driven by targeting one or a combination of pathways, Tinengotinib can target a wide range of cancer types. The unique binding mode with FGFR enables Tinengotinib to overcome polyclonal mutations, rendering it target FGFR-driven cancers (such as FGFR altered CCA and pan-FGFR solid tumor), and the distinct combination of the key pathways makes it capable of being efficacious in a broad range of cancer types (including prostate cancer, breast cancer and BTC). For details regarding Tinengotinib’s mechanisms of action, see “Business – Core Product: Tinengotinib – Potential First-in-class, Unique MTK Inhibitor – Mechanism of Action.” For more information regarding the ongoing and planned clinical trials of Tinengotinib, see “Business – Core Product: Tinengotinib – Potential First-in-class, Unique MTK Inhibitor – Summary of Clinical Trials – Overview of Clinical Studies of Tinengotinib.”

As of the Latest Practicable Date, there was one MTK inhibitor targeting FGFR approved by the FDA, namely, erdafitinib. As of the Latest Practicable Date, there were three MTK inhibitors targeting FGFR, as well as one or more of JAK, Aurora and VEGFR at clinical stage globally and in China. Tinengotinib is a unique MTK inhibitor targeting FGFR/VEGFR, JAK and Aurora. No other MTK inhibitor has demonstrated the same target combination and applications, and thus such drug profile of Tinengotinib is without competing drug candidate. For details, see “Industry Overview – Small Molecule Oncology Targeted Therapy – MTK Inhibitor – Competitive Landscape.”

CCA

Our Core Product Tinengotinib is the world’s first and the only investigational drug that has entered registrational stage to treat FGFR inhibitor relapsed or refractory CCA patients. FGFR inhibitors have been approved for the treatment of FGFR-altered CCA after chemotherapy. However, disease progression after FGFR inhibitors occurred in almost all

SUMMARY

patients. The absence of recommendations for subsequent treatment options in NCCN or CSCO guidelines has created an unmet medical need. Researchers have reported that secondary polyclonal mutations in the FGFR2 kinase domain are a major prominent acquired resistance mechanism. In a pooled analysis of clinical studies in the U.S., as of March 28, 2024, among 43 CCA patients who had progressed on prior FGFR inhibitors, after being treated with Tinengotinib and had at least one tumor scan, the objective response rate (“**ORR**”) was 30% (13/43), the disease control rate (“**DCR**”) was 93% (40/43), and the median progression free survival (“**PFS**”) was 6.0 months. The promising clinical data was also observed in the clinical trial conducted in the China. In China, two of three (66.7%) CCA patients who had progressed on prior FGFR inhibitors were treated with Tinengotinib and achieved partial response (“**PR**”). As of March 28, 2024, one patient lasted for more than 8 months, and the other patient has lasted for 14 months, who is still on treatment. Results of Tinengotinib treating FGFR inhibitor relapsed or refractory CCA patients were presented at 2023 ESMO annual conference and 2024 ASCO GI annual conference as oral presentations and published as poster presentation at 2024 Cholangiocarcinoma Foundation annual conference. Two pivotal/registrational trials in China and certain other regions were initiated in November 2023 and December 2023, respectively. For details regarding Tinengotinib’s competitive advantage for the treatment of CCA, see “Business – Core Product: Tinengotinib – Potential First-in-Class, Unique MTK Inhibitor – Competitive Advantages.”

Addressable Market and Competitive Landscape

According to Frost & Sullivan, the number of CCA patients globally increased from approximately 234.9 thousand in 2018 to 280.0 thousand in 2023. For more details of CCA incidence, see “Industry Overview – Small Molecule Oncology Targeted Therapy – Major Indications of MTK Inhibitors – CCA.” FGFR alterations (including fusion and rearrangement, point mutation and gene amplification) are observed in 25.2% of CCA patients, and FGFR fusions and rearrangements are observed in 7.4% of CCA patients.

CCA is an aggressive type of tumor that can progress rapidly and become fatal due to invasion across all body areas if treatment is not administered at an early stage. Currently, CCA is considered incurable unless fully resected in the early-stage through surgery. CCA is frequently diagnosed at an advanced, unresectable stage because of the late presentation of nonspecific clinical symptoms of the disease and the lack of effective screening modalities. Surgery including liver transplantation is the primary treatment for eligible patients in all kinds of CCA, facilitated by neo-adjuvant therapy or other pre-operative therapies to obtain surgical eligibility. However, there was a high recurrence rate, perioperative complications and poor patient survival rate among CCA patients treated with surgery and liver transplantation. To be specific, the actual five-year survival rate after the transplantation is approximately 30%, according to the Frost & Sullivan. For late-stage CCA with progressed and/or metastatic disease, chemotherapy combination of gemcitabine and cisplatin is presently the first-line treatment. Targeted therapy is viable if the patients are qualified for genetic markers including, but not limited to, FGFR2, NTRK, MSI-H/dMMR and IDH1, which allows for more precise treatment. For more details of CCA treatment and limitations, see “Industry Overview – Small Molecule Oncology Targeted Therapy – Major Indications of MTK Inhibitors – CCA.”

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As of the Latest Practicable Date, the FDA had approved three FGFR inhibitors for the treatment of CCA, i.e. futibatinib, infigratinib and pemigatinib, and one FGFR inhibitor for the treatment of urothelial cancer, i.e. erdafitinib. On May 16, 2024, the FDA announced the final withdrawal of the approval of infigratinib for previously treated, unresectable locally advanced or metastatic CCA with a FGFR2 fusion or other rearrangement. In China, only pemigatinib was approved by the NMPA for the treatment of CCA. Nonetheless, the approved FGFR inhibitors are not able to address drug resistance to prior FGFR inhibitors.

As of the Latest Practicable Date, there were four FGFR inhibitors in clinical development globally for CCA that had progressed on prior FGFR inhibitor treatment, along with two FGFR inhibitors in clinical development for CCA that had progressed on prior FGFR inhibitor treatment in China. On a global scale, as of the Latest Practicable Date, Tinengotinib stood out as the only drug candidate in registrational stage for treating CCA that has progressed on the prior FGFR inhibitor treatment. For details, see “Industry Overview – Small Molecule Oncology Targeted Therapy – Major Indications of MTK Inhibitors – CCA – FGFR Inhibitor – Competitive Landscape.”

mCRPC

Tinengotinib is also the world’s first and the only investigational drug capable of simultaneously and effectively inhibiting the FGFR/JAK pathway with clinical evidence in the treatment of mCRPC. Currently, novel hormone therapies, including enzalutamide, apalutamide and abiraterone, have been established as the standard of care for mCRPC patients. However, resistance will inevitably develop after a period of hormone therapy treatment. Recent academic discoveries have identified that activation of FGFR and JAK pathways will stimulate the cell state transformation from androgen sensitive cancer cells to neuroendocrine cancer cells and cause drug resistance. Simultaneous inhibition of FGFR and JAK pathways would be able to reverse the cell state transformation, or lineage plasticity, back to androgen sensitive cancer cells and re-sensitize to hormone therapies. In a pooled analysis of patients in the U.S. and China, Tinengotinib monotherapy has shown encouraging antitumor efficacy in heavily pre-treated mCRPC patients. According to our Phase I/II clinical trials of Tinengotinib as monotherapy in 22 efficacy-evaluable heavily pre-treated mCRPC patients who are resistant to hormonal treatments, the preliminary efficacy observed in 13 patients with measurable lesions was promising, showing an ORR of 46% (6/13) and a DCR of 85% (11/13). 43% patients had prostate-specific antigen reduction of more than 50%. The median radiographic PFS was 5.6 months (N=22). The results have been published at 2024 ASCO GU annual conference. Further combination study to explore Tinengotinib and novel hormone therapies will be initiated to target mCRPC patients who have developed resistance to prior hormone therapy treatment. For details regarding Tinengotinib’s competitive advantage for the treatment of mCRPC, see “Business – Core Product: Tinengotinib – Potential First-in-class, Unique MTK Inhibitor – Competitive Advantages.”

SUMMARY

Addressable Market and Competitive Landscape

According to Frost & Sullivan, the number of new cases of mCRPC around the world increased from 176.4 thousand in 2018 to 203.9 thousand in 2023. It is expected to grow to 220.2 thousand in 2026 and further to 238.0 thousand in 2030. In China, due to the change in dietary habit to high protein and high fat in recent years, the risks of having prostate cancer are increasing. Nevertheless, the diagnosis rate is relatively low due to the insufficient awareness and attention to this disease as well as no obvious specific symptoms in the early stage. The incidence of mCRPC in China increased from 42.8 thousand in 2018 to 50.5 thousand in 2023. The number is expected to grow to 57.3 thousand in 2026 and further reach 67.1 thousand in 2030.

Enzalutamide and abiraterone, are an important group of treatment for prostate cancer, also known as novel hormone therapies (“**NHT**”) and they are also the backbone treatment of current therapies. However, patients who received NHT treatment will become resistant to these treatments. Currently, there is a lack of an effective small molecular targeted therapy that universally addresses mCRPC patients in the second-line setting. Therefore, innovative therapy for mCRPC is still in urgent need. For more details of mCRPC treatment and limitations, see “Industry Overview – Small Molecule Oncology Targeted Therapy – Major Indications of MTK Inhibitors – mCRPC.”

Other Indications

- **Breast cancer.** Similar promising efficacy of Tinengotinib has also been observed in heavily pre-treated Hormone receptor-positive (“**HR+**”)/human epidermal growth factor receptor 2-negative (“**HER2-**”) breast cancer patients and triple-negative breast cancer (“**TNBC**”) patients. In a pooled analysis of breast cancer patients in the U.S. and China, Tinengotinib monotherapy demonstrated an ORR of 50% (8/16) and a DCR of 88% (14/16) in patients who were originally diagnosed as HR+/HER2-. Notably, among the 16 patients, five transformed TNBC patients reached 60% ORR (3/5) and 100% DCR (5/5). One HR+/HER2- patient has been on the treatment for over 20 months and reached confirmed complete response. For details regarding the market size of breast cancer, see “Industry Overview – Small Molecule Oncology Targeted Therapy – Major Indications of MTK Inhibitors – HER2- Breast Cancer.”

SUMMARY

- **Biliary tract cancer.** Preclinical data demonstrates Tinengotinib is capable of modulating tumor microenvironment, indicating its potential to enhance the efficacy of immunotherapy. From our Phase Ib/II clinical trial, among nine efficacy-evaluable patients treated with Tinengotinib plus atezolizumab, the ORR and the DCR were 33% (3/9) and 78% (7/9), respectively. The combination therapy is generally safe and well tolerated. These encouraging data suggest Tinengotinib’s great potential in combination therapy with immunotherapies.
- **Pan-FGFR solid tumor.** Tinengotinib has unique binding mode to FGFR 1/2/3 kinase proteins, enabling it to be potent to key mutations within FGFR 1/2/3 kinase domains. This differentiated feature has brought good clinical responses to a variety of solid tumor patients with FGFR 1/2/3 alterations, especially point mutations. In a pooled retrospective analysis, 51 patients with documented or detected FGFR 1/2/3 mutations and measurable target lesions have been treated with Tinengotinib and demonstrated an ORR of 33% and a DCR of 88%. The median PFS reached 6.9 months.

OTHER ONCOLOGY PIPELINE PRODUCTS

- **TT-00973** is an internally discovered and developed, highly potent AXL/FLT3 inhibitor with significantly high potency against AXL. AXL kinase is a key player in survival, metastasis, and drug resistance in cancer, aberrant activation of AXL signaling is associated with poor prognosis in many types of cancers. AXL represents a promising therapeutic target in cancer treatment, both as single agent and in combination with other therapies. TT-00973 is potent in abrogating AXL activation in tumor cells, and demonstrates effective antitumor activity in murine xenograft models with AXL overexpression. We have received the IND approval from the NMPA in August 2022. We are conducting a Phase I dose escalation study in patients with solid tumors in China with the first patient enrolled in April 2023, and have observed that TT-00973 was well tolerated and achieved partial responses in patients with solid tumors.
- **TT-01488** is an internally developed, non-covalent, reversible BTK inhibitor to overcome acquired resistance developed from marketed covalent BTK inhibitors in various types of relapsed or refractory hematological malignancies. In a head-to-head kinase panel screening, in addition to its higher potency, TT-01488 demonstrated strong kinase selectivity on EGFR and Tec, indicating its potential to have fewer off-target side effects and thus a better safety profile. In the lymphocytic xenograft models, TT-01488 showed encouraging antitumor effect. We received the IND approval from the FDA and the NMPA in January 2022 and April 2022, respectively. Currently, we are conducting a Phase I dose-escalation clinical study of TT-01488 for B-cell lymphoma in China with the first patient enrolled in March 2023. Promising efficacy of complete response and partial response have been observed in patients with acquired resistance to irreversible BTK inhibitors during the Phase I dose-escalation study.

SUMMARY

NON-ONCOLOGY PIPELINE PRODUCTS

- **TT-01688** is a highly selective oral S1P1 modulator currently in clinical stage, with the potential to treat various inflammatory diseases. According to Frost & Sullivan, the prevalence of UC and AD in China was approximately 541.6 thousand and 71.6 million, respectively, in 2023. For patients receiving biologics, over 60% of patients with moderate to severe UC fail to achieve one-year clinical remission, and over 40% of patients with moderate to severe AD fail to achieve a four-point improvement according to the Worst Pruritus Numerical Rating Scale. As of the Latest Practicable Date, no selective S1P1 modulator was approved for UC or AD treatment in China with several candidates undergoing clinical development, among which TT-01688 was one of the most clinically advanced selective S1P1 modulators. It has high activity against S1P1 with negligible effect on S1P2 and S1P3 as well as G1R, which is associated with potential cardiovascular adverse reactions. Its superior safety and PK/PD profiles have been demonstrated in the Phase I clinical trial. Although not a head-to-head study, in the Phase I clinical trial, the biological efficacy of TT-01688 is equal to or better than that of ozanimod and etrasimod, TT-01688 is well-tolerated with all the AEs being mild or moderate in severity in the Phase I clinical trial in healthy adult subjects. We initiated a Phase Ib clinical trial of TT-01688 for the treatment of UC in China in May 2022, and a Phase II clinical trial of TT-01688 for the treatment of AD in China in September 2022.
- **TT-00920** is an internally discovered and developed, potential first-in-class, highly selective oral PDE9 inhibitor, targeting chronic heart failure. According to Frost & Sullivan, the prevalence of heart failure has been steadily increasing, reaching approximately 32.4 million globally and 12.5 million in China in 2023. Based on left ventricular ejection fraction, heart failure is classified into heart failure with preserved ejection fraction (“**HFpEF**”) and heart failure with reduced ejection fraction (“**HFrEF**”), each with unique pathophysiology. On the one hand, although there has been significant advancement in the research and development of therapies for HFrEF, there is still a need for innovative drugs to further improve clinical efficacy. Preclinical studies have shown that TT-00920 restored cardiac NP/cGMP signaling, significantly enhanced cardiac function, and reversed ventricular remodeling in heart failure. In addition, compared to monotherapy, TT-00920 in combination with valsartan (an angiotensin receptor antagonist) demonstrated superior efficacy, suggesting that TT-00920 may synergize with existing treatments for heart failure. TT-00920 also exhibited low central nervous system (“**CNS**”) exposure and high cardiac distribution in the preclinical study, favoring the treatment of heart failure and avoiding CNS adverse reactions. Also, in the completed Phase I trials in healthy subjects in China and the U.S., TT-00920 was well tolerated, and demonstrated favorable pharmacokinetic properties and anticipated biomarker changes.

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- **TT-01025** is an internally discovered and developed, irreversible VAP-1 inhibitor, intended as an oral treatment for NASH. According to Frost & Sullivan, the prevalence of NASH was 42.5 million in China in 2023. VAP-1 is a novel clinical target for anti-inflammation. In head-to-head comparisons in preclinical studies, the results showed that TT-01025 has very low brain penetration with no significant CNS MAO-B inhibition at 100 μ M, suggesting the risk of such drug interactions in TT-01025 is minimal. We completed the Phase I study of TT-01025 in healthy subjects in China in April 2022, suggesting that TT-01025 was safe and well-tolerated at a single dose of up to 300 mg and multiple doses of up to 100 mg. As of the Latest Practicable Date, there was no VAP-1 inhibitor either approved by the FDA or the NMPA. As of the Latest Practicable Date, there were seven VAP-1 inhibitors at clinical stage globally, but only three were for the treatment of NASH. Meanwhile, as of the Latest Practicable Date, TT-01025 stood out as the only VAP-1 inhibitor that was in clinical trial in China.

For the details of our pipeline products, see “Business.”

Our “ACE” Approach

We consistently adopt our proprietary ACE optimization approaches to efficiently optimize the drug research and development process for each asset to maximize their therapeutic potential as well as clinical and commercial value. The following are the characteristics of our “ACE” optimization techniques.

- Adaptive, focusing on clinically meaningful drug differentiation. Through robust biological science-driven discovery capabilities, we carefully select and evaluate potential targets with solid biological mechanisms and close disease associations. Through competitive landscape analysis, we identify key limitations and deficiencies imposed by existing drugs, and establish differentiated molecule to proactively take measures at each stage of preclinical and clinical design to ensure future products are highly competitive in their respective fields. This allows us to identify differentiated compounds with potential competitive advantages rapidly. Using Tinengotinib as an example, during the molecule screening process, our goal was to identify a potent compound targeting key FGFR kinase domain mutations. By developing a set of internally designed biological assays for screening compound scaffolds, we successfully identified a novel scaffold, which ultimately led to the discovery of Tinengotinib.
- Comprehensive, focusing on high quality drug properties. While developing drug candidates with differentiated profile, we also recognize the importance to improve their druggability. We have developed a comprehensive list of drug parameters to select a final drug candidate with a most desirable drug profile. Internally, a number of parameters are used to evaluate drug candidates, including those pertaining to potency, selectivity, bioavailability, safety and PK/PD profiles. These comprehensive evaluations can help us better understand the nature of each drug candidate, boosting the likelihood of clinical development success.

SUMMARY

- Expandable, focusing on indication expansions. We strategically tailor our drug candidates to expand into new indications. Such strategy is accomplished mainly through two routes. First is to leverage our R&D system and our in-depth understanding of mechanisms of action of candidates, their potential targeted patient population, and the unmet medical needs in the relevant treatment field to develop innovative drug candidates with multi-potential to address clinical needs in a number of treatment fields. Second is to further explore our drug candidates’ potential in combination with existing treatment to fully capture their market opportunities.

Our innovative pipeline is nurtured by our full-integrated end-to-end R&D system, which is established through the discovery, accumulation, application and verification of our R&D technology. Our R&D system is capable of performing key R&D steps ranging from early-stage target identification and mechanism of action verification, molecular discovery and optimization, to late-stage clinical development and translational medicine research. Our fully integrated R&D platform integrates all the necessary capabilities to streamline our target-to-market timeline. These capabilities will be housed in four main functional units: drug discovery, clinical development, CMC and regulatory affairs. The platform fostered our core competitiveness of designing highly differentiated molecules *de novo* based on the structure-activity relationship between the drug and its targets, and achieving a two-way research cycle of “Bench to Bed” and “Bed to Bench.”

Our Global Collaborations

We benefit from the network and industry resources of our prominent global partners and have created a broad global collaboration network among biopharmaceutical companies. Our global partners comprise leading pharmaceutical companies, including LG Chem, Roche, Teijin, and EA Pharma. Our partnerships cover various business collaboration models, including clinical collaboration, joint research and development, and in-licensing arrangement. Through these international collaborations, we have gained access to a spectrum of innovative technologies and international clinical development resources, positioning us for future global commercialization.

Our Team

We have assembled a stable management team with extensive experience in both multinational and Chinese pharmaceutical companies. Our management team has an average of more than 15 years of industry experience and we have a proven track record of drug innovation. Since inception, our management team has been working together, bringing in synergistic and complementary expertise that covers the R&D process, spanning discovery, translational research, clinical development, regulatory affairs and business development. We believe that our diverse experience and collaborative culture are largely responsible for the continued success of our business and innovation.

SUMMARY

Dr. Frank Wu, our founder, Chairman and CEO, has over 27 years of science and leadership experience in biopharmaceutical companies. Before founding our Company, Dr. Wu was the general manager of Shandong XuanZhu Pharmaceutical. He has more than ten years of research leadership experience at Boehringer Ingelheim Pharmaceuticals Inc. and Guilford Pharmaceuticals Inc. He was a former member of the prestige American Chemistry Society Division of Medicinal Chemistry long range planning committee.

OUR COMPETITIVE STRENGTHS

- Registrational Stage Tinengotinib Leading in Addressing Global Unmet Needs;
- Highly Differentiated Pipeline Targeting Oncology and Other Diseases;
- Insightful Drug R&D Life Cycle Driven by “ACE” Approach;
- Strong Global Capabilities Covering R&D, Regulatory Affairs and Business Development; and
- Management Team with Rich Industry Experience and Strong Execution Capabilities.

OUR STRATEGIES

- Advance Clinical Trials of Our Drug Candidates;
- Establish a Commercial Network for Promoting Tinengotinib Globally;
- Continue to Execute Our Global Strategy via Broad and Diversified Collaboration; and
- Continuously Attract, Retain and Incentivize Talent of High Quality and Diversity.

RESEARCH AND DEVELOPMENT

We believe that fully-integrated in-house R&D capabilities are critically important to our success in global competition. As of the Latest Practicable Date, our R&D team consisted of 94 members in total, including 61 holding doctorate degrees or master degrees. For more information on our R&D employees, see “Business – Research and Development – Drug Discovery” and “Business – Research and Development – Clinical Development – Clinical Development Team.”

We are generally responsible for the global development of our drug candidates. For our drug candidates, we conducted clinical activities including: (i) coordinating all clinical development activities, (ii) designing the key aspects of the clinical study; (iii) designing and coordinating the selection process for qualified CROs to assist in engaging clinical sites and coordinating clinical studies once commenced; (iv) supervising the clinical studies; and (v) overseeing extensive regulatory outreach and coordination in China, the U.S. and globally.

SUMMARY

In line with industry practice, we collaborate with contract research organizations (“CROs”) to conduct and support our preclinical and clinical studies. We select our CROs by weighing various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. We engaged 82 and 93 CROs in 2022 and 2023, respectively. To the best of our Company’s knowledge, except for PharmaBlock, they are all Independent Third Parties.

In 2022 and 2023, the expenses attributable to CROs were RMB110.0 million and RMB192.2 million, respectively, with 72.6% and 73.1% of such expenses attributable to R&D of Tinengotinib.

In light of our R&D strategies, the amount of R&D expenses varies with the number and scale of projects each year. In 2022 and 2023, the amount of R&D expenses attributed to the Core Product Tinengotinib was RMB167.1 million and RMB236.4 million, respectively.

MANUFACTURING AND COMMERCIALIZATION

As of the Latest Practicable Date, we had not established an internal clinical manufacturing facility. Collaborating with leading CMO and CDMO partners, we currently outsource the production of product candidates to support relevant clinical trials in the U.S., China and other relevant regions. Given the highly sophisticated nature of the drug substance and drug product manufacturing process, we support our CMO and CDMO partners with our extensive CMC know-hows in production, packaging, transportation, and storage of our products.

We engaged one CMO in each of 2022 and 2023. We also engaged two CDMOs and one CDMO in 2022 and 2023, respectively. To the best of our Company’s knowledge, none of them have any past or present relationships with our Group, our Directors, our Shareholders holding more than 5% of our issued share capital, our senior management or any of their respective associates.

In 2022, the expenses attributable to the CMO were RMB0.5 million, which were used for the research and development of TT-00920. In 2023, the expenses attributable to the CMO were RMB0.1 million, which were used for the research and development of TT-01488. In 2022 and 2023, the expenses attributable to CDMOs were RMB28.5 million and RMB8.5 million, respectively, with 88.5% and 85.3% of such expenses attributable to research and development of our Core Product Tinengotinib.

We plan to formulate a commercialization and marketing plan in anticipation of future product launch. We plan to start with commercialization of Tinengotinib for CCA treatment in China. Patients suffered from this disease often seek medical attention in a handful of hospitals reputed for treatment of CCA. Considering the targeted patient population of Tinengotinib is readily reachable, we are currently poised to establish an in-house commercial team. We believe that an experienced marketing leader will be critical to success in commercialization.

SUMMARY

We will soon start the hiring process for a potential marketing director to join us, who will lead the marketing strategy and future commercialization plan. Our commercialization team will be responsible for market strategy, product positioning, market access and promotion activities.

Our international commercialization approach will be centered around international collaboration. Specifically, we look forward to collaborating with world-leading pharmaceutical companies with abundant marketing resources and deep root in local region to maximize the value of Tinengotinib overseas. We expect that upon receiving the marketing approvals, the collaborator will assume responsibility for promoting the product in overseas markets and will also continue to assist Tinengotinib in developing subsequent indications, including, mCRPC, breast cancer, and BTC. See “Business – Commercialization” for more details.

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we (i) owned 30 issued patents in China, and 62 issued patents in the U.S. and other jurisdictions, and (ii) filed 15 published patent applications in China, and 125 published patent applications in the U.S. and other jurisdictions relating to certain of our product candidates and platform technologies.

As of the Latest Practicable Date, we (i) owned 13 issued patents in China, the U.S. and other jurisdictions, and (ii) filed 46 patent applications, including 12 patent applications in Greater China, five patent applications in the U.S. and 29 patent applications in other jurisdictions relating to our Core Product Tinengotinib.

CUSTOMERS

During the Track Record Period, we derived revenue primarily from milestone payments from LG Chem in connection with the out-licensed TT-01025. To the knowledge of our Directors, none of our Directors, their respective associates or any of our Shareholders holding more than 5% of our issued share capital as of the Latest Practicable Date had an interest in LG Chem.

RAW MATERIALS AND SUPPLIERS

Our suppliers are mainly CROs, CMOs, CDMOs and equipment providers. In 2022 and 2023, our purchases from our five largest suppliers in aggregate accounted for 52.0% and 48.4% of our total purchases for the respective years, respectively, and our purchases from our largest supplier alone accounted for 20.5% and 19.0% of our total purchases for the respective years, respectively. To the best of knowledge of our Directors, all of our five largest suppliers in each year during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the best knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers in each year during the Track Record Period.

SUMMARY

SUMMARY HISTORICAL FINANCIAL INFORMATION

This summary of key financial information set forth below has been derived from, and should be read in conjunction with, our consolidated audited financial statements, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this document, as well as the information set forth in the section headed “Financial Information.”

Summary of Our Consolidated Statements of Profit or Loss and Other Comprehensive Income

We currently have no products approved for commercial sale and have not generated any revenue from product sales. During the Track Record Period, our revenue primarily consisted of the milestone payments from LG Chem in connection with the out-licensed TT-01025. We were not profitable and incurred operating losses during the Track Record Period. For the years ended December 31, 2022 and 2023, we incurred loss of RMB251.9 million and RMB343.4 million, respectively. We recorded losses as a result of the significant research and development costs and administrative expenses incurred during the Track Record Period. For more details, see “Financial Information – Description of Certain Selected Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Research and Development Costs,” “Financial Information – Description of Certain Selected Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Administrative Expenses.”

The following table sets forth selected components of our consolidated statements of profit or loss and other comprehensive income for the years indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Revenue	124	1,181
Cost of sales	–	–
Gross profit	124	1,181
Other income	18,733	22,491
Other gains	42,017	17,105
Other expenses	(157)	(221)
Research and development costs	(262,511)	(344,475)
Administrative expenses	(49,946)	(39,219)
Impairment losses on financial assets	(23)	(8)
Finance costs	(181)	(248)

SUMMARY

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
LOSS BEFORE TAX	(251,944)	(343,394)
Income tax expenses	—	—
LOSS FOR THE YEAR	(251,944)	(343,394)
Other comprehensive gain/(loss) for the year	(193)	189
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(252,137)	(343,205)

Summary of Our Consolidated Statements of Financial Position

Our net current assets decreased from RMB1,065.3 million as of December 31, 2022 to RMB743.0 million as of December 31, 2023, primarily due to (i) a decrease in cash and cash equivalents of RMB487.3 million, and (ii) a decrease in pledged and short-term bank deposits of RMB142.8 million, partially offset by an increase in financial assets at FVTPL of RMB341.5 million.

The following table sets forth selected information from our consolidated statements of financial position as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
NON-CURRENT ASSETS		
Property, plant and equipment	12,029	11,639
Intangible assets	997	982
Right-of-use assets	2,469	19,982
Prepayments for other receivables and other assets	11,831	8,886
Total non-current assets	27,326	41,489
CURRENT ASSETS		
Inventories	245	160
Prepayments, other receivables and other assets	35,295	7,271
Financial assets at FVTPL	—	341,541
Pledged and short-term bank deposits	142,841	—
Cash and cash equivalents	983,934	496,629

SUMMARY

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Total current assets	1,162,315	845,601
CURRENT LIABILITIES		
Trade payables	72,238	78,578
Other payables and accruals	21,942	20,527
Contract liabilities	196	–
Lease liabilities	2,688	3,457
Total current liabilities	97,064	102,562
NET CURRENT ASSETS	1,065,251	743,039
TOTAL ASSETS LESS CURRENT LIABILITIES		
	1,092,577	784,528
NON-CURRENT LIABILITIES		
Lease liabilities	–	1,350
Contract liabilities	978	–
Total non-current liabilities	978	1,350
Net assets	1,091,599	783,178
EQUITY		
Share capital	379,954	381,617
Reserves	711,645	401,561
Total equity	1,091,599	783,178

Summary of Our Statements of Cash Flows

As a development-stage biopharmaceutical company, we incurred negative cash flows from our operations during the Track Record Period. During the Track Record Period, our primary uses of cash were to fund the development of our drug pipeline, clinical trials, procurement of services, payment for the purchase of plant and equipment, administrative expenses and other recurring expenses, while we funded our capital expenditures mainly through equity financing.

SUMMARY

The following table sets forth summary data from our statements of cash flows for the years indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Cash outflows from operating activities before movements in working capital	(289,458)	(355,067)
Changes in working capital	47,190	27,585
Interest received	5,379	8,156
Net cash flows used in operating activities	(236,889)	(319,326)
Net cash flows from/(used in) investing activities	209,231	(186,938)
Net cash flows from financing activities	235,436	15,759
Net increase in cash and cash equivalents	207,778	(490,505)
Cash and cash equivalents at beginning of the year	748,634	983,934
Effect of foreign exchange rate changes, net	27,522	3,200
Cash and cash equivalents at end of the year	983,934	496,629

For the years ended December 31, 2022 and 2023, we had net cash outflows from operating activities in an amount of RMB236.9 million and RMB319.3 million, respectively. Our net cash outflow from operating activities for the years ended December 31, 2022 and 2023 was primarily attributable to our loss before tax, which was primarily because we incurred significant research and development costs and administrative expenses as a result of the business expansion and the development of our pipeline products during the Track Record Period. For more details, see “Financial Information – Liquidity and Capital Resources – Operating Activities.”

We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. In view of our net operating cash outflows throughout the Track Record Period, we plan to improve such position by (i) rapidly advancing our pipeline products towards commercialization to generate revenue from product sales. In particular, we have initiated a pivotal Phase II clinical trial of Tinengotinib for the treatment of CCA in China and we enrolled the first patient in November 2023. We have also initiated a Phase III registrational clinical trial of Tinengotinib for the treatment of CCA in certain regions outside China, and we enrolled the first patient in December 2023 in the U.S.; (ii) adopting comprehensive measures to effectively control our costs and operating expenses, primarily including research and development costs and administrative expenses. For example, we would share the pharmacology models for different projects to split costs; (iii) enhancing working capital management efficiency. For example, we plan to adopt technological solutions to optimize our operational process and enhance our efficiency; and (iv) successfully launching the [REDACTED] to obtain the [REDACTED].

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Our Directors are of the opinion that, taking into account (i) the financial resources available to our Company, including cash and cash equivalents of RMB496.6 million as of December 31, 2023, financial assets at FVTPL of RMB341.5 million as of December 31, 2023, available financing facilities and the estimated net [REDACTED] from the [REDACTED], (ii) the expected commercialization timetable of our Core Product and (iii) our cash burn rate, we will have sufficient working capital to cover at least 125% of our costs, including research and development costs and administrative expenses, for at least the next twelve months from the date of this document.

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, and (ii) capital expenditures, which includes purchase of property, equipment and plant and purchase of intangible assets. Taking into account our cash and cash equivalents and financial assets at FVTPL as of December 31, 2023, assuming an average cash burn rate going forward of 1.5 times the average level in 2022 and 2023, we estimate that we will be able to maintain our financial viability for [REDACTED] months or, if we take into account the estimated net [REDACTED] from the [REDACTED], [REDACTED] months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

Key Financial Ratio

The table below sets forth our key financial ratio for the periods or as of the dates indicated:

	As of December 31,	
	2022	2023
Current ratio ⁽¹⁾	12.0	8.2

Note:

(1) Current ratio represents current assets divided by current liabilities as of the same dates.

For more information on our key financial ratio, see “Financial Information – Key Financial Ratio.”

SUMMARY

RISK FACTORS

There are certain risks relating to an investment in our Shares. A detailed discussion of the risk factors is set forth in the section headed "Risk Factors." A summary of key risk factors is set forth below. Any of the following developments may have a material and adverse effect on our business, financial condition, results of operations and prospects:

- If we or our licensors are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially adversely affected.
- Our business and financial prospects depend substantially on the success of our clinical- and preclinical-stage drug candidates and our ability to identify additional drug candidates, complete their clinical development, obtain their regulatory approvals or achieve their commercialization.
- Our drug candidates, once approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.
- If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.
- We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If we fail to maintain our relationships with these third-party service providers, or if these third parties do not successfully carry out their contractual duties, comply with proper practices and standards or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.
- We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.

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- We have no track record and limited experience in commercialization of products. If we are unable to build or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our future products or sell our future products, which will materially affect our ability to generate product sales revenue.
- We have incurred significant net losses since our inception, and we anticipate that we will continue to incur net losses for the foreseeable future and may never become profitable. Investors are at risk of losing substantially all of their investments in our Shares.
- We operate in a rapidly changing industry and we face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, or developing drug candidates or treatments that are safer, more effective, more effectively marketed or cost less than ours, or receive regulatory approval or reach the market earlier. As a result, our drug candidates may not achieve the sales we anticipate and could be rendered non-competitive or obsolete.

You should read the entire section headed “Risk Factors” in this document before you decide to [REDACTED] in the [REDACTED].

OUR CONTROLLING SHAREHOLDERS AND PRE-[REDACTED] INVESTMENTS

As of the Latest Practicable Date, Dr. Wu, our executive Director and chairman of the Board, was directly and indirectly, through Nanjing Yipu and Nanjing Jiminrui, interested in approximately 34.29% of our total issued share capital. Immediately upon completion of the [REDACTED], assuming that the [REDACTED] is not exercised, Dr. Wu will be directly or indirectly interested in approximately [REDACTED]% of our total issued share capital and therefore, Dr. Wu, Nanjing Yipu and Nanjing Jiminrui will be regarded as our Controlling Shareholders under the Listing Rules upon the [REDACTED]. For further details, see the section headed “Relationship with our Controlling Shareholders” in this document.

Throughout the development of our Company, we have entered into several rounds of financing agreements with our Pre-[REDACTED] Investors. For further details of the identity and background of the Pre-[REDACTED] Investors, see “History, Development and Corporate Structure – Pre-[REDACTED] Investments.”

DIVIDEND

No dividend has been paid or declared by our Company during the Track Record Period. We currently expect to retain all future earnings for use in the operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the near future. Any declaration and payment as well as the amount of dividends will be subject to our Articles of Association and the PRC Company Law. The declaration and payment of any

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dividends in the future will be determined by our Board, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. Our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution.

As confirmed by our PRC Legal Adviser, according to the PRC law, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for, and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the near future. There is no assurance that dividends of any amount will be declared to be distributed in any year.

THE [REDACTED]

The [REDACTED] by us consists of:

- the [REDACTED] by us of initially [REDACTED] H Shares, or [REDACTED], for [REDACTED] by the public in Hong Kong, referred to in this document as the [REDACTED]; and
- the [REDACTED] by us of initially [REDACTED] H Shares, or [REDACTED], outside the U.S. (including to professional, institutional and other investors within Hong Kong) in offshore transactions in reliance on Regulation S and in the U.S. to qualified institutional buyers in reliance on Rule 144A or another exemption from the registration requirements under the U.S. Securities Act, referred to in this document as the [REDACTED].

The number of [REDACTED] and [REDACTED], or together, [REDACTED], is subject to reallocation as described in the section headed “Structure of the [REDACTED]” in this document.

APPLICATION FOR [REDACTED] ON THE STOCK EXCHANGE

We have applied to the Stock Exchange for the approval for the [REDACTED] of, and permission to deal in the [REDACTED] to be issued by us pursuant to the [REDACTED] (including any Shares which may be issued pursuant to the conversion of Unlisted Shares into H Shares and the exercise of the [REDACTED]).

SUMMARY

[REDACTED] STATISTICS⁽¹⁾

	Based on the [REDACTED] of HK\$[REDACTED]	Based on the [REDACTED] of HK\$[REDACTED]
[REDACTED] of our Shares ⁽²⁾	<u>HK\$[REDACTED] million</u>	<u>HK\$[REDACTED] million</u>
Unaudited [REDACTED] adjusted net tangible assets per Share ⁽³⁾	<u>HK\$[REDACTED]</u>	<u>HK\$[REDACTED]</u>

Notes:

- (1) All statistics in this table are on the assumption that the [REDACTED] are not exercised.
- (2) The calculation of [REDACTED] is based on [REDACTED] Shares expected to be in [REDACTED] immediately after completion of the [REDACTED].
- (3) The unaudited [REDACTED] adjusted net tangible assets per Share is calculated after making the adjustments referred to in “Financial Information – Unaudited [REDACTED] Statement of Adjusted Net Tangible Assets.”

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED] and [REDACTED], and estimated expenses payable by us in connection with the [REDACTED], assuming the [REDACTED] being not exercised and an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the [REDACTED] stated in this Document). If the [REDACTED] is set at HK\$[REDACTED] per Share (being the high-end of the [REDACTED] stated in this Document), the net [REDACTED] from the [REDACTED] will increase by approximately HK\$[REDACTED]. If the [REDACTED] is set at HK\$[REDACTED] per Share (being the low-end of the [REDACTED] stated in this Document), the net [REDACTED] from the [REDACTED] will decrease by approximately HK\$[REDACTED].

We intend to use the net [REDACTED] from the [REDACTED] as follows, assuming the [REDACTED] is not exercised and assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the [REDACTED] stated in this document:

- (i) Approximately [61.0]%, or HK\$[REDACTED], will be allocated to fund the research and development of our Core Product, Tinengotinib;
- (ii) Approximately [20.4]%, or HK\$[REDACTED], will be allocated to fund the research and development of our other pipeline products;

SUMMARY

- (iii) approximately [8.6]% or HK\$[REDACTED], will be allocated for establishment of our commercialization network, including the establishment of our own commercial team for promotion and sales; and
- (iv) Approximately [10.0]%, or HK\$[REDACTED], will be allocated to our general working capital and general corporate purposes.

See “Future Plans and Use of [REDACTED].”

[REDACTED] EXPENSES

Our [REDACTED] expenses mainly include [REDACTED] fees and [REDACTED] and professional fees paid to legal advisers and the Reporting Accountants for their services rendered in relation to the [REDACTED] and the [REDACTED]. Assuming full payment of the [REDACTED] fee, the estimated total [REDACTED] expenses (based on the mid-point of our indicative [REDACTED] for the [REDACTED] and assuming that the [REDACTED] is not exercised) for the [REDACTED] are approximately RMB[REDACTED] million and are expected to represent approximately [REDACTED]% of the gross [REDACTED] of the [REDACTED], comprising of (i) [REDACTED] expenses, including [REDACTED] and other expenses, of RMB[REDACTED] million; and (ii) [REDACTED] expenses of RMB[REDACTED] million, including (a) fees paid and payable to our legal advisers and Reporting Accountants of RMB[REDACTED] million; and (b) other fees and expenses, including [REDACTED] fees, of RMB[REDACTED] million. During the Track Record Period, we incurred [REDACTED] expenses of RMB[REDACTED] million which were attributable to the issue of Shares and will be deducted from equity upon the [REDACTED]. We expect to incur [REDACTED] expenses of approximately RMB[REDACTED] million after the Track Record Period, of which an estimated amount of RMB[REDACTED] million is expected to be recognized as administrative expenses and the remaining amount of RMB[REDACTED] million is expected to be recognized directly as a deduction from equity upon the [REDACTED].

RECENT DEVELOPMENTS

Clinical Trials

The recent developments of our drug candidates since the end of the Track Record Period and up to the Latest Practicable Date include:

- In February 2024, Tinengotinib was granted the Orphan Drug Designation for BTC from the EMA;
- In February 2024, we obtained the IND approval from the NMPA for conducting Phase II clinical trial of Tinengotinib combination therapy for the treatment of mCRPC;

SUMMARY

- In February 2024, we obtained the IND approval from the EMA for conducting registrational Phase III clinical trial of Tinengotinib monotherapy in five European Union countries, i.e. Belgium, Germany, Italy, Spain, and Poland;
- In March 2024, we obtained the IND approval from the EMA for conducting registrational Phase III clinical trial of Tinengotinib monotherapy in three European Union countries, i.e. France, Austria and Portugal; and
- In June 2024, we obtained the IND approval from the MHRA for conducting registrational Phase III clinical trial of Tinengotinib monotherapy in the United Kingdom.

No Material Adverse Change

Our Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or trading position since December 31, 2023 (being the date on which the latest audited consolidated financial information of our Company was prepared) and there is no event since December 31, 2023 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I to this document.

DEFINITIONS

In this document, unless the context otherwise requires, the following terms and expressions shall have the meanings set out below.

“Accountants’ Report”	the accountants’ report prepared by Ernst & Young, the text of which is set out in Appendix I to this document
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	Accounting and Financial Reporting Council
“Articles” or “Articles of Association”	the articles of association of our Company adopted on March 18, 2024 with effect upon [REDACTED] (as amended from time to time), a summary of which is set out in Appendix V to this document
“associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Audit Committee”	the audit committee of our Board
“Board” or “Board of Directors”	the board of Directors of our Company
“Business Day” or “business day”	a day on which banks in Hong Kong are generally open for normal business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong
“CAGR”	compound annual growth rate
“CCASS”	the Central Clearing and Settlement System established and operated by HKSCC
“CCPA”	the California Consumer Privacy Act of 2018

[REDACTED]

“CDE”	Center for Drug Evaluation of NMPA (國家藥品監督管理局藥品審評中心), a division of the NMPA mainly responsible for review and approval of IND and NDA
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DEFINITIONS

“China” or “the PRC”	the People’s Republic of China, which only in the context of describing PRC rules, laws, regulations, regulatory authority, and any PRC entities or citizens under such rules, laws and regulations and other legal or tax matters in this document, excludes Taiwan, Hong Kong and the Macau Special Administrative Region of the People’s Republic of China
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Company”, “our Company” or “the Company”	TransThera Sciences (Nanjing), Inc. (藥捷安康(南京)科技股份有限公司), a joint stock company with limited liability incorporated in the PRC, the predecessor of which was Nanjing TransThera Biosciences Co., Ltd. (南京藥捷安康生物科技有限公司), a limited liability company established in the PRC on April 15, 2014, and in the context requires, include its predecessor
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Controlling Shareholder(s)”	Dr. Wu, Nanjing Yipu and Nanjing Jiminrui
“core connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Core Product”	has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, refers to our Core Product Tinengotinib
“COVID-19”	an infectious disease caused by the SARS-CoV-2 virus
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會)
“Designated Bank”	HKSCC Participant’s [REDACTED] Designated Bank

DEFINITIONS

“Director(s)”	the director(s) of our Company
“Dr. Wu”	Dr. Frank WU (吳永謙), an executive Director, chief executive officer, the chairman of our Board of the Company and one of our Controlling Shareholders
“EA Pharma”	EA Pharma Co., Ltd., a Japanese company engaged in a gastrointestinal specialty pharma
“EIT Law”	the PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》)
“EMA”	European Medicines Agency
“Employee Incentive Platforms”	Nanjing Yipu, Nanjing Yicheng and TT Therapeutics
“Employee Incentive Schemes”	the employee incentive schemes of our Company approved and adopted by our Board, a summary of the principal terms of which is set forth in “Appendix VI – Statutory and General Information – Further Information about our Directors, Supervisors and Substantial Shareholders – 5. Employee Incentive Schemes”
“EU”	European Union
“Extreme Conditions”	the occurrence of “extreme conditions” as announced by any government authority of Hong Kong due to serious disruption of public transport services, extensive flooding, major landslides, large-scale power outage or any other adverse conditions before Typhoon Signal No. 8 or above is replaced with Typhoon Signal No. 3 or below
“FDA”	the U.S. Food and Drug Administration
“FDCA”	the Federal Food Drug and Cosmetic Act
“FIIF II”	Future Industry Investment Fund II (Limited Partnership) (先進製造產業投資基金二期(有限合夥)), a limited partnership established under the laws of the PRC on June 18, 2019 and one of our Pre-[REDACTED] Investors
“FINI”	Fast Interface for New Issuance, an online platform operated by HKSCC for admission to trading and, where applicable, the collection and processing of specified information on subscription in and settlement for all new listings

DEFINITIONS

“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market research and consulting company
“Frost & Sullivan Report”	the industry report commissioned by our Company and independently prepared by Frost & Sullivan, summary of which is set forth in the section headed “Industry Overview” in this document
“FVTPL”	fair value through profit or loss
“Genecare Development”	Genecare Development Limited (基科發展有限公司), a private company limited by shares incorporated under the laws of Hong Kong on September 18, 2007 and one of our Pre-[REDACTED] Investors
“Gentai”	Nanjing Gentai Pharmaceutical Technology Co Ltd (南京互泰醫藥技術有限公司), a PRC pharmaceutical company engaged in researching, developing and manufacturing small molecule drugs focusing on cancer treatment, an Independent Third Party
“GFA”	gross floor area
	[REDACTED]
“GP Healthcare Capital Phase II”	Shanghai GP Healthcare Equity Investment Enterprise (Limited Partnership) (上海金浦醫療健康股權投資合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on March 31, 2017 and one of our Pre-[REDACTED] Investors
“GP Healthcare Capital Phase III”	Shanghai GP Healthcare Phase III Venture Capital Fund Partnership (Limited Partnership) (上海金浦健康三期創業投資基金合夥企業(有限合夥)) (formerly known as Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) (上海金浦健康三期股權投資基金合夥企業(有限合夥))), a limited partnership established under the laws of the PRC on October 10, 2020 and one of our Pre-[REDACTED] Investors
“Greater China”	the PRC, Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan of the PRC

DEFINITIONS

“Group”, “our Group”, “our”, “we” or “us” the Company and all of its subsidiaries, or any one of them as the context may require

“Guide” The Guide for New Listing Applicants, as published by the Stock Exchange on November 29, 2023 and effective on January 1, 2024, as amended or supplemented or otherwise modified from time to time

“H Share(s)” overseas [REDACTED] foreign ordinary share(s) in the share capital of our Company with a nominal value of RMB1.00 each, which are to be [REDACTED] in Hong Kong dollars and to be [REDACTED] on the Hong Kong Stock Exchange

[REDACTED]

“HKSCC” the Hong Kong Securities Clearing Company Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited

[REDACTED]

“HKSCC Nominees” HKSCC Nominees Limited, a wholly owned subsidiary of the HKSCC

DEFINITIONS

“HKSCC Operational Procedures”	the Operational Procedures of HKSCC in relation to CCASS, containing the practices, procedures and administrative requirements relating to operations and functions of CCASS, from time to time in force
“HKSCC Participant”	a participant admitted to participate in CCASS as a direct clearing participant, a general clearing participant or a custodian participant;
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars” or “HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong

[REDACTED]

“IARC”	International Agency for Research on Cancer
“IASB”	the International Accounting Standards Board
“IFRSs”	International Financial Reporting Standards

DEFINITIONS

“IIT Law”	the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》)
“Independent Third Party(ies)”	any person(s) or entity(ies) who is not a connected person of the Company within the meaning of the Listing Rules

[REDACTED]

DEFINITIONS

[REDACTED]

“JPY”	Japanese Yen, the lawful currency of Japan
“Joint Sponsors”	the joint sponsors of the [REDACTED] of the H Shares on the [REDACTED] as named in “Directors, Supervisors and Parties Involved in the [REDACTED]”
“Latest Practicable Date”	June 20, 2024, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication
“LG Chem”	LG Chem, Ltd., a South Korean pharmaceutical company, engaged in the business of developing, manufacturing and commercializing pharmaceutical products, an Independent Third Party

[REDACTED]

“Listing Rules” or “Hong Kong Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended, supplemented or otherwise modified from time to time)
“Main Board”	the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the GEM of the Hong Kong Stock Exchange
“MFDS”	the Ministry of Food and Drug Safety of South Korea
“MHRA”	the Medicines and Healthcare Products regulatory agency of the United Kingdom
“MOF”	Ministry of Finance of the PRC (中華人民共和國財政部)

DEFINITIONS

“MOFCOM”	Ministry of Commerce of the PRC (中華人民共和國商務部)
“MSKCC”	Memorial Sloan Kettering Cancer Center
“Nanjing Jiminrui”	Nanjing Jiminrui Biotech Partnership (Limited Partnership) (南京吉旻瑞生物科技合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on August 29, 2016 and one of our Controlling Shareholders
“Nanjing Yicheng”	Nanjing Yicheng Biotechnology Partnership (Limited Partnership) (南京益誠生物科技合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on June 30, 2023 and one of our Employee Incentive Platforms
“Nanjing Yipu”	Nanjing Yipu Bioscience Technology Partnership (Limited Partnership) (南京益璞生物科技合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on August 29, 2016 and one of our Employee Incentive Platforms and our Controlling Shareholders
“NCCR”	National Committee for Clinical Research
“NIPA”	the National Intellectual Property Administration of the PRC (中華人民共和國國家知識產權局)
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
“Nomination Committee”	the nomination committee of the Board
“NPC”	the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)

[REDACTED]

DEFINITIONS

[REDACTED]

“Overseas Listing Trial Measures”	The Trial Measures for the Administration on Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) promulgated by the CSRC on February 17, 2023, which became effective on March 31, 2023, as amended, supplemented or otherwise modified from time to time
“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
“PCT”	Patent Cooperation Treaty
“PharmaBlock”	PharmaBlock Sciences (Nanjing), Inc. (南京藥石科技股份有限公司), a joint stock limited liability company incorporated in the PRC on December 26, 2006 which is listed on the Shenzhen Stock Exchange (stock code: 300725) and a Shareholder of our Company
“PRC Company Law”	the Company Law of the People’s Republic of China (中華人民共和國公司法)

DEFINITIONS

“PRC Government”	the central government of the PRC and all governmental subdivisions (including provincial, municipal and other regional or local government entities) and instrumentalities thereof or, where the context requires, any of them
“PRC Legal Adviser”	Jia Yuan Law Offices, the Company’s PRC Legal Adviser
“PRC Securities Law”	the Securities Law of the PRC (《中華人民共和國證券法》), as amended, supplemented or otherwise modified from time to time
“Pre-[REDACTED] Investments”	the investment(s) in our Company undertaken by the Pre-[REDACTED] Investors pursuant to the respective equity transfer agreement(s) and/or capital increase agreement(s), details of which are set out in the section headed “History, Development and Corporate Structure” in this document
“Pre-[REDACTED] Investors”	the investors who acquired interest in our Company pursuant to the respective equity transfer agreement(s) and capital increase agreement(s), details of which are set out in the section headed “History, Development and Corporate Structure” in this document
“Qualified Institutional Buyers” or “QIBs”	qualified institutional buyers within the meaning of Rule 144A under the U.S. Securities Act
“Regulation S”	Regulation S under the U.S. Securities Act
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Roche”	F. Hoffmann-La Roche Ltd, a Swiss biotech company for cancer treatment, against virus diseases and for treatment of metabolic diseases, an Independent Third Party
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國外匯管理局)
“SAT”	the State Administration of Taxation of the PRC (中華人民共和國國家稅務總局)

DEFINITIONS

“SDIC Greater Bay Area Fund”	SDIC (Guangdong) Scientific and Technological Achievement Transformation Venture Capital Fund Partnership (Limited Partnership) (國投(廣東)科技成果轉化創業投資基金合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on December 16, 2020 and one of our Pre-[REDACTED] Investors
“SDICVC Ningbo Fund”	SDIC (Ningbo) Scientific and Technological Achievement Transformation Venture Capital Fund Partnership (Limited Partnership) (國投(寧波)科技成果轉化創業投資基金合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on December 13, 2018 and one of our Pre-[REDACTED] Investors
“SFC” or “Securities and Futures Commission”	the Securities and Futures Commission of Hong Kong
“SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each
“Shareholder(s)”	holder(s) of the Share(s)
“sophisticated investor(s)”	has the meaning ascribed thereto under Chapter 2.3 of the Guide for New Listing Applicants published by the Stock Exchange
	[REDACTED]
“State Council”	the State Council of the PRC (中華人民共和國國務院)
“Structural Reform Fund”	China Structural Reform Fund Corporation Limited (中國國有企業結構調整基金股份有限公司), a joint stock limited liability company incorporated on September 22, 2016 and one of our Pre-[REDACTED] Investors
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	member(s) of our Supervisory Committee
“Supervisory Committee”	the supervisory committee of our Company

DEFINITIONS

“Teijin”	Teijin Pharma Limited, a Japanese pharmaceutical company in the discovery, development, manufacture, commercialization and marketing of pharmaceutical products, an Independent Third Party
“TFDA”	Taiwan Food and Drug Administration
“Track Record Period”	the financial years ended December 31, 2022 and 2023
“TransThera HK”	TransThera Sciences (HK) Limited, a limited company incorporated under the laws of Hong Kong on August 18, 2022 and is a wholly-owned subsidiary of our Company
“TransThera US”	TransThera Sciences (US) Inc., a stock corporation incorporated under the laws of State of Delaware of the United States on September 19, 2022 and is an indirectly wholly-owned subsidiary of our Company
“TT Therapeutics”	TT THERAPEUTICS LLC, a limited liability company incorporated under the laws of State of Delaware of the United States on October 26, 2022 and one of our Employee Incentive Platforms

[REDACTED]

“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“USPTO”	the U.S. Patent and Trademark Office
“U.S. dollars”, “US\$” or “USD”	the United States dollars, the lawful currency of the U.S.
“U.S. Securities Act”	the U.S. Securities Act of 1933, as amended, supplemented or otherwise modified from time to time, and the rules and regulations promulgated thereunder

GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain technical terms used in this document in connection with us and our business. These may not correspond to standard industry definitions, and may not be comparable to similarly terms adopted by other companies.

“ALC”	absolute lymphocyte count, a test that measures the number of lymphocytes (white blood cells) in a certain liquid volume of blood, calculated by multiplying the total number of white blood cells in a certain liquid volume of blood against the percentage of white blood cells which are lymphocytes
“ACE platform”	Adaptive Comprehensive Expandable platform, a methodology platform built up by us, which guides our innovative approach to small molecule drug discovery and development
“AD”	atopic dermatitis, an inflammation of the skin caused by immune system dysfunction usually developing in early childhood, but can occur in any age. It is more common in that is more common in people who have a family history of the condition, of which the main symptom is a rash and itching
“ADT”	androgen depletion therapy
“AE(s)”	adverse event(s), any untoward medical occurrence in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials. AEs do not necessarily have a causal relationship with the treatment
“AI”	aromatase inhibitor
“AKT”	protein kinase B, a collective name of a set of three serine/threonine-specific protein kinases that play key roles in multiple cellular processes such as glucose metabolism, apoptosis, cell proliferation, transcription, and cell migration
“AML”	acute myeloid leukemia, a cancer of the myeloid line of blood cells, characterized by the rapid growth of abnormal cells that build up in the bone marrow and blood and interfere with normal blood cell production

GLOSSARY OF TECHNICAL TERMS

“antibody”	a blood protein produced in response to and counteracting a specific antigen. Antibodies combine chemically with substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances in the blood
“antitumor activity”	preventing or inhibiting the formation or growth of tumors
“AOC2”	amine oxidase copper-containing 2, a protein that in humans is encoded by the AOC2 gene
“AR”	androgen receptor
“ARB”	angiotensin-receptor blocker
“ATP”	adenosine triphosphate
“Aurora A”	also known as serine/threonine-protein kinase 6, an enzyme that in humans is encoded by the Aurora A Kinase gene, contributing to the regulation of cell cycle progression
“Aurora B” or “AURKB”	a protein that functions in the attachment of the mitotic spindle to the centromere
“AXL”	a member of the TAM family (Tyro3, Axl, and MerTK) of receptor tyrosine kinases, with the high-affinity ligand growth arrest-specific protein 6 (Gas6), the first of this family discovered in studies identifying genes that transform NIH 3 T3 cells
“BCR”	B-cell antigen receptor, a transmembrane protein on the surface of a B-cell
“B-cell”	B lymphocyte, a type of white blood cell of the lymphocyte subtype
“best-in-class”	the drug with the best clinical advantage within a drug class

GLOSSARY OF TECHNICAL TERMS

“BICC1”	Bicaudal family RNA binding protein 1, endogenous FGFR2-Bicaudal family RNA binding protein 1 fusion is a common FGFR2 aberration driving cholangiocarcinoma
“BICR”	blinded, independent, central review
“BID”	bis in die, which means twice a day
“binding avidity”	the cumulative strength of the binding interactions between two molecules, which is typically measured and reported by the equilibrium dissociation constant (K_D)
“biomarker”	a naturally occurring molecule, gene, or characteristic by which a particular pathological or physiological process, disease, etc. can be identified
“BTC”	biliary tract carcinoma
“BTK” or “Bruton’s tyrosine kinase”	a tyrosine kinase that is encoded by the BTK gene, which plays a crucial role in B-cell development
“C481S”	a BTK acquired drug-resistant mutation induced by treatment with first- and second-generation of BTK inhibitors
“C491S”	an irreversible inhibitor specific mutation in the FGFR2 kinase domain, which mutates a cysteine active site to serine. This mutation prevents inhibitors from binding to the FGFR2 protein, thereby raising drug resistance
“C57BL/6”	a common inbred strain of laboratory mouse
“CBR”	clinical benefit rate
“CCA”	cholangiocarcinoma, a cancer that forms in the slender tubes (bile ducts) that carry the digestive fluid bile
“CD” or “Crohn’s disease”	a chronic, inflammatory bowel disease that affects the lining of the digestive tract and can sometimes cause life-threatening complications. CD symptoms can include abdominal pain, diarrhea, weight loss, anemia, and fatigue

GLOSSARY OF TECHNICAL TERMS

“CD8 ⁺ ”	cluster of differentiation 8, a critical subtype of T-cells and mediators of adaptive immunity
“CDK”	cyclin-dependent kinase
“CDMO”	contract development and manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“CDX”	cell line-derived xenograft
“cell line”	a population of cells that descend from a single cell and contain the same genetic makeup, and can be propagated repeatedly
“cGMP”	cyclic guanosine monophosphate, a cyclic nucleotide derived from guanosine triphosphate, whose most likely mechanism of action is activation of intracellular protein kinases in response to the binding of membrane-impermeable peptide hormones to the external cell surface
“chemoresistance”	the ability of cancer cells to evade or to cope with the presence of chemotherapy
“chemotherapy”	the therapeutic use of chemical agents to treat disease; especially: the administration of one or more cytotoxic drugs to destroy or inhibit the growth and division of malignant cells in the treatment of cancer
“clinical trial/study”	any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous

GLOSSARY OF TECHNICAL TERMS

“CLL” or “SLL”	chronic lymphocytic leukemia, or small lymphocyte lymphoma, a type of blood cancer in which the bone marrow makes too many lymphocytes
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“CMO”	contract manufacturing organization, a company that provides support to other companies in the pharmaceutical industry in the form of manufacturing services outsourced on a contract basis
“CNS”	central nervous system, the part of the nervous system consisting primarily of the brain and spinal cord
“cohort”	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
“combination therapy” or “combo”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
“corticosteroids”	class of steroid hormones drug that lowers inflammation in the body and reduces immune system activity
“CR” or “complete response”	complete regression or complete response, disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CRPC”	castration-resistant prostate cancer, a form of advanced prostate cancer, that no longer completely responds to treatments that lower testosterone
“CTAs”	clinical trial applications
“CTCAE”	Common Terminology Criteria for Adverse Events, also called common toxicity criteria
“CYP”	Cytochromes P450, a superfamily of enzymes containing heme as a cofactor that functions as monooxygenases

GLOSSARY OF TECHNICAL TERMS

“cytokine”	small secreted proteins released by cells that have a specific effect on the interactions and communications between cells
“cytotoxic”	toxic to living cells
“dCCA”	distal cholangiocarcinoma, an extrahepatic lesion arising in the extrahepatic bile ducts above the ampulla of Vater and below the confluence of the left and right bile ducts
“DAMP”	damage-associated molecular patterns
“DCR”	disease control rate
“dissociation constant” or “ K_D ”	a specific type of equilibrium constant that measures the propensity of a larger object to separate (dissociate) reversibly into smaller components, as when a complex falls apart into its component molecules, or when a salt splits up into its component ions
“DLBCL”	diffuse large B-cell lymphoma, a heterogeneous disease defined by transcriptional classifications, specific signaling and survival pathways, and multiple low-frequency genetic alterations
“DLT”	dose-limiting toxicity, the occurrence of severe toxicities during the first cycle of systemic cancer therapy
“DNA”	deoxyribonucleic acid
“DOR” or “duration of response”	the length of time measured from the time measurement criteria are first met for CR/PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for progressive disease the smallest measurements recorded on study)
“double-blind”	with respect to a clinical trial or study, the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s)
“DRDE”	recommended dose for dose expansion
“EASI”	Eczema Area and Severity Index, which is usually used as the pharmacodynamics effect endpoint of atopic dermatitis

GLOSSARY OF TECHNICAL TERMS

“ECOG”	Eastern Cooperative Oncology Group, which uses 5 points score to assess performance status and is considered simple tool to use in daily clinical practice
“EGFR”	epidermal growth factor receptor, a transmembrane protein that is a receptor for members of the epidermal growth factor family (EGF family) of extracellular protein ligands
“EHS”	environmental, health and safety
“endpoint”	with respect to a clinical study or trial, the outcome that is measured, whether referring to occurrence of disease, symptom, sign or laboratory abnormality constituting a target outcome, in which case “endpoint” will be preceded by the outcome term, such as in “clinical remission endpoint” or “maintenance therapy endpoint”
“ERK”	extracellular signal-regulated kinase
“estrogen receptor” or “ER”	a group of proteins found inside cells, and receptors that are activated by the hormone estrogen (17 β -estradiol)
“FGFR”	fibroblast growth factor receptor, a family of tyrosine kinase receptors including FGFR1-4, which play a key role in regulating cell survival and proliferation, and a growing body of evidence suggest they also play a role in cancer progression
“FIH” or “first-in-human”	first-in-human, a type of clinical trial in which a new drug, procedure, or treatment is tested in humans for the first time. First-in-human studies take place after the new treatment has been tested in the laboratory and in animal studies and are usually conducted as Phase I clinical trials
“first-in-class”	a drug that first uses a new or unique mechanism of action for treating a medical condition
“first-line treatment”	with respect to any disease, the first line of treatment or therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment of a given type and stage of disease. It is also called primary treatment or therapy

GLOSSARY OF TECHNICAL TERMS

“FLT3”	FMS-like tyrosine kinase 3
“FOLFOX”	a combination of chemotherapy drugs, including folinic acid, fluorouracil and oxaliplatin
“Gas6”	growth arrest specific 6
“GBC”	gallbladder carcinoma, a disease in which malignant (cancer) cells form in the tissues of the gallbladder
“GCP” or “good clinical practice”	an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible
“GIRK”	G protein-coupled inwardly rectifying K ⁺ channel, a family of lipid-gated inward-rectifier potassium ion channels which are activated (opened) by the signaling lipid PIP ₂ and a signal transduction cascade starting with ligand-stimulated G protein-coupled receptors (GPCRs)
“GMP”	Good Manufacturing Practice, a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product
“HER2”	human epidermal growth factor receptor 2
“HER2–”	human epidermal growth factor receptor 2-zero, including HER2-low
“HER2-low”	human epidermal growth factor receptor 2-low expression with a score of 1+ or 2+ according to immunohistochemistry test results along with a negative fluorescence <i>in situ</i> hybridization test
“HF”	heart failure

GLOSSARY OF TECHNICAL TERMS

“HFpEF”	heart failure with preserved ejection fraction, a form of heart failure that occurs when a left ventricular ejection fraction (LVEF) is greater than 50%, along with different pro-inflammatory and metabolic comorbidities leading to an inability of the left ventricle to relax properly
“HFrEF”	heart failure with reduced ejection fraction, a form of heart failure that occurs when a left ventricular ejection fraction (LVEF) is 40% or less, along with substantial cardiomyocyte loss, leading to an inability of the left ventricle to contract properly
“HGR”	human genetic resources
“HR+”	hormone receptor-positive
“hyperphosphatemia”	an electrolyte disorder in which there is an elevated level of phosphate in the blood
“IC ₅₀ ”	half maximal inhibitory concentration, a quantitative measure that indicates how much of a particular inhibitory substance (e.g. drug) is needed to inhibit, <i>in vitro</i> , a given biological process or biological component by 50%
“iCCA”	intrahepatic CCA, a subtype of CCA that originates in the bile ducts within the liver
“IIT”	investigator initiated trial
“IL-4R α antibody”	interleukin-4 receptor alpha antibody
“immunosuppressants”	drugs or medicines that depress or prevent activity of the immune system
“ <i>in vitro</i> ”	Latin for “in glass”, studies <i>in vitro</i> are conducted outside of a living organism in a laboratory environment using test tubes, petri dishes, etc. using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules

GLOSSARY OF TECHNICAL TERMS

“ <i>in vivo</i> ”	Latin for “within the living”, studies <i>in vivo</i> are those in which the effects of various biological entities are tested on whole, living organisms as opposed to a partial or dead organism, or those done <i>in vitro</i>
“IND”	investigational new drug or investigational new drug application
“indication”	a disease condition which makes a particular treatment or procedure advisable
“inflammatory bowel disease” or “IBD”	a term for two conditions (Crohn’s disease and ulcerative colitis) that are characterized by chronic inflammation of the gastrointestinal (GI) tract
“inhibitor”	a chemical or substance added or applied to another substance to slow down a reaction or to prevent an unwanted chemical change
“JAK”	janus kinases, a family of intracellular, non-receptor tyrosine kinases that transduce cytokine-mediated signals <i>via</i> the JAK-STAT pathway
“kinase”	an enzyme that catalyzes the transfer of phosphate groups from high-energy, phosphate-donating molecules to specific substrates
“KOLs”	key opinion leaders
“LVEF”	left ventricular ejection fraction, the central measure of left ventricular systolic function, the fraction of chamber volume ejected in systole (stroke volume) in relation to the volume of the blood in the ventricle at the end of diastole (end-diastolic volume)
“lymphocyte”	a form of small leucocyte (white blood cell) with a single round nucleus, occurring especially in the lymphatic system
“Lyn”	a protein that in humans is encoded by the LYN gene, which has been described to have an inhibitory role in myeloid lineage proliferation

GLOSSARY OF TECHNICAL TERMS

“MAD”	multiple ascending dose given to patients, with respect to administering drugs or medicine to cohorts during clinical trials
“MAH”	marketing authorization holder
“MAO-B”	monoamine oxidase B, an enzyme that in humans is encoded by the MAOB gene
“MCL”	mantle-cell lymphoma, a type of non-Hodgkin’s lymphoma, which is a form of cancer that affects the lymphatic system
“mCPRC”	metastatic castrate-resistant prostate cancer, a form of advanced prostate cancer that spreads beyond the prostate
“metastatic”	with respect to any disease, including cancer, disease producing organisms or malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
“mono” or “monotherapy”	therapy that uses a single drug to treat a disease or condition
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects. The MTD is determined in clinical trials by testing increasing doses on different groups of subjects until the highest dose with acceptable side effects is found
“MTK”	multi-targeted kinase
“mutation”	permanent alteration in the DNA sequence that makes up a gene
“N549K”	the molecular brake mutation in the FGFR2 kinase domain
“NAFLD” or “nonalcoholic fatty liver disease”	excessive fat build-up in the liver without another clear cause such as alcohol use, including two types: non-alcoholic fatty liver (NAFL) and non-alcoholic steatohepatitis, with the latter also including liver inflammation

GLOSSARY OF TECHNICAL TERMS

“NAS”	NASH Activity Score, developed as a tool to measure changes in NASH during therapeutic trials
“NASH” or “non-alcoholic steatohepatitis”	the liver manifestation of a metabolic disorder, and the most severe form of non-alcoholic fatty liver disease
“NDA”	new drug application, submission of which is the vehicle through which drug sponsors formally propose that the relevant drug regulatory authority approve a new pharmaceutical for sale and marketing
“NHL”	non-Hodgkin lymphoma, a type of cancer that develops in the lymphatic system
“NHT”	novel hormone therapies
“nM”	nanomole/liter
“NP”	natriuretic peptide
“NP/cGMP”	cyclic guanosine monophosphate activated by natriuretic peptide modulated mechanism
“NRDL”	the National Reimbursement Drug List
“NSCLC”	non-small cell lung cancer, any type of epithelial lung cancer other than small-cell lung carcinoma
“Orphan Drug Designation”	a status assigned to medicines developed for rare condition
“oncology”	branch of medicine that deals with the prevention, diagnosis, and treatment of cancer
“open-label”	being or relating to a clinical trial in which the treatment given to each subject is not concealed from either the researchers or the subject
“optimal biological dose”	the optimal dose associated with biological efficacy in early-phase trials

GLOSSARY OF TECHNICAL TERMS

“Orphan Drug”	drug or biologic candidate intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. or intended to diagnose, prevent or treat a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand people in the Community when the application is made in the EU
“ORR”	objective response rate
“OS”	overall survival
“PAMP”	pathogen-associated molecular patterns
“pan-FGFR inhibitor”	pan-inhibitor of fibroblast growth factor receptor family proteins
“PARP”	poly ADP ribose polymerase
“pCCA”	perihilar CCA, a subtype of CCA that stems from aberrant growth of the ductal epithelium in the extrahepatic biliary tree
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T-cells, B-cells and macrophages. The normal function of PD-1 is to turn off the T-cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of a T-cell attaches to certain proteins on the surface of a normal cell or a cancer cell, the T-cell turns off its ability to kill the cell
“PD-1 antibody”	monoclonal antibody targeting PD-1
“PDE”	phosphodiesterase, an enzyme that catalyzes the hydrolysis of the 3'-phosphoester bond of cAMP or cGMP to their respective biologically inactive noncyclic nucleotides 5'-AMP or 5'-GMP
“PDE9”	phosphodiesterase type 9
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T-cell that causes the T-cell to turn off its ability to kill the cancer cell

GLOSSARY OF TECHNICAL TERMS

“PDX”	patient-derived xenografts
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works
“pharmacodynamics”	the study of how a drug affects an organism
“pharmacology”	a branch of medicine and pharmaceutical sciences which is concerned with the study of drug or medication action, where a drug can be broadly or narrowly defined as any man-made, natural, or endogenous molecule which exerts a biochemical or physiological effect on the cell, tissue, organ, or organism
“Phase I”	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“Phase II”	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“Phase III”	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
“pivotal trial”	the clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
“PK” or “pharmacokinetics”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug

GLOSSARY OF TECHNICAL TERMS

“PKG”	protein kinase G
“PLC γ 2”	phospholipase C gamma 2, which plays a significant role in transmembrane signaling
“PR”	partial response
“PRDL”	provincial or local medical insurance catalogues for the National Medical Insurance Program
“preclinical study”	preclinical studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether a drug is ready for clinical trials
“primary endpoint”	with respect to a clinical study or trial, the main predefined result that is measured at the end of a study (e.g., the number of deaths or the difference in survival between the treatment group and the control group). A primary endpoint should reflect clinically relevant effects and is typically selected based on the principal objective of the study
“progesterone receptor”	a protein found inside cells activated by the steroid hormone progesterone
“proof of concept”	a realization of a certain method or idea in order to demonstrate its feasibility, or a demonstration in principle with the aim of verifying that some concept or theory has practical potential
“protein”	large biological molecules or macromolecules, consisting of one or more long chains of amino acid residues
“QD”	quaque die, which means once daily
“R&D”	research and development
“RAAS”	renin-angiotensin-aldosterone system
“radiotherapy”	a type of cancer treatment that uses beams of intense energy to kill cancer cells

GLOSSARY OF TECHNICAL TERMS

“receptor tyrosine kinases”	high-affinity cell surface receptors for many polypeptide growth factors, cytokines, and hormones
“receptor”	a region of tissue, or a molecule in a cell membrane, which responds specifically to a particular signal, that is any of a neurotransmitter, hormone, antigen, or other substance. “Receptor modulator” is a type of drug that has different effects in different tissues, as it may behave as an agonist in some tissues but as an antagonist in others
“registrational trial”	a controlled or uncontrolled human clinical trial approved by the health authorities that is intended to generate sufficient data and results to support the filing of an application of new drug approval and be the basis for regulatory approval of a drug candidate
“RP2D”	recommended Phase II dose
“S1P”	Sphingosine-1-phosphate, a signaling sphingolipid, also known as lysosphingolipid. In the immune system, S1P is recognized as a major regulator of trafficking of T- and B-cells
“S1P1”	Sphingosine-1-phosphate receptor 1, a G-protein-coupled receptor which binds the bioactive signaling molecule S1P
“SAD”	single ascending dose, with respect to administering drugs or medicine to cohorts during clinical trials
“SAE(s)”	serious adverse event(s), in the context of clinical trials, any undesirable medical event judged to be related to the investigational treatment that results in death, is life-threatening, requires hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or requires intervention to prevent permanent impairment or damage
“SCLC”	small cell lung cancer, the least common type of lung cancer, but it spreads faster than non-small cell lung cancer

GLOSSARY OF TECHNICAL TERMS

“SD”	stable disease, disease that is neither decreasing nor increasing in extent or severity
“second-line treatment”	with respect to any disease, the second line of treatment or therapy or therapies that are tried when the first-line treatments do not work adequately. A break with the primary treatment and an adoption of a new regimen signals “second-line treatment.” This may be because the first-line therapy did not work, may have had some limited efficacy, or may have produced unacceptable side effects. Often the FDA, the NMPA or other drug regulatory authority will specifically approve a new drug for second line therapy. This labeling is common for new drugs that treat cancers which already have accepted treatments
“single agent”	treatment using a single pharmaceutical product
“small molecule drug(s)”	a kind of drug(s) that is an organic compound of low molecular weight (<900 daltons) that regulates a biological process
“SOC”	standard of care, treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
“solid tumor”	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them. Examples of solid tumors are sarcomas and carcinomas
“SSAO”	semicarbazide sensitive amine oxidase, a multi-functional enzyme widely present in nature, which converts primary amines into their corresponding aldehydes, while generating H ₂ O ₂ and NH ₃ , also known as VAP-1
“surface plasmon resonance” or “SPR”	the resonant oscillation of conduction electrons at the interface between negative and positive permittivity material stimulated by incident light
“sVAP-1”	soluble VAP-1

GLOSSARY OF TECHNICAL TERMS

“SYK”	spleen associated tyrosine kinase
“synergistic effect”	an effect arising between two or more agents, entities, factors, or substances that produces an effect greater than the sum of their individual effects
“syngeneic”	genetically similar or identical organisms
“TAM”	tumor-associated macrophages
“T-cell(s)”	a lymphocyte of a type produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity. T-cells can be distinguished from other lymphocytes, such as B-cells and natural killer cells, by the presence of a T-cell receptor on the cell surface
“TEAE(s)”	treatment-emergent adverse event(s), AE(s) not present prior to treatment, or an already present event that worsens either in intensity or frequency following treatment
“Tec”	a tyrosine kinase that in humans is encoded by the TEC gene
“TME”	tumor microenvironment
“TNBC” or “triple-negative breast cancer”	triple-negative breast cancer, a type of breast cancer with cancer cells that do not have any of the receptors commonly found in breast cancer, including estrogen or progesterone (each, a female sex hormone) receptors or HER2 receptors. TNBC accounts for about 15% of all breast cancers and has fewer treatment options, since it does not respond to hormone therapy or HER2-targeted agents
“tolerability”	the degree to which overt AEs of a drug can be tolerated by a patient. Tolerability of a particular drug can be discussed in a general sense, or it can be a quantifiable measurement as part of a clinical study

GLOSSARY OF TECHNICAL TERMS

“toxicity”	the degree to which a substance or a mixture of substances can harm humans or animals. Acute toxicity involves harmful effects in an organism through a single or short-term exposure. It is expressed generally as a dose response
“TRAEs”	treatment-related adverse events, any adverse event that in the investigator’s opinion may have been caused by the study medication with reasonable possibility
“tumor microenvironment”	the normal cells, molecules, and blood vessels that surround and feed a tumor cell. A tumor can change its microenvironment, and the microenvironment can affect how a tumor grows and spreads
“TYRO3”	a tyrosine-protein kinase receptor
“tyrosine kinase”	an enzyme that can transfer a phosphate group from ATP to a protein in a cell
“UC” or “ulcerative colitis”	ulcerative colitis, a chronic, inflammatory bowel disease that causes inflammation in the digestive tract
“urothelial cancer”	a type of cancer that begins in urothelial cells which are cells that line the urethra, bladder, ureters, renal pelvis, and some other organs that make up the urinary system
“V564F”	the gate keeper mutation in the FGFR2 kinase domain
“VAP-1”	vascular adhesion protein-1, an endothelial surface glycoprotein and a member of the copper-containing amine oxidase/semicarbazide-sensitive amine oxidase (AOC/SSAO) enzyme family
“VEGFR”	vascular endothelial growth factor receptor, a signal protein produced by cells that stimulates the formation of blood vessels
“WM”	Waldenström macroglobulinemia, a malignant disorder of the bone marrow and lymphatic tissues, a type of lymphoma and characterized by the presence of abnormally large numbers of B-cells
“WT”	wide-type

FORWARD-LOOKING STATEMENTS

This document contains certain forward-looking statements relating to our plans, objectives, beliefs, expectations, predictions and intentions, which are not historical facts and may not represent our overall performance for the periods of time to which such statements relate. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks, uncertainties and other factors facing our Company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our business strategies and plans to achieve these strategies;
- our ability to complete the development and obtain the relevant requisite regulatory approvals;
- our ability to commercialize in a timely manner;
- our future debt levels and capital needs;
- changes to the political and regulatory environment in the industry and markets in which we operate;
- our expectations with respect to our ability to acquire and maintain regulatory licenses or permits;
- changes in competitive conditions and our ability to compete under these conditions;
- future developments, trends and conditions in the industry and markets in which we operate;
- general economic, political and business conditions in the markets in which we operate;
- effects of the global financial markets and economic crisis;
- our financial conditions and performance;
- our dividend policy; and
- change or volatility in interest rates, foreign exchange rates, equity prices, volumes, operations, margins, risk management and overall market trends.

FORWARD-LOOKING STATEMENTS

In some cases, we use the words "aim," "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "going forward," "intend," "ought to," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "will," "would" and similar expressions to identify forward-looking statements. In particular, we use these forward-looking statements in the "Business" and "Financial Information" sections of this document in relation to future events, our future financial, business or other performance and development, the future development of our industry and the future development of the general economy of our key markets.

The forward-looking statements are based on our current plans and estimates and speak only as of the date they were made. We undertake no obligation to update or revise any forward-looking statements in light of new information, future events or otherwise. Forward-looking statements involve inherent risks and uncertainties and are subject to assumptions, some of which are beyond our control. We caution you that a number of important factors could cause actual outcomes to differ, or to differ materially, from those expressed in any forward-looking statements.

Our Directors confirm that the forward-looking statements are made after reasonable care and due consideration. Nonetheless, due to the risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect, or at all.

Accordingly, you should not place undue reliance on any forward-looking statements in this document. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

RISK FACTORS

An [REDACTED] in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to [REDACTED] in our Shares. Particularly, we are seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the biotech industry involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your investments in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the market price of our Shares could decline, and you may lose all or part of your investment.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our business, comprising (a) risks relating to our intellectual property rights; (b) risks relating to clinical development of our drug candidates; (c) risks relating to manufacturing and commercialization of our drug candidates and (d) risks relating to our reliance on third parties; (ii) risks relating to government regulations; (iii) risks relating to our financial position and need for additional capital; (iv) risks relating to our operations; and (v) risks relating to the [REDACTED].

RISKS RELATING TO OUR BUSINESS

Risks Relating to Our Intellectual Property Rights

If we or our licensors are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially adversely affected.

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technologies that we consider commercially important by filing patent applications in China, the U.S. and other jurisdictions, and relying on patents or pharmaceutical regulatory protection or employing a combination of these methods to protect such drug candidates and technologies. In particular, we have sought patents in China, the U.S. and various other jurisdictions for our drug candidates. For further information on our patent portfolio, see “Business – Intellectual Property.” If we or our licensors are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

RISK FACTORS

The patent prosecution process can be expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. Furthermore, the patent position of pharmaceutical companies may involve complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights can be highly uncertain.

The requirements for patentability differ in certain jurisdictions. Certain jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, certain jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

In China, patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, lack of novelty or other deficiencies in the patent applications. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we were the first to file for patent protection of such inventions. Furthermore, China and, recently, the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. If a third party can establish that we were not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties may be granted a patent relating to a technology which we invented.

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our drug candidates in all jurisdictions throughout the world would be prohibitively expensive for us. Our intellectual property rights in certain jurisdictions may have a different scope and strength compared to those in some other jurisdictions. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of some other jurisdictions. Consequently, in some cases, we may not be able to obtain issued patents or other intellectual property rights covering our drug candidates in

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some jurisdictions and, as a result, we may not be able to prevent third parties from using our inventions in all jurisdictions, or from selling or importing drugs made using our inventions in and into certain jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent and other intellectual property protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patent or other intellectual property protection, but where enforcement rights are not as strong as those in markets such as the U.S. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Some pharmaceutical companies have encountered various problems in protecting and defending intellectual property rights in certain jurisdictions. The legal systems in some jurisdictions do not favor the enforcement of patents, trade secrets and other intellectual property rights, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights in these jurisdictions. Proceedings to enforce our patents and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we develop or license. In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the NIPA for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Even if we are able to obtain patent protection for our drug candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. For example, expiration of a patent is generally 20 years for inventions in China and in the U.S., the expiration of a patent is generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic drugs once the patent has expired. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any

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potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in “Business – Intellectual Property” in this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our owned and licensed (if any in the future) patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

The implementation of patent linkage, patent term extension and data and market exclusivity for pharmaceutical products in China and the U.S., as applicable, remain uncertain and could increase the risk of early generic competition for our drug candidates in China.

In the U.S., the Federal Food Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as “Hatch-Waxman,” provides the opportunity for limited patent term extension. Hatch-Waxman permits a patent-term restoration that provides a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval; only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. Depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that

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third party. If we are unable to obtain patent term extensions or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain generics applications during the pendency of litigation between the generics applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain generics marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain new indication or usage innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

After the implementation of the Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial) (藥品專利糾紛早期解決機制實施辦法(試行)) (the “**Early Resolution Measures**”) released by the NMPA in conjunction with the NIPA on July 4, 2021, the implementation of fourth amended Patent Law of the People’s Republic of China (中華人民共和國專利法) (the “**Fourth Amended Patent Law**”) on June 1, 2021, and the implementation of the Implementing Rules for the Patent Law of the People’s Republic of China (中華人民共和國專利法實施細則) (the “**Implementing Rules**”) on January 20, 2024, a process for patent linkage and a patent term extension regime are established in China. According to the Fourth Amended Patent Law, in order to compensate for the time taken for regulatory review and approval of a new drug in China, the patentee of any invention patent related to the new drug may submit application for a patent term extension. The patent term extension should not exceed five years, and the total effective patent term after the new drug’s approval for commercialization shall not exceed 14 years. According to the Implementing Rules, the period for compensation shall be determined based on the number of days interval from the filing date of the patent application to the date when the new drug is approved to be marketed in China minus five years. Further, according to the Early Resolution Measures, a patent information registration platform shall be established for listed drugs in China to publicize relevant patent information on drugs that have been approved for marketing. When a generic drug applicant submits an application for a drug marketing license, it will make a declaration regarding each relevant patent based on patent information from the registration platform. If the patentee or innovative drug applicant has objections to the declaration by the generic applicant, then either the patentee or the applicant may file an infringement claim with the People’s Court or apply for an administrative ruling with the NIPA within 45 days of the publication of the generic drug application on the registered platform. However, practicability of the Early Resolution Measures remains to be tested in time, and it may not be mature enough to protect us against generic competition in practice. These factors may result in weaker protection for us against generic competition in China.

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Our rights to develop and commercialize our drug candidates are subject, in part, to the license to certain patent rights and proprietary technology from third parties, and the validity and enforceability of our own patents. Our competitive position, business, financial condition, results of operations and prospects may be influenced by infringements against our patents, or by infringement claims against us.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property. If we or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the USPTO and other patent agencies in several stages over the lifetime of a patent. In certain circumstances, we rely on our licensors to pay these fees due to relevant governmental patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in

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abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We depend, in part, on intellectual property licensed from third parties, and termination of any of these licenses or disruption to our business relationship with our licensors could result in monetary damages or the loss of significant rights, which would harm our business.

We are dependent on patents, know-how, and proprietary technology, both our own and licensed from others. We are currently party to and may in the future enter into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents and patent applications. In particular, we have in-licensed intellectual property rights from LG Chem to develop TT-01688 in Greater China. For details, please see "Business – Collaboration and License Agreements – License-in Agreement with LG Chem." Any termination of these licenses could result in the loss of such rights and could adversely affect our ability to commercialize our drug candidates. These license agreements may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under any of our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our business.

Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. In addition, if any such license is terminated, we may be required to cease our development and commercialization of certain of our drug candidates, and if our competitors or other third parties obtain such license, they would be able to seek regulatory approval of, and to market such products and technologies.

In addition, the agreements under which we license intellectual property or technology from third parties are, and any such future license agreements are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates.

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We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce patents and patent applications that are material to our business.

Patents relating to our drug candidates are controlled by certain of our licensors. Each of our licensors generally has rights to file, prosecute, maintain, and defend the patents we have licensed from such licensor. We generally have the first right to enforce our patent rights, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our drug candidates, our ability to develop and commercialize those drug candidates may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. In addition, We cannot be certain that activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control.

Changes in patent laws of China, the U.S. or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and future products.

As is the case with other pharmaceutical and biopharmaceutical companies, our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing pharmaceutical and biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

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In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, according to the Fourth Amended Patent Law, in order to compensate for the time taken for regulatory review and approval of a new drug in China, the patentee of any invention patent related to the new drug may submit application for a patent term extension. The patent term extension should not exceed five years, and the total effective patent term after the new drug's approval for commercialization shall not exceed 14 years. According to the Implementing Rules, the period for compensation shall be determined based on the number of days interval from the filing date of the patent application to the date when the new drug is approved to be marketed in China minus five years.

Recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility and narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

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If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, and we may be subject to claims asserting ownership of what we regard as our own intellectual property.

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors, agents and other third parties that have access to them. However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach or violate the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants, and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisors, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such

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intellectual property rights would harm our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates and technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar drug candidates or technology, without payment to us, or could limit the duration of the patent protection covering our drug candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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If our trademarks and trade names are not adequately protected, then we may not be able to build brand recognition in our markets of interest and our business may be adversely affected.

We currently own issued trademark registrations, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance of the same. We cannot assure you that any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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Risks Relating to Clinical Development of Our Drug Candidates

Our business and financial prospects depend substantially on the success of our clinical- and preclinical-stage drug candidates and our ability to identify additional drug candidates, complete their clinical development, obtain their regulatory approvals or achieve their commercialization.

Our business is dependent on our ability to successfully complete the development of our drug candidates, obtain the relevant requisite regulatory approvals, manufacture and commercialize our future approved drugs in a timely manner. We have devoted significant efforts and financial resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our drug candidates. The success of our drug candidates will depend on several factors, including but not limited to:

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- timely product testing, validation and regulatory review;
- receipt of regulatory approvals for our drug candidates;
- sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- obtaining sufficient supplies of any drug products that are used in combination with our drug candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party contract manufacturers;
- the ability of our CROs, other third party contractors and third party research organizations to conduct or assist in conducting our clinical trials in a safe and efficient manner, that complies with our specified trial protocols and applicable laws, and that protects the integrity of the resulting data;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;

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- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- obtaining required marketing authorizations and launching commercial sales in China, the U.S. and other targeted markets, if and when approved;
- competition with other drug candidates and drugs competition with existing or potential new treatments for any anticipated indications of our drug candidates;
- convenience and ease of administration of our products and acceptance of our products by patients;
- successfully launching commercial sales of our drug candidates, if and when approved, including by appropriately pricing our drug candidates, promptly collecting payments due to us and obtaining reimbursement from private and governmental third-party payors;
- efficiently and cost-effectively building up our marketing platform and distribution channels; and
- maintaining acceptable safety profile of our drug candidates following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to obtain approval for our drug candidates, and/or to successfully commercialize our future approved products, and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Our drug candidates, once approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

Our drug candidates, once approved, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. In addition, physicians, patients and third-party payers may prefer other products to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved;

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- physicians, hospitals, medical treatment centers and patients considering our drug;
- efficacy and safety of our drug candidates;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labelling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labelling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payers and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities; and
- the effectiveness of our sales and marketing efforts.

If any approved drug candidates that we commercialize fail to achieve market acceptance among physicians, patients, hospitals, medical treatment centers or others in the medical community, we will not be able to generate significant revenue. For example, Tinengotinib, our Core Product, as a third-line treatment to second-line patients with drug resistance, will be new to the market and has a limited addressable market size within the CCA population. It may have relatively less market acceptance at the beginning of its future commercialization. As a result, we may need to make substantial investments in hospital penetration, physician education and patient education in order to gain market acceptance. Even if our future approved drug candidates achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced that are more favorably received than our drug candidates, are more cost-effective or render our drug candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

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Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies or early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different studies and trials of the same drug candidate due to numerous factors (including changes in trial procedures set forth in protocols), differences in the size and type of the patient populations (including genetic differences), patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Our future clinical trial results may not be favorable.

Even if our future clinical trial results show favorable efficacy and safety profile, not all patients may benefit. For certain drugs, and in certain indications, it is possible that many patients may not respond to the agents at all, some responders may relapse after a period of response and certain viral strains may develop or appear particularly resistant.

Even though we have obtained orphan drug designation for Tinengotinib for the treatment of CCA in the U.S. and BTC in the EU, we may not be able to obtain or maintain the benefits associated with orphan drug status, including market exclusivity.

Regulatory authorities in some jurisdictions, including the U.S. and the EU, may designate drugs for relatively small patient populations as orphan drugs. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication during the period of exclusivity. Our Tinengotinib was granted Orphan Drug Designation by both the FDA for the treatment of CCA and by EMA for the treatment of BTC.

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However, the orphan drug designation does not necessarily guarantee market exclusivity in a given market as exclusivity may be suspended under certain circumstances. For example, in the U.S., orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective, or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, even after a drug is granted orphan exclusivity and approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Therefore, even if we obtain orphan drug exclusivity for a product candidate or additional product candidates, that exclusivity may not effectively protect the product candidate(s) from competition because different drugs can be approved for the same condition.

If we encounter difficulties or delays in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including but not limited to: (i) the size and nature of the patient population; (ii) the patient eligibility criteria defined in the protocol; (iii) the size of the study population required for analysis of the trial's primary endpoints; (iv) the proximity of patients to trial sites; (v) the design of the trial; (vi) our ability to recruit clinical trial investigators with the appropriate competencies and experience; (vii) clinicians' and patients' perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; (viii) our ability to obtain and maintain patient consents; (ix) the risk that patients enrolled in clinical trials will not complete a clinical trial; and (x) the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients may opt to enroll in a trial conducted by one of our competitors. As the number of qualified clinical investigators and clinical trial sites is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. If we experience delays in the completion of, or even termination of, any clinical trial of our drug candidates, the requisite regulatory approvals and then commercialization of our future drug products will be similarly delayed or adversely affected. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and materially adversely affect our ability to advance the development of our drug candidates, which in turn could materially adversely affect our business, financial condition, results of operations and prospects.

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If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.

During the clinical trial process, failure can occur at any time. The results of preclinical studies and investigational clinical trials of our drug candidates may not be predictive of the results of confirmatory clinical trials. Drug candidates in confirmatory clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and/or feasibility clinical trials. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the physical conditions of the patient populations and the rate of dropout among clinical trial participants. Clinical trials of our drug candidates may produce negative or inconclusive results. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. If we decide or are required by regulators to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate or abandon our product development programs, or if we are unable to successfully complete clinical trials of our drug candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be subject to substantial liabilities; (ii) be delayed in or even prevented from obtaining regulatory approval for our drug candidates; (iii) obtain approval for indications that are not as broad as intended; (iv) have the product removed from the market after obtaining regulatory approval; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the product is distributed or used; or (vii) be unable to obtain reimbursement for use of the product.

If we cannot maintain or develop clinical collaborations and relationships with KOLs, physicians and experts, our results of operations and prospects could be adversely affected.

Our relationships with KOLs, physicians and experts play an important role in our R&D and marketing activities. We extensively interact with KOLs, physicians and experts to gain first-hand knowledge of clinical needs and clinical practice trends, which is critical to our ability to develop new market-responsive drug candidates. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with KOLs, physicians and experts, or that our efforts to maintain or strengthen such relationships will yield the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our R&D process, may be inaccurate and lead us to develop products that do not have significant market potential. Even if their insights and perceptions are correct, we may fail to develop commercially viable products. Moreover, we cannot assure you that our academic promotion and marketing strategy will continue to serve as an effective marketing strategy. Industry participants may no longer

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want to collaborate with us or attend our conferences, and our marketing strategy may no longer be able to yield larger hospital coverage or increased sales commensurate to our efforts spent. If we are unable to develop new products or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these drug candidates on a timely basis or at all, which would have an adverse effect on our business.

Some of our drug candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a drug candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to conduct human clinical trials, including based on IND applications and clinical trial applications (CTAs) in China, the U.S. and/or other regulatory authorities, as applicable. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict (i) if the NMPA, the FDA or other regulatory authorities will accept our proposed clinical programs or (ii) if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our preclinical programs on the timelines that we expect, if at all, and we cannot be sure that submission of IND applications, CTAs or similar applications will result in the NMPA, the FDA or other regulatory authorities allowing clinical trials to begin.

We may seek approval from the NMPA, the FDA or other comparable regulatory authorities to use data from registrational trials via accelerated development pathways for our drug candidates, such as innovative or breakthrough therapy. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that we contemplate, which would increase the expense of obtaining, and delay the receipt of, necessary marketing approvals, if we receive them at all. In addition, even if we are able to use an accelerated approval pathway, it may not lead to expedited approval of our drug candidates, or approval at all, and we will likely be required to conduct post-approval clinical outcomes trials which, if failed, may cause us to discontinue marketing of our approved drug candidates for the relevant indications.

The NMPA, the FDA and comparable regulatory authorities in other jurisdictions may allow the use of data from a registrational trial and grant accelerated approval to a drug candidate to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the drug candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. For example, the FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure

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that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug. The accelerated approval pathway, such as innovative or breakthrough therapy, may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. Prior to seeking such accelerated approval, we will continue to seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval.

There can be no assurance that in the future the regulatory authorities will agree with our surrogate endpoints or intermediate clinical endpoints, or that we will decide to pursue or submit any additional NDAs for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for our drug candidates, or withdrawal of a drug candidate, would result in a longer time period until commercialization of such drug candidate, could increase the cost of development of such drug candidate, and could harm our competitive position in the marketplace.

In addition, even if we are able to use an accelerated approval pathway, it may not lead to expedited approval of our drug candidates, or approval at all. Furthermore, if we obtain accelerated approval of a drug candidate based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the drug candidate and, if the post-approval trial is not successful, we may not be able to continue marketing the drug for the relevant indication.

Preliminary, interim and top-line data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, “top-line” or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data

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should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of Shares to fluctuate significantly.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success.

As we have limited financial and managerial resources, we focus our drug pipeline on research programs and drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which we may not be able to do successfully.

The global small molecule market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2022 and 2023, our research and development expenses were RMB262.5 million and RMB344.5 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

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Risks Relating to Manufacturing and Commercialization of Our Drug Candidates

We have no experience in manufacturing pharmaceutical products on a commercial scale, which is a highly exacting and complex process. Our business could be materially and adversely affected if we encounter problems in manufacturing our drug candidates or future drug products.

We have no experience in manufacturing of our products for commercial use. Moreover, the manufacturing of pharmaceutical products is highly complex. If we manufacture our products for commercial use by ourselves in the future, problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Manufacturing methods and formulation are sometimes altered through the development of drug candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause the drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of

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drug candidates and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in drug approvals and jeopardize our ability to commence product sales and generate revenue.

We may also encounter problems in achieving adequate or clinical-grade products that meet NMPA, FDA or other comparable regulatory agency standards or specifications, maintaining consistent and acceptable production costs, and experience shortages of qualified personnel, raw materials or key contractors. In these cases, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our products for commercial sale.

We have no track record and limited experience in commercialization of products. If we are unable to build or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our future products or sell our future products, which will materially affect our ability to generate product sales revenue.

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates. Our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing drug candidates.

We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our drug candidates, we will likely pursue collaborative arrangements regarding the sales and marketing of our drug candidates. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We may also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

There can be no assurance that we will be able to further develop and successfully maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

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If we are unable to meet the increasing demand for our existing drug candidates and future drug products, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business could suffer.

Manufacturers of drug products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel and compliance with strictly-enforced regulations. If our contracted manufacturers or suppliers encounter unanticipated delays and expenses as a result of any of these difficulties, or if construction, regulatory evaluation and/or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining facilities could also require us to raise additional funds from other sources.

To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand of our drug candidates, if approved, we will need to scale up the production process by a significant factor over the initial level of production. If we are unable to do so, the cost of this scale-up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our approved drug candidates in a sufficient quantity to meet future demand.

In anticipation of commercialization of our drug candidates, we aim to significantly expand our manufacturing capacity, mainly through the collaboration with contract manufacturers and the construction of manufacturing facilities. However, the timing and success of these plans are subject to significant uncertainty. Moreover, such plans are capital intensive and require significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all.

Furthermore, even if we build manufacturing facilities in the future, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp up period, there may be significant changes in the macroeconomics of the pharmaceutical industry, including, among other things, market demand, product and supply pricing trends and customer preferences. Any adverse trends in these respects could result in operational inefficiency and unused capacity in our facilities.

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If the market opportunities for our drug candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.

We currently focus our product development on drug candidates for oncology and other areas. Our estimates regarding our eligible patient population, pricing and available coverage and reimbursement determine our estimated market size, which may differ significantly from the actual market addressable by our drug candidates. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and analyses. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our drug candidates may be limited or may not be receptive to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our drug candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in achieving cost of goods at commercial scale that provide for an attractive margin.

We have not yet established manufacturing capacity at sufficient commercial scale and may underestimate the cost and time required to do so, or overestimate cost reductions from economies of scale that can be realized with our manufacturing processes. We may ultimately be unable to manage the cost of goods for our drug candidates to levels that will allow for a margin in line with our expectations and return on investment if and when those drug candidates are commercialized.

Guidelines, recommendations, and studies published by various organizations could disfavor our drug candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' drugs and drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to our competitive drug candidates, could result in current or potential decreased use, sales of, and revenues from one or more of our drug candidates. Furthermore, our success depends in part on our and our business partners' ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third parties' guidelines, recommendations or studies.

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The increasing use of social media platforms presents new risks and challenges.

Social media are increasingly being used to communicate about the diseases that our products are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of non-compliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our own or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our drug candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events occur or we otherwise fail to comply with applicable regulations, we may incur liability, face overly restrictive regulatory actions or incur other harm to our business.

Risks Relating to Our Reliance on Third Parties

We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If we fail to maintain our relationships with these third-party service providers, or if these third parties do not successfully carry out their contractual duties, comply with proper practices and standards or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.

We have relied, and plan to continue to rely, upon third-party CROs, to generate, monitor and/or manage data for our ongoing preclinical and clinical programs. We rely on these parties for the execution of our preclinical studies and clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements (including but not limited to international restrictions, such as sanctions) and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Switching or adding additional CROs may incur additional cost and requires management time and focus. Our CROs may have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us (i) if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, (ii) if we make a general assignment for the benefit of our creditors or (iii) if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our R&D programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of

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services as our original provider. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs timely or to do so on commercially reasonable terms, and we may not be able to meet our desired clinical development timelines.

In addition, our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. Our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates if (i) CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, (ii) they need to be replaced or (iii) the quality or accuracy of the clinical data that they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons. For example, we, our CROs for our clinical programs, and our clinical investigators are also required to comply with GCPs, which are regulations and guidelines enforced by the NMPA, the FDA and other regulatory authorities, for our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with these regulations, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other regulatory authorities may require us to perform additional or repeat clinical trials before approving our marketing applications, which would delay the regulatory approval process.

In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including obtaining regulatory approval, and our arrangements with these collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to (i) undertake R&D programs and conduct clinical trials, (ii) manage or assist with the regulatory filings and approval process and (iii) assist with our commercialization efforts. We do not control our collaborators; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators and whether any of our collaborators breach or terminate their agreements with us.

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To the extent that we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our third-party service providers, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.

We have in the past entered into, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. We entered into two license agreements with LG Chem including one license-out agreement regarding our drug candidate TT-01025 in August 2020 and one license-in agreement for research and development, manufacturing and commercialization of our drug candidate TT-01688 in April 2021. In September 2020, we entered in a Patent Transfer Agreement with Gentai, pursuant to which Gentai transferred to us its patent rights and interests in the BTK inhibitors for development of our drug candidate TT-01488. In March 2021, we entered into a master clinical supply agreement and its supplements with Roche to explore the combination therapy of Tinengotinib and atezolizumab for the treatment of BTC. We entered into two collaboration and license agreements with Teijin relating to the research of undisclosed targets in October and December 2020. In addition, in July 2023, we entered into a collaboration and license agreement with EA Pharma relating to the research of one novel target for inflammatory and metabolic diseases. For details, see “Business – Collaboration and License Agreements.” Our strategic collaboration with partners involves numerous risks, which may include the following:

- collaboration partners have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaboration partners may not pursue development and commercialization of our drug candidates or may fail to effectively implement commercialization plans and strategies, or may not continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaboration partners may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new design of a drug candidate for clinical testing;

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- collaboration partners with marketing and distribution rights to one or more products fail to effectively implement commercialization plans and strategies, or may not commit sufficient resources to their marketing and distribution;
- collaboration partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- our collaborators may breach the collaborations, and any termination of collaborations may result in our inability to generate revenue in the foreseeable future and a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and/or
- collaboration partners may own or co-own intellectual property covering our drug candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

We may also form or seek additional collaborations or strategic alliances or enter into licensing arrangements in the future. We may not achieve the revenue and cost synergies expected from the collaborations. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaborations, increases in other expenses, operating losses or problems in the business unrelated to our collaborations. As a result, there can be no assurance that these synergies will be achieved.

We may also face significant competition in seeking appropriate strategic partners and the negotiation process can be time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates in the future because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

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We collaborate with third parties to manufacture our clinical drug supplies, and expect to continue doing so in the foreseeable future. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We currently collaborate with CDMOs for the manufacturing of our drug candidates. We have not yet caused our drug candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our drug candidates. We also intend to continue to use third parties as part of our manufacturing process, including for the manufacturing of critical reagents and materials. Our anticipated reliance on a limited number of third-party manufacturing partners may expose us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and applicable health authorities must approve any manufacturers. This approval would require new testing and good manufacturing practices compliance inspections by health authorities. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of the materials used in the manufacturing of our products.
- Our third-party manufacturing partners might be unable to timely manufacture materials used in the manufacture of our drug candidates, or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Our contract manufacturers may not perform as agreed, may not devote sufficient resources to us, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute the materials used in the manufacture of our drug candidates.
- Manufacturers are subject to ongoing periodic unannounced inspection by the NMPA and other regulatory authorities to ensure strict compliance with GMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturing partners' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturing partners in the manufacturing process for our products, or in the manufacture of the custom materials used in the manufacture thereof.
- Our third-party manufacturing partners could breach or terminate their agreement with us.

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- Raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects, or may introduce variability into our final products.
- Our contract manufacturers and critical suppliers may be subject to inclement weather, as well as natural or man-made disasters.

We depend on a stable and adequate supply of quality materials, including reagents and consumables and R&D and manufacturing equipment, from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.

We procure raw materials and equipment for the development and manufacture of our drug candidates from qualified suppliers. We expect to continue to rely on third parties to supply such materials and equipment of our drug candidates. For details, see “Business – Raw Materials and Suppliers.”

In addition, we believe that adequate alternative sources for such supplies exist and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationship with alternative sources based on supply continuity risk assessment. However, there is a risk that, if supplies were interrupted, our business and results of operation would be materially harmed. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates.

Moreover, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of regulatory approval, but there is no assurance that current suppliers have the capacity to meet our demand. Any significant delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical studies, regulatory approval of our drug candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time.

We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In the event of significant price increases for such materials, we cannot assure you that we will be able to raise the prices of our future drug products and services sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability. Additionally, although we have implemented quality inspection on the materials before using them in the manufacturing process, we cannot assure you that we will be able to identify all of the quality issues.

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In addition, there is no assurance that these third-party suppliers will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortage of the materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or recall of our future drug products. The non-compliance of these third-party suppliers may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material and adverse effect on our business, financial condition and results of operation.

RISKS RELATING TO GOVERNMENT REGULATIONS

All material aspects of the research, development, manufacturing and commercialization of our drug candidates are heavily regulated.

All jurisdictions in which we intend to develop and commercialize our drug candidates regulate these activities in great depth and detail. We adopt a global development strategy and intend to focus our activities in the major markets including China and the U.S. These jurisdictions all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of the development and approval, manufacturing, marketing, sales and distribution of pharmaceutical products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development or approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, or total or partial suspension of production or distribution. Any occurrence of the foregoing could have material adverse effect on our business.

In many countries or regions where a drug is intended to be ultimately sold, including China and the U.S., the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop such drug. For example, we may need to obtain clearance from NMPA, the FDA or other regulatory authorities as part of IND application to seek authorization to begin clinical trials, and file an NDA, BLA or other similar applications to seek marketing approval. Although we have passed all relevant inspections and obtained clearance in relation to discovery and development from the NMPA, the FDA and other regulatory authorities in all material respects during the Track Record Period, we cannot assure you that we will be able to do so going forward. Any failure to comply with existing regulations and industry standards could result in fines or other punitive actions against us, and the disqualification of data for

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submission to regulatory authorities, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and adversely affect our reputation and financial results.

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in both preclinical studies and well-controlled clinical trials, and, with respect to approval in China, the U.S. and other regulatory authorities, to the satisfaction of the NMPA, the FDA and other comparable regulatory authorities, respectively, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the NDA must include significant information regarding the chemistry, manufacturing and controls for the drug candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA to the NMPA, the FDA or the other comparable regulatory authorities, the NMPA, the FDA or the other comparable regulatory authorities decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the NMPA, FDA or the other comparable regulatory authorities.

We have limited experience in filing for regulatory approval for our drug candidates, and we have not yet demonstrated ability to receive regulatory approval for our drug candidates. So far, we have not independently submitted an NDA. As a result, our ability to successfully submit any NDA, and obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

Regulatory authorities outside of China and the U.S. also have requirements or approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements and approval processes can vary widely from jurisdiction to jurisdiction and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdiction, and obtaining regulatory approval in one jurisdiction does not mean that regulatory approval will be obtained in any other jurisdiction. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time-consuming. The foreign regulatory approval process may include all of the risks associated with obtaining NMPA, FDA or the comparable other regulatory authorities' approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

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The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside China and the U.S., and approval is never guaranteed. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA, the FDA and other regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

Adverse events caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Drug-related adverse events and serious adverse events have been reported in our clinical trials. See “Business – Core Product: Tinengotinib – Potential First-In-Class, Unique MTK Inhibitor – Summary of Clinical Trials,” “Business – Non-Oncology Pipeline Products – TT-01688: Highly Selective, Oral S1P1 Modulator – Summary of Clinical Trials,” “Business – Non-Oncology Pipeline Products – TT-00920: Oral PDE9 Inhibitor – Summary of Clinical Trials,” and “Business – Non-Oncology Pipeline Products – TT-01025: Irreversible VAP-1 Inhibitor – Summary of Clinical Trial.” Undesirable adverse events caused by our drug candidates, or caused by our drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including but not limited to:

- regulatory authorities could interrupt, delay or halt pending clinical trials;
- we may suspend, delay or alter development or marketing of our drug candidates;
- regulatory authorities may order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;
- regulatory authorities may delay or deny approval of our drug candidates;
- regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug candidate or impose other limitations on an approved drug candidate;

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- we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation mitigation strategy, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to conduct post-market studies;
- we could be subject to litigation proceedings and held liable for harm caused to patients exposed to or taking our drug candidates may suffer from adverse events related to the treatment and patients;
- the patient enrolment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated; and
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, and could significantly harm our business, results of operations and prospects.

Any of our future approved drug candidates will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our future approved drug candidates.

Any of our future approved drug candidates will be subject to ongoing or additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including requirements of regulatory authorities in China, the U.S. (including federal and state) and other jurisdictions.

Manufacturers and manufacturers’ facilities are required to comply with extensive requirements of NMPA, FDA and other regulatory authorities and ensure that quality control and manufacturing procedures conform to GMP regulations. As such, our future CMOs, CDMOs and we will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any new drug application, or NDA, other marketing application, and previous responses to any inspection observations, particularly if we were to build manufacturing facilities in the future. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidate. The NMPA, the FDA or other regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval. In addition, if the NMPA, the FDA or other regulatory authority approves our drug candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with GMP and GCP, for any clinical trials that we conduct post-approval.

The NMPA, the FDA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, the FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses unless expressly authorized, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to any of our drug candidates, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on clinical trials;
- regulatory refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties being imposed on us.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity.

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If we are able to commercialize any of our approved drug candidates, we may face uncertainties from national, provincial or other third-party drug reimbursement practices or unfavorable pricing regulations, which could harm our business and prospects.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from jurisdiction to jurisdiction. We intend to seek approval to market our drug candidates in the U.S. and China, and in other jurisdictions. In the U.S. and China, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In China, the Ministry of Human Resources and Social Security of China or provincial human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the NRDL, or provincial or local medical insurance catalogues for the National Medical Insurance Program (“PRDL”), regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drug candidates will be included in the NRDL or the PRDL. Products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or the PRDL due to the affordability of the government’s Basic Medical Insurance. In particular, the PRC government has implemented significant reforms of the pharmaceutical industry in recent years and may enforce additional measures in the future which may adversely affect our pricing strategy. Even if our drug candidates have already obtained regulatory approval, any adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drug candidates. Patients are unlikely to use any of our future approved drug candidates unless coverage is provided and

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reimbursement is adequate to cover a significant portion of the cost of the drugs. Because some of our drug candidates may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

Increasingly, third-party payers require that companies provide them with predetermined discounts from list prices and may challenge the prices charged for medical products. We cannot be sure that reimbursement will be available for any approved drug candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidates that we commercialize. Obtaining or maintaining reimbursement for our future approved drug candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates that we successfully develop.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the NMPA and the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable payment rates from both governments funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could, in the event of noncompliance, expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain approval from the NMPA, the FDA, or other comparable regulatory authorities approval for any of our drug candidates and begin commercializing those drugs in China, the U.S. and our other target markets, our operations may be subject to various fraud and abuse laws in China and the U.S., including, without limitation, the PRC Anti-Unfair Competition Law (中華人民

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共和國反不正當競爭法), PRC Criminal Law (中華人民共和國刑法), the Federal Anti-Kickback Statute and the Federal False Claims Act, and the Physician Payments Sunshine Act. These laws may impact, among other things, our proposed sales, marketing and education programs.

In addition, we are subject to similar healthcare laws in other jurisdictions, some of which may be broader in scope than others and may apply to healthcare services reimbursed by any source, which may include not only governmental payers, but also private insurers. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirement, we could be subject to penalties.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the Federal False Claims Act as well as under the false claims laws of several states.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Government authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business.

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If safety, efficacy or other issues arise with any drug product used in combination with or to facilitate the use of our drug candidates, we may be unable to market such drug candidates or may experience significant regulatory delays.

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination therapy. For example, we entered into collaboration agreement with Roche to explore the combination of Tinengotinib and atezolizumab for the treatment of BTC in the China. If the NMPA revokes or denies its approval of a component therapeutic, in either the clinical design, clinical administration, therapy approval or commercialization stage, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts. In addition, we may even fail our commercialization effort because products that facilitate the use of our drug candidates incur safety, efficacy or availability issues. The lack of regulations presents uncertainties to our commercialization efforts and may have an adverse effect on our business and results of operations.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they will be held liable for damage caused thereby. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects' medical records. However, these measures may not be always effective. For example, our information technology systems could be breached

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through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials frequently also involve professionals from third party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure to protect the confidentiality of patients’ medical records and personal data, or any restriction on or liability as a result of, our use of medical data, could have a material adverse effect on our business, financial condition and results of operations.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, China’s Cyber Security Law (《中華人民共和國網絡安全法》), which became effective in June 2017, created China’s first national-level data protection for “network operators,” which may include all organizations in China that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China.

The regulations of the People’s Republic of China on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) which became effective on July 1, 2019 and was revised on March 10, 2024 stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s HGR at clinical institutions without export of HGR materials. However, the two parties shall file the type, quantity and usage of the HGR to be used with the administrative department of science and technology under the State Council before clinical trials. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

In addition, there are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as “protected health information”) and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and

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the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

Additionally, the Gramm-Leach-Bliley Act of 1999 (along with its implementing regulations) (the “**GLBA**”) restricts certain collection, processing, storage, use and disclosure by covered companies of certain personal information, requires notice to individuals of privacy practices and provides individuals with certain rights to prevent the use and disclosure of certain non-public or otherwise legally protected information. The GLBA also imposes requirements regarding the safeguarding and proper destruction of personal information through the issuance of data security standards or guidelines. In addition, many U.S. states have laws that protect the privacy and security of sensitive and personal information. Certain U.S. state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Consumer Privacy Act of 2018 (the “**CCPA**”), which went into effect on January 1, 2020, imposes stringent data privacy and security requirements and obligations with respect to the personal information of California residents and households. Among other things, it requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information that may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was amended in September 2018, November 2019 and November 2020, and it is possible that further amendments will be enacted. It remains unclear how various provisions of the CCPA will be interpreted and enforced, and multiple states have enacted or are expected to enact similar laws. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we may be subject.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, fines, penalties, judgments and negative publicity, and may otherwise materially and adversely affect our business, financial condition and results of operations. We may not be able to respond quickly or effectively to regulatory, legislative and other developments, and these changes may in turn impair our ability to offer our existing or planned drug candidates or increase our cost of doing business. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including

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changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Our [REDACTED] may be impeded and our business operations may be adversely affected by the Measures for Cybersecurity Review or the Regulation on the Administration of Cyber Data Security (Draft for Comments).

On December 28, 2021, the Cyberspace Administration of China (“CAC”), jointly with the other 12 governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “MCR”), which became effective from February 15, 2022. Pursuant to Article 2 of the MCR, besides the procurement of network products and services by critical information infrastructure operators, any data processing activity by network platform operators that affects or may affect national security shall be subject to the cybersecurity review. In accordance with Article 7 of the MCR, network platform operators mastering personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when listing abroad.

On November 14, 2021, CAC promulgated the Regulation on the Administration of Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》) (the “**Draft Cyber Data Security Regulation**”). Given that the Draft Cyber Data Security Regulation had not come into force as of the Latest Practicable Date, the applicability of various requirements under the Draft Cyber Data Security Regulation is still subject to further official guidance and applicable implementation rules.

As of the Latest Practicable Date, (i) we have not been notified of the results of any determination that we have been identified as a critical information infrastructure operator or that any of our systems have been identified as critical information infrastructure by the relevant governmental authorities; (ii) the MCR provides no further explanation or interpretation for “online platform operator” and “list abroad”, and does not stipulate that an online platform operator which intends to list in Hong Kong will be subject to cybersecurity review; (iii) Hong Kong is not a foreign country or region and does not fall within the scope of “abroad” under the MCR, and there is no specific guidance or implementation rules to indicate otherwise; (iv) the MCR provides no further explanation or interpretation for “affect or may affect national security”, which remains to be clarified and elaborated by the CAC, and we have not received any notification of cybersecurity review from relevant governmental authorities due to our impact or potential impact on national security; (v) the volume of personal information we process is far less than one million people; and (vi) we believe that our collection and handling of the personal information do not constitute any data processing activities that may affect national security under the Draft Cyber Data Security Regulation. Therefore, as advised by our PRC Legal Advisor, our Directors believe that as long as there is

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no material change to our current business and if no further rules are introduced and no significant changes to the enforcement of the MCR by governmental authorities, cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us.

However, the MCR and the Draft Cyber Data Security Regulation were both released recently, certain provisions of which are still unclear and are subject to the finalization or clarifications by relevant authorities. As such, the PRC regulatory authorities may have broad discretion in the interpretation of “affect or may affect national security”. Moreover, given that the Draft Cyber Data Security Regulation was still in the draft form for comments and had not come into force as of the Latest Practicable Date, the applicability of various requirements thereunder is still subject to further official guidance and applicable implementation rules. If we were deemed as a data processor that “affects or may affect national security” by the PRC regulatory authorities under their broad discretion, we may be subject to cybersecurity review. If we fail to pass such cybersecurity review, our [REDACTED] may be impeded, our business operations may be adversely affected, and/or we may be subject to other severe penalties and/or action by the competent government authorities.

On July 7, 2022, the CAC promulgated the Measures for the Security Assessment of Data Cross-border Transfer (《數據出境安全評估辦法》), which took effect on September 1, 2022. The Measures for the Security Assessment of Data Cross-border Transfer requires the data processor providing data overseas and falling under any of the following circumstances apply for the security assessment of cross-border data transfer by the national cybersecurity authority through its local counterpart: (i) where the data processor intends to provide important data overseas; (ii) where the critical information infrastructure operator and any data processor who has processed personal information of more than 1,000,000 people intend to provide personal information overseas; (iii) where any data processor who has provided personal information of 100,000 people or sensitive personal information of 10,000 people to overseas recipients accumulatively since January 1 of the last year intends to provide personal information overseas; and (iv) other circumstances where the security assessment of data cross-border transfer is required as prescribed by the CAC. As advised by our PRC Legal Advisor, the volume of personal information we process does not meet the aforesaid trigger thresholds, and our business does not involve the aforesaid cross-border transfer of important data, the Measures for the Security Assessment of Data Cross-border Transfer is not applicable to us currently.

Negative results from off-label use of our future drug products could materially harm our business reputation, product brand name and financial condition and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA, the FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our drug candidates, upon regulatory approval, may be subject to off-label drug use and may be prescribed in a patient

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population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our drug candidates, upon regulatory approval, less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition, including the price of our Shares. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates. The illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our drug candidates, upon regulatory approval, and could have a negative impact on our reputation and business.

Changes in laws and regulations relating to the pharmaceutical industry may result in additional compliance risks.

The majority of our operations are conducted in China, and are governed principally by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. The laws and regulations in China is subject to further revisions or interpretations from time to time. New laws, regulations, guidelines and interpretations that are promulgated in the future may affect our rights and obligations.

For example, there is a trend of enhanced regulations on oncology drug market in the PRC recently. On November 19, 2021, the CDE issued the “Clinical Value-Oriented Anti-tumor Drug Clinical Research and Development Guidelines” (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》) (the “**Guidelines**”) with the purpose to better address the needs of patients and to promote the clinical value-oriented R&D of anti-tumor drugs. Such regulations expose our R&D of oncology drugs to higher requirements. According to the Guidelines, when clinical trials of innovative drugs are designed to choose controlled drugs, the best supportive treatment should be preferred over placebo. To be specific, if an indication already has the current best drug recommendation in the treatment guidelines, the new drug should be compared with the existing drug.

As the Guidelines aim to select more high-quality drugs and we have been developing candidates that meet the potential patients’ medical needs, this new focus of regulatory policies promoting value-oriented research and development activities in China is in line with our development strategies and may further facilitate our clinical trials and studies. To the best knowledge of Directors, we are able to fully comply with the relevant requirements of the Guidelines. However, we cannot assure you that there will be no adverse regulatory changes in the implementation of Guidelines in the PRC, or other regulatory changes in the PRC that have benefitted our business during the Track Record Period will continue to benefit our business going forward. If we are unable to comply with, or are deemed to be in violation of its detailed provisions and principles, our clinical development activities and overall business operations may be materially adversely affected.

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Any failure to comply with the PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

Our directors, executive officers and other employees who are PRC residents may participate in our future employee equity incentive plans. Upon our [REDACTED], we will be an overseas [REDACTED] company, and therefore, we and our directors, executive officers and other employees who are PRC citizens or who have resided in China for a continuous period of not less than one year and who will be granted restricted share units, restricted shares or options are subject to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plan of Overseas Publicly Listed Company (國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知), according to which, employees, directors, supervisors and other management members participating in any future share incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to limited exceptions, are required to register with the SAFE, through a domestic qualified agent and complete certain other procedures. We are required to comply with the regulations at the time if we adopt additional equity incentive plans for our directors and employees under PRC law.

We are subject to PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. Although we believe that in the past, we have acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or action that could adversely affect our business, financial condition and results of operations. Such adjustments or changes, together with any uncertainty resulting therefrom, could have an adverse effect on our business, financial condition and results of operations.

We may be subject to the impact of currency conversion system.

The PRC government imposes controls on the convertibility of Renminbi into foreign currencies and in certain cases, the remittance of currency out of China. A majority of our revenue in the near future is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under China’s current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from SAFE, but we are required to present relevant documentary evidence

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of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The PRC government may also at its discretion restrict access in the future to foreign currencies for current account transactions. Since 2015, in response to China’s declining foreign currency reserves, the PRC Government has placed increasingly stringent restrictions on the convertibility of the Renminbi into foreign currencies. In the future, the PRC government may take measures, at its discretion, to restrict access to foreign currencies for capital account and current account transactions under certain circumstances. If such measures are implemented, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

You may experience difficulties in effecting service of legal process and enforcing judgments against us and our management based on Hong Kong or other foreign laws.

We are incorporated under the laws of the PRC, and a majority of our assets are located in the PRC. In addition, a majority of our Directors, Supervisors and senior management personnel reside within the PRC, and substantially all of their assets are located within the PRC. As a result, it may not be possible for investors to effect service of process upon us or our Directors, Supervisors and senior management personnel in China.

In July 2006, the Supreme People’s Court of the PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “**Arrangement**”). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a PRC court is expressly selected as the court having sole jurisdiction for the dispute. Therefore, it may not be possible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors to effect service of process against certain of our assets or Directors in China in order to seek recognition and enforcement of foreign judgments in China.

On January 18, 2019, the Supreme People’s Court of the PRC and Hong Kong entered into an agreement regarding the scope of judgments which may be enforced between China and Hong Kong (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》)

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(the “**New Arrangement**”). The New Arrangement became effective on January 29, 2024 both in China and in Hong Kong and replaced the Arrangement. The New Arrangement provides that the court where the judgment was sought could apply jurisdiction in accordance with the certain rules set forth in the New Arrangement without the parties’ agreement. Although the New Arrangement has been signed, the outcome and effectiveness of any action brought under the New Arrangement may still be uncertain. We cannot assure you that an effective judgment that complies with the New Arrangement can be recognized and enforced in a PRC court.

Gains on the sales of H Shares and dividends on the H Shares may be subject to PRC income taxes.

Holders of H Shares, being non-PRC resident individuals or non-PRC resident enterprises, whose names appear on the register of members of H Shares of our Company, are subject to PRC income tax in accordance with the applicable tax laws and regulations, on dividends received from us and gains realized through the sale or transfer by other means of shares by such shareholders.

According to the Individual Income Tax Law of the PRC and the Implementation Regulations for the Individual Income Tax Law of the PRC, both came into effect on January 1, 2019, the tax applicable to non-PRC resident individuals is proportionate at a rate of 20% for any dividends obtained from within China or gains on transfer of shares and shall be withheld and paid by the withholding agent. Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (the “**Tax Arrangement**”) executed on August 21, 2006, the PRC Government may levy taxes on the dividends paid by PRC companies to Hong Kong residents in accordance with the PRC laws, but the levied tax (in the case the beneficial owner of the dividends are not companies directly holding at least 25% of the equity interest in the company paying the dividends) shall not exceed 10% of the total dividends.

According to the Enterprise Income Tax Law of the PRC, which was newly revised and implemented on December 29, 2018, and the Implementation Regulations for the Enterprise Income Tax Law of the PRC, which was newly revised and implemented on April 23, 2019, if a non-resident enterprise has no presence or establishment within China, or if it has established a presence or establishment but the income obtained has no actual connection with such presence or establishment, it shall pay an enterprise income tax on its income derived from within China with a reduced rate of 10%. Pursuant to the Tax Arrangement, dividends paid by PRC resident enterprises to Hong Kong residents can be taxed either in Hong Kong or in accordance with the PRC laws. However, if the beneficial owner of the dividends is a Hong Kong resident, the tax charged shall not exceed: (i) 5% of the total amount of dividends if the Hong Kong resident is a company that directly owns at least 25% of the capital of the PRC resident enterprise paying dividends; (ii) otherwise, 10% of the total amount of dividends.

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The interpretation and enforcement of applicable tax laws and regulations in the PRC by the PRC tax authorities, including whether and how income tax will be levied on non-PRC resident shareholders, will be determined according to the laws and regulations then in effect. Non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers by other means of the H Shares.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant net losses since our inception, and we anticipate that we will continue to incur net losses for the foreseeable future and may never become profitable. Investors are at risk of losing substantially all of their investments in our Shares.

Investment in pharmaceutical drug development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. We have incurred losses in each period since our inception. As of December 31, 2022 and 2023, we had total comprehensive loss for the year of RMB252.1 million and RMB343.2 million, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development costs and administrative expenses.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue to expand our development of, and seek regulatory approvals for, our drug candidates, and continue to build up our commercialization and sales workforce in anticipation of the future roll-out of our drug candidates. Typically, it takes years to develop one new drug from the drug-discovery stage to when it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a development-stage or commercial-stage biopharmaceutical company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, and our ability to generate revenues. If any of our drug candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the value of our Company may also cause you to lose substantially all or part of your investment.

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We had operating cash outflows during the Track Record Period. We may need to obtain substantial additional financing to fund our operations and meet capital expenditure requirements, and if we are unable to obtain sufficient financing when needed on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, development activities and commercialization efforts relating to our drug candidates.

We believe our current cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED] will be sufficient to meet our anticipated cash needs for at least the next 12 months from the date of this document. However, our drug candidates will require the completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Our operations have consumed substantial amounts of cash since inception. Our net cash flows used in operating activities amounted to RMB236.9 million and RMB319.3 million during the years ended December 31, 2022 and 2023, respectively. We expect to continue to spend substantial amounts on product discovery, advancing the clinical development of our drug candidates, and launching and commercializing any drug candidates for which we receive regulatory approval. Our existing capital resources may not be sufficient to enable us to complete all development or commercially launch all of our current drug candidates for the currently anticipated indications and to invest in additional clinical development programs. Accordingly, we will likely require further funding through public or private offerings, debt financing, collaboration, and licensing arrangements or other sources. Our future funding requirements will depend on many factors, including:

- the progress, timing, scope, results and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the progress of third-party clinical trials relating to products with respect to which we have rights of first refusal, options or other rights to acquire;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the cost and timing of development and completion of commercial-scale manufacturing activities;
- the number and characteristics of drug candidates that we may develop;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- selling and marketing costs associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;

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- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- general cash requirements for maintaining our R&D platform and process development; and
- our headcount growth and associated costs.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Any inability to obtain additional funding when we need it could result in a material and adverse effect on our business.

Our results of operations, financial conditions, and prospects may be adversely affected by fair value changes and credit risks associated with our financial assets at FVTPL.

During the Track Record Period, we had certain financial assets at FVTPL, representing wealth management products we purchased primarily from commercial banks, including China CITIC Bank, China Merchants Bank and Bank of Nanjing. As of December 31, 2023, we recorded financial assets at FVTPL of RMB341.5 million. We adopt a prudent approach in selecting wealth management products. We may continue to invest in wealth management products in the future when we believe that we have surplus cash on-hand and the potential investment returns are attractive. For more details, see “Financial Information – Discussion of Certain Selected Items From the Consolidated Statements of Financial Position – Financial Assets at FVTPL.” However, there can be no assurance that our internal management and investment strategy will be effective and adequate with respect to our purchased wealth management products.

We are exposed to credit risks in relation to the financial assets, which may adversely affect our net changes in their fair value. The financial assets at FVTPL are stated at fair value, and net changes in their fair value are recorded as other gains, and therefore directly affect our results of operations. We cannot assure you that market conditions and regulatory environment will create fair value gains and we will not incur any fair value losses on our financial assets at FVTPL in the future. If we incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

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Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Share-based payment may cause shareholding dilution to our existing Shareholders and have a material and adverse effect on our financial performance.

We operate the share incentive plans for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Company’s operations. For further details, see note 27 to the Appendix I to this document. In the years ended December 31, 2022 and 2023, we recorded share-based payment expenses of RMB7.0 million and RMB14.8 million, respectively. To further incentivize our employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

RISKS RELATING TO OUR OPERATIONS

Any failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any

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approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations. In China, a drug marketing authorization holder can manufacture the drugs either through its own manufacturing facility or to entrust CMOs who are required to secure a pharmaceutical manufacturing permit and to comply with certain requirements of GMP for each production facility from the NMPA and its relevant branches. According to Measure for the Supervision and Administration of Drug Production (藥品生產監督管理辦法) which implemented since July 1, 2020, the MAH that entrusts CMOs to manufacture the drugs will also be required to apply for a pharmaceutical manufacturing permit. Therefore, if acting as a MAH in the future, we will also be required to obtain a pharmaceutical manufacturing permit, even if we entrust CMOs to manufacture our drugs. In addition, we are responsible for the entire manufacturing and marketing chain and the whole life cycle of any drug we manufacture, and we assume full legal liability for non-clinical, clinical trials, manufacturing, marketing and distribution and adverse drug reaction monitoring. For distribution, we or a partner will need to obtain a pharmaceutical distribution permit from the NMPA and its relevant branches, and to comply with requirements of good supply practice.

Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot ensure that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, suppliers and other contractors and consultants, could be subject to natural or man-made disasters or business interruptions which is beyond our control. In particular, we currently rely on CROs for conducting research and development of our drug candidates, and such collaborations may be affected by government shutdowns or funding withdrawals. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and could increase our costs and expenses. In addition, damage or extended periods of interruption to our corporate, development, research due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. Our insurance might not cover all losses under such circumstances and our business and financial condition may be seriously harmed by such delays and interruption.

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The loss of any key members of our senior management team or our inability to attract and retain highly skilled scientists, clinical and other qualified employees could adversely affect our business.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other employees. The loss of services of any of these individuals or one or more of our senior management could delay or prevent the successful development of our drug candidates.

While we have implemented a number of initiatives in an effort to attract, retain and motivate our qualified and competent staff, there is no assurance that these measures will be effective or that supply of skilled labor in local markets will be sufficient to fulfill our needs. Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. Competition for qualified employees in the biopharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain experienced senior management or key clinical and scientific personnel in the future. The departure of one or more of our senior management or key clinical and scientific personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to replacing them in a timely manner or at all, which may disrupt our drug development progress and have a material and adverse effect on our business and results of operations. In addition, we will need to hire additional employees as we expand our commercialization team. We may not be able to attract and retain qualified employees on acceptable terms.

We operate in a rapidly changing industry and we face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, or developing drug candidates or treatments that are safer, more effective, more effectively marketed or cost less than ours, or receive regulatory approval or reach the market earlier. As a result, our drug candidates may not achieve the sales we anticipate and could be rendered non-competitive or obsolete.

The development and commercialization of new drugs is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies worldwide. There are a number of large pharmaceutical companies and biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of CCA, mCRPC, HER2– breast cancer, BTC, heterogeneous solid tumors or other indications for which we are developing our drug candidates. Some of these competitors have better resources and expertise than us. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

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Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, FDA, or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our drug candidates.

Mergers and acquisitions in the pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and well-established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

In the future, we may be involved in lawsuits or other legal proceedings, which could adversely affect our business, financial condition, results of operations and reputation.

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. But we may in the future be involved in lawsuits or other legal proceedings arising in the ordinary course of business. Litigation and governmental proceedings can be expensive, lengthy and disruptive to normal business operations, and can require extensive management attention and resources, regardless of their merit. In addition, we cannot predict the results of complex legal proceedings and an unfavorable resolution of a lawsuit or proceeding could have adverse impact on our business, results of operations, financial condition and reputation.

Our employees, service providers, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and applicable anti-bribery, and insider trading.

We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations.

However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

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Product and professional liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates, which could materially and adversely affect the success of our business.

We face an inherent risk of product and professional liability as a result of the clinical trial and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in decreased demand for our drug candidates; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management’s time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labelling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any approved drug candidate; and a decline in the market price of our Shares.

It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

Our internal information technology and other infrastructure, or those used by our partners or other contractors or consultants, may fail or suffer security breaches, which may require us to expend additional resources to protect our technology and information systems and could materially adversely affect our business, financial condition, results of operations and prospects.

Despite the implementation of security measures, our information technology systems and those of our current or future partners, CROs, consultants and other service providers or suppliers are vulnerable to damage from cyber-attacks, computer viruses, malicious codes, unauthorized access, employee theft or misuse, natural disasters, fire, power loss, terrorism, war, and telecommunication and electrical failures, among other things. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely

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manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed. In addition, a security breach may result in the loss of, damage to, or public disclosure of personally identifiable information, and such an event could have serious negative consequences, including disputes, regulatory action, investigation, litigation, fines, penalties and damages, and time-consuming and expensive litigation, any of which could have a material adverse effect on our business, financial condition, results of operations, or prospects.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or suppliers that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have a material adverse impact on us and our business, including loss of data and damage to equipment, among other things. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, system malfunction or intentional or accidental release or loss of information maintained in the information systems and networks of us and our suppliers, including but not limited to personal information of our employees and patients. In addition, external parties may attempt to penetrate our systems or those of our suppliers or fraudulently induce our personnel or the personnel of our suppliers to disclose sensitive information in order to gain access to our data or systems. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or

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hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, results of operations, financial condition or prospects. If we experience any such material system failure or security breach and interruptions in our operations, it could result in a material disruption of our development programs and our business operations, a breach of sensitive personal information or a loss or corruption of critical data assets including trade secrets or other proprietary information. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

If a material breach of our information technology systems or those of our suppliers occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated. As we engage in more electronic transactions with payers, suppliers and patients, and collect and store an increasing volume of data, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We may not have adequate insurance coverage to compensate for any losses associated with a system failure, any breach of our computer systems or other cybersecurity attack or any violation of any privacy laws or other obligations. Any breach or failure of our or our suppliers' computer systems, information technology and other infrastructure could materially adversely affect our business, financial condition, results of operations and prospects.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, cause dilution to our Shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;

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- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control.

Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or may be susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

Our business could be adversely affected by the effects of epidemics, including COVID-19, avian influenza, severe acute respiratory syndrome (SARS), influenza A (H1N1), Ebola or another epidemic. For example, the COVID-19 pandemic and its recurrence have in the past caused temporary disruption to certain aspects of our operations, including clinical development, which had a negative impact on our operations during the Track Record Period. Any aforementioned occurrences could cause severe disruption to our daily operations and may even require a temporary closure of our offices and laboratories.

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If we fail to comply with environmental, health and safety laws and regulations, or if we, or any future CMOs, use hazardous and biological materials in a manner that causes injury or violates applicable law, we could become subject to fines or penalties or incur costs that could materially adversely affect the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. In addition, our construction projects can only be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved the relevant facilities in certain jurisdictions. We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our construction projects may affect our abilities to develop, manufacture and commercialize our drug candidates as we plan. As requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may not be able to comply with, or accurately predict any potential substantial cost of complying with, these laws and regulations. If we fail to comply with environmental protection, and health and safety laws and regulations, we may be subject to rectification orders, substantial fines, potentially significant monetary damages, or production suspensions in our business operations. As a result, any failure by us to control the use or discharge of hazardous substances could have a material and adverse impact on our business, financial condition, results of operations and prospects.

We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

We have historically received government grants, subsidies and other incentives for our research and development activities. Expiration of, or changes to, these incentives or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.

We have historically benefited from government grants as incentives for our research and development activities. We recorded government grants of RMB12.7 million and RMB10.3 million for the years ended December 31, 2022 and 2023, respectively. See “Financial Information – Description of Certain Selected Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Other Income” and Note 7 to the Accountants’ Report in Appendix I to this document for further details. During the Track Record Period, we had additional deductible allowance for qualified research and development costs of RMB42.1 million and RMB78.9 million in 2022 and 2023, respectively. For more details, see note 13 to the Accountants’ Report in Appendix I to this document. Our government grants and incentives

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may vary from period to period going forward and our results of operations may be affected as a result. Our eligibility for government grants and incentives is dependent on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities and the research and development progress made by other peer companies. The incentives are subject to the discretion of the central government or relevant local government authorities, which could determine at any time to eliminate or reduce these financial incentives, generally with prospective effect. In addition, the policies according to which we historically received government grants and incentives may be halted by the relevant government entities at their sole discretion. There is no assurance that we will continue to receive such government grants and incentives, or at all. Since our receipt of the government grants is subject to periodic time lags and inconsistent government practice, as long as we continue to receive these government grants, our net income in a particular period may be higher or lower relative to other periods depending on the potential changes in these government grants and incentives in addition to any business or operational factors that we may otherwise experience. The discontinuation of government grants and other incentives currently available to us could have a material adverse effect on our business, financial condition and results of operations.

Increased labor costs could slow our growth and affect our profitability.

Most of our workforce is employed in China. The average labor cost in China has been steadily increasing over the past years as a result of government-mandated wage increases and other changes in the PRC labor laws. Further changes in the labor laws, rules and regulations may be promulgated by the Chinese government in the future and our operations may be materially adversely affected if such laws, rules or regulations impose additional burden on the employers. The labor cost will continue to increase in the future which is in line with the economic growth in China. Competition for employees would require us to pay higher wages, which would result in higher labor costs.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. We also maintain insurance policies for adverse events in clinical trials, liabilities of directors, supervisors and senior management, and fixed assets. We currently do not maintain product liability insurance. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

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Any failure to comply with the PRC regulations regarding mandatory social insurance may subject us to fines and other legal or administrative sanctions.

According to the Social Insurance Law (中華人民共和國社會保險法), the Regulations on the Administration of Housing Provident Funds (住房公積金管理條例) and other applicable PRC regulations, any employer operating in China must contribute social insurance premium and housing provident funds for its employees. Any failure to open social insurance or housing provident fund registration account may trigger an order of correction where correction is not made within a specified period of time, the competent authority may further impose fines. Any failure to make timely and adequate contribution of social insurance premium or housing provident funds for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium or housing provident funds within a specified period of time, and the competent authority may further impose fines or penalties. During the Track Record Period, we have made contribution of social insurance premium and housing provident funds for employees. As of the Latest Practicable Date, we have not received any order of correction or any fines or penalties from the competent authority. However, we cannot assure you that we may not involve in any issues relating to the social insurance in the future.

Changes in international trade policies, particularly with regard to China, may adversely impact our business and operating results.

We have established global strategic collaboration partnerships with a series of global pharmaceutical companies, including Roche, LG Chem, Teijin and EA Pharma. We have also conducted or intend to conduct clinical trials in parallel separately in China, the U.S., the EU and other regions for some of our drug candidates. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions.

For example, the U.S. government has imposed, and has proposed to impose additional, new, or higher tariffs on certain products imported from China, among other trade policies and restrictions. China has responded by imposing, and proposing to impose additional, new, or higher tariffs on certain products imported from the United States. On January 15, 2020, China and the United States entered into the Economic and Trade Agreement between the Government of the People’s Republic of China and the Government of the United States of America and (《中華人民共和國政府和美利堅合眾國政府經濟貿易協議》) as a phase one trade deal, effective on February 14, 2020. The U. S. government has also broadened the restrictions on the sale of goods manufactured outside the United States that are produced using certain controlled U.S.-origin technology or software to companies on a special list (the “Entity List”), and the restrictions on the use of U.S.-origin semiconductor manufacturing equipment that produces semiconductor devices for companies on the Entity List.

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On September 19, 2020, the Ministry of Commerce of the People’s Republic of China promulgated the Regulations on the List of Unreliable Entities (《不可靠實體清單規定》) (the “**List of Unreliable Entities**”). A working mechanism composed of relevant government agencies will be established to administer the regime of the List of Unreliable Entities. A foreign entity that is designated onto the List of Unreliable Entities may be subject to several measures, including but not limited to: (i) being restricted or prohibited from engaging in import or export activities related to China; and (ii) being restricted or prohibited from investing in China. When an enterprise, organization, or individual of China must conduct business with a designated foreign entity in special circumstances, the enterprise, organization, or individual shall submit an application to the working mechanism for approval, and only when approval is granted may such enterprise, organization, or individual conduct the corresponding transaction.

On June 10, 2021, the Standing Committee of National People’s Congress passed the Countering Foreign Sanctions Law (《中華人民共和國反外國制裁法》), which became effective on the same day. The Countering Foreign Sanctions Law provides a legal basis not only for the Chinese government to take action in response to foreign sanctions, but also for Chinese citizens and organizations to bring civil actions for injunctive relief or damages. Under the Countering Foreign Sanctions Law, the competent department of the State Council may place any individuals and organizations that are directly or indirectly involved in making, determining, or implementing the discriminatory restrictive measures as provided therein on the Countermeasure List. A foreign individual or organization on the Countermeasure List may be subject to one or several countermeasures, including but not limited to prohibitions or restrictions on commercial transactions, cooperation or such other activities with organizations and individuals within the territory of China. Furthermore, pursuant to the Countering Foreign Sanctions Law, any organization and individual within the territory of China shall comply with the countermeasures. Any organization or individual who fails to comply or cooperate in implementing the countermeasures may be held liable in accordance with law.

Moreover, current geopolitical tensions involving China may have a negative impact on us. The recently proposed BIOSECURE Act is aimed at discouraging federal contracting with entities that use biotechnology equipment or services provided by certain Chinese biotechnology companies. Finally, in February 2024, certain U.S. senators and representatives sent a letter to the Biden administration requesting to add certain Chinese entities, including one of our suppliers, to various U.S. government lists. While the Biden administration has yet to take action on this, if any of our suppliers gets listed on any of the aforementioned lists, it could materially impact our procurement from such supplier(s). Any delay in identifying and entering into commercially reasonable business relationship with a new supplier could harm our ability to develop products on time or within budget, which could materially adversely affect our business, financial condition and results of operations.

While we have not started commercialization of any of our drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future drug products, the competitive position of our future drug products, the hiring of scientists and other research and development personnel, and import or

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export of raw materials in relation to drug development, or prevent us from selling our future drug products in certain countries. There can be no assurance that existing and potential collaboration partners will not alter their perception of us or their preferences as a result of such adverse changes.

Our risk management and internal control systems, as well as the risk management tools available to us, may not fully protect us against various risks inherent in our business.

We have established risk management and internal control systems consisting of relevant organizational frameworks, policies, procedures and risk management methods in order to manage our risk exposure, primarily including market risk, credit risk, liquidity risk, operational risk, compliance risk and legal risk, and we expect to continue to improve such risk management and internal control systems from time to time. However, our risk management and internal control systems may not be fully effective in mitigating our risk exposure in all market environments or against all types of risks, including risks that are unidentified or unanticipated.

In addition, we will become a [REDACTED] company upon completion of this [REDACTED] and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. In order to address our internal controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program, adopting new policies, and providing extensive and ongoing training on our controls, procedures and policies to our employees. In addition, in preparation for this [REDACTED], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

Our risk management capabilities are limited by the information, tools or technologies available to us. If our internal control system fails to detect potential risks in our business as intended, or is otherwise exposed to weaknesses and deficiencies, our business, financial condition and results of operations could be materially and adversely affected.

Effective implementation of our risk management and internal controls policies and procedures also depends on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct. If we fail to implement our policies and procedures in a timely manner, or fail to identify risks that

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affect our business with sufficient time to plan for contingencies for such events, our business, financial condition and results of operations could be materially and adversely affected, particularly with respect to the maintenance of our relevant approvals and licenses granted by the relevant authorities.

Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may adversely affect our reputation and may, as a result, negatively affect our business, financial condition and results of operations.

We, our Shareholders, Directors, officers, employees and business partners may be subject to negative media coverage and publicity from time to time. Any negative publicity concerning us, our affiliates, our Shareholders, Directors, officers, employees and business partners, management, even if untrue, could adversely affect our reputation and business prospects. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees and business partners were non-compliant with any laws or regulations or became involved in lawsuits, disputes, or other legal proceedings or became subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity. In addition, referrals and word of mouth can significantly contribute to our ability to establishing new partnerships. As a result, any negative publicity about us could adversely affect our ability to maintain our existing collaboration arrangements or attract new collaboration partners, and we may not be able to diffuse such negative publicity to the satisfaction of our investors and customers.

We are subject to registration or other requirements of government in China for cross-border sales or licensing of technology.

China imposes controls on the import and export of technology and software products. Under the Regulations on Administration of Import and Export of Technologies (技術進出口管理條例) promulgated by the State Council, which were amended in November 2020, the term “technology import and export” is defined to include, among other things, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approval by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts (技術進出口合同登記管理辦法), issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology.

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We are subject to the risks of doing business globally, including risks relating to political and economic instability and changes in diplomatic and trade relationships, which may materially and adversely affect our business and results of operations.

Because we operate in China, the U.S. and other jurisdictions, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;
- the burden of complying with a variety of foreign laws including difficulties in effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

Furthermore, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships, which could cause our results to fluctuate and our revenue to decline. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially and adversely affect our business and results of operations.

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Fluctuations in exchange rates could result in foreign currency exchange losses.

Since the majority of the assets and operations of our Company are located in the PRC, the financial statements set forth in Appendix I to this document are presented in RMB. Certain of our cash at bank is denominated in the USD while our expenses are mainly denominated in RMB. Furthermore, pursuant to the agreements we entered into with LG Chem and certain other third parties, payments shall be denominated in the USD. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. The exchange rate of RMB against USD and other foreign currencies fluctuates is affected by, among other things, the policies of the PRC government and changes in and international political and economic conditions, as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between RMB, USD, Hong Kong dollars or other currencies in the future. In addition, the PBOC regularly intervenes in the foreign exchange market to limit fluctuations in RMB exchange rates and achieve policies goals. There remains significant international pressure on the PRC Government to adopt a more flexible currency policy, which, together with domestic policy considerations, could result in a significant appreciation of RMB against USD, Hong Kong dollars or other foreign currencies.

Our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. As a result, any appreciation of RMB against USD, Hong Kong dollars or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Any of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

RISKS RELATING TO THE [REDACTED]

No [REDACTED] currently exists for our Shares, and an active [REDACTED] market for our Shares may not develop and the [REDACTED] for our Shares may decline or become volatile.

No [REDACTED] currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED] (on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of the Shares following the [REDACTED]. We have applied to the Hong Kong Stock Exchange for the [REDACTED] of, and permission to [REDACTED] in, the Shares. A [REDACTED] on the Hong Kong Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] market for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will rise following the [REDACTED].

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The price and trading volume of our Shares may be volatile, which could lead to substantial losses to investors.

The price and trading volume of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of our Shares. In addition to market and industry factors, the price and trading volume of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, the results of intellectual property disputes involving us, regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in price not directly related to our performance.

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future.

The [REDACTED] of the Shares is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the Shares in the [REDACTED] will experience an immediate dilution in [REDACTED] consolidated net tangible asset value. There can be no assurance that if we were to immediately liquidate after the [REDACTED], any assets will be distributed to Shareholders after the creditors' claims. To expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the Shares may experience dilution in the net tangible asset value per Share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time.

Future sales or perceived sales of a substantial number of our Shares in the public market following the [REDACTED] could materially and adversely affect the price of our Shares and our ability to raise additional capital in the future, and may result in dilution of your shareholding.

Prior to the [REDACTED], there has not been a public market for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing market price of our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal

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and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our Shares in the public market or the perception that these sales may occur could significantly decrease the prevailing market price of our Shares and our ability to raise equity in the future.

As the [REDACTED] of our Shares is higher than our net tangible book value per share, purchasers of our Shares in the [REDACTED] may experience immediate dilution upon such purchases. Purchasers of Shares may also experience further dilution in shareholdings if we issue additional Shares in the future.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] net tangible asset value. In order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time.

Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on price appreciation of our Shares for a return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, investors should not rely on an investment in our Shares as a source for any future dividend income. Our Board of Directors has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future operating results and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on investment in our Shares, if any, will likely depend entirely upon any future price appreciation of the Shares. There is no guarantee that our Shares will appreciate in value or even maintain the price at which the holders of our Shares are purchased. The holders of our Shares may not realize a return on their investment in our Shares and may even lose their entire investment in the Shares.

There can be no assurances that we will declare and distribute any amount of dividends in the future.

We cannot guarantee when, if or in what form and amount dividends will be declared or paid on our Shares following the [REDACTED]. A decision to declare or pay any dividend and the amount of dividends is subject to the discretion of our Directors, depending on, among other considerations, our operations, earnings, cash flows and financial position, operating and capital expenditure requirements, our strategic plans and prospects for business development,

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our constitutional documents and applicable law. In addition, as a holding company, our ability to declare future dividends will depend on the availability of dividends, if any, received from our operating subsidiaries. The calculation of our operating subsidiaries’ profit under applicable accounting standards differs in certain aspects from the calculation under IFRSs.

Accordingly, we may not have sufficient or any profit to enable us to make dividend distributions to our Shareholders in the future, even if our IFRSs financial statements indicate that our operations have been profitable. For details, see “Financial Information – Dividend.”

We have significant discretion as to how we will use the net [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the net [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return to our Shareholders. We plan to use the net [REDACTED] from the [REDACTED] to continue the research and development activities of our drug candidates to commercialization and strengthen our research and development capabilities. For details of our intended use of [REDACTED], see “Future Plans and Use of [REDACTED].” However, our management will have discretion as to the actual application of our net [REDACTED]. You are entrusting your funds to our management, upon whose judgment you must depend, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

Any possible conversion of our Unlisted Shares into H Shares in the future could increase the number of our H Shares in the market and negatively impact the market price of our H Shares.

Our Unlisted Shares are currently not listed or traded on any stock exchange. We have applied for the conversion of Unlisted Shares into H Shares. See “History, Development and Corporate Structure” and “Share Capital – Conversion of our Unlisted Shares into H Shares.” The PRC Company Law provides that in relation to the public offering of a company, the shares of that company which are issued prior to the public offering shall not be transferred within one year from the date of listing of the public offering. Therefore, if our Unlisted Shares are traded, upon obtaining the requisite approval and after the conversion, in the form of H Shares on the Hong Kong Stock Exchange one year after the [REDACTED], the number of our H Shares available in the market will be increased, and the market price of our H Shares may be negatively impacted.

Facts, forecasts and statistics in this document relating to pharmaceutical markets may not be fully reliable.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources, including information provided or published by government agencies, and we can guarantee neither the quality nor reliability of such source materials. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, the information from official government sources

RISK FACTORS

has not been independently verified by us, the Joint Sponsors, the [REDACTED], the [REDACTED], any of their respective directors, employees, agents or advisers or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate or not comparable to statistics produced for other economies. Accordingly, the information from official government sources contained herein should not be unduly relied upon. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.

You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the [REDACTED].

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We do not have sufficient control over the press and media coverage, and analysts might issue negative views or recommendations on us, which could have an adverse effect on the market price of H Shares. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective [REDACTED] are cautioned to make their [REDACTED] decisions on the basis of the information contained in this document only and should not rely on any other information.

WAIVER FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

In preparation for the [REDACTED], our Company has sought and [has been granted] the following waiver from strict compliance with the relevant provisions of the Listing Rules and the following exemption from compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

WAIVER IN RESPECT OF MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rules 8.12 and 19A.15 of the Listing Rules, we must have a sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong.

Our headquarters and most of our business operations are based, managed and conducted in the PRC. As our executive Directors play very important roles in our business operation, it is in our best interest for them to be based in the places where our Company has significant operations. We consider it practicably difficult and commercially unreasonable for us to arrange for two executive Directors to be ordinarily reside in Hong Kong, either by means of relocation of our executive Directors to Hong Kong or appointment additional executive Directors. Therefore, we do not have, and in the foreseeable future will not have, sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rules 8.12 and 19A.15 of the Listing Rules.

Accordingly, we have applied to the Hong Kong Stock Exchange for, and the Hong Kong Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rules 8.12 and 19A.15 of the Listing Rules, provided that our Company implements the following arrangements:

- (a) We have appointed Mr. Wu Di (吳笛) and Ms. Wong Tik (黃荻) as our authorized representatives pursuant to Rule 3.05 of the Listing Rules. The authorized representatives will act as our Company’s principal channel of communication with the Hong Kong Stock Exchange. The authorized representatives will be readily contactable by phone, facsimile and email to promptly deal with enquiries from the Hong Kong Stock Exchange, and will also be available to meet with the Hong Kong Stock Exchange to discuss any matter within a reasonable period of time upon request of the Hong Kong Stock Exchange;
- (b) When the Hong Kong Stock Exchange wishes to contact our Directors on any matter, each of the authorized representatives will have all necessary means to contact all of our Directors (including our independent non-executive Directors) promptly at all times. Our Company will also inform the Hong Kong Stock Exchange as soon as practicable in respect of any changes in the authorized representatives in accordance with the Listing Rules. We have provided the Hong Kong Stock Exchange with the contact details (i.e. mobile phone number, office phone number, email address and fax number (if any)) of all Directors to facilitate communication with the Hong Kong Stock Exchange;

WAIVER FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

- (c) We confirm and will ensure that all Directors who do not ordinarily reside in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and can meet with the Hong Kong Stock Exchange within a reasonable period upon the request of the Hong Kong Stock Exchange;
- (d) We have appointed Central China International Capital Limited as our compliance advisor upon [REDACTED] pursuant to Rule 3A.19 of the Listing Rules for a period commencing on the [REDACTED] and ending on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED]. Our compliance advisor will have access at all times to our authorized representatives, our Directors and our senior management as prescribed by Rule 3A.23 of the Listing Rules and will act as the additional channel of communication with the Hong Kong Stock Exchange when the authorized representatives are not available; and
- (e) Meetings between the Hong Kong Stock Exchange and our Directors can be arranged through our authorized representatives or our compliance advisor, or directly with our Directors within a reasonable time frame.

EXEMPTION FROM COMPLIANCE WITH SECTION 342(1)(b) OF THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE AND PARAGRAPH 27 OF PART I AND PARAGRAPH 31 OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all prospectuses to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance and set out the reports specified in Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

Paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires a company to include in its document a statement as to the gross trading income or sales turnover (as the case may be) of the company during each of the three financial years immediately preceding the issue of the document, including an explanation of the method used for the computation of such income or turnover and a reasonable breakdown between the more important trading activities.

WAIVER FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance further requires a company to include in its document a report by the auditors of the company with respect to (i) the profits and losses of the company for each of three financial years immediately preceding the issue of the document and (ii) the assets and liabilities of the company of each of the three financial years immediately preceding the issue of the document.

Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance provides that the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from the compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interest of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or would otherwise be unnecessary or inappropriate.

Rule 4.04(1) of the Listing Rules requires that the consolidated results of the issuer and its subsidiaries in respect of each of the three financial years immediately preceding the issue of the listing document be included in the accountants’ report to this document.

Rule 18A.03(3) of the Listing Rules requires that a biotech company must have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management. Rule 18A.06 of the Listing Rules requires that a biotech company must comply with Rule 4.04 of the Listing Rules modified so that references to “three financial years” or “three years” in Rule 4.04 shall instead be references to “two financial years” or “two years”, as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the listing document.

In compliance with the abovementioned requirements under the Listing Rules, the Accountants’ Report is prepared to cover the financial years ended December 31, 2022 and 2023.

As such, the Joint Sponsors have applied, on behalf of our Company, to the SFC for a certificate of exemption from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance regarding the inclusion of the accountants’ report covering the full three financial years immediately preceding the issue of this document on the following grounds:

- (a) our Company is primarily engaged in the research and development, application and commercialization of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [REDACTED] required under Chapter 18A of the Listing Rules;

**WAIVER FROM STRICT COMPLIANCE WITH THE LISTING RULES
AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

- (b) the Accountants' Report for each of the years ended December 31, 2022 and 2023 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (c) given that our Company is only required to disclose its financial results for each of the financial years ended December 31, 2022 and 2023 in accordance with Chapter 18A of the Listing Rules and preparation of the financial results for the year ended December 31, 2021 would require additional work to be performed by our Company and our auditors, strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule would be unduly burdensome for our Company;
- (d) notwithstanding that the financial results set out in this document are only for the financial years ended December 31, 2022 and 2023 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements; and
- (e) the Accountants' Report covering the financial years ended December 31, 2022 and 2023 (as set out in Appendix I to this document), together with other disclosures in this document, has already provided adequate and reasonable up-to-date information in the circumstances for the potential investors to make an informed assessment of the business, assets and liabilities, financial position, management and prospects and to form a view on the track record of our Company. Therefore, the exemption would not prejudice the interest of the investing public.

The SFC [has granted] a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with section 342(1)(b) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the conditions that particulars of the exemption are set out in this document and that this document will be issued on or before [REDACTED].

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Dr. Frank Wu (吳永謙)	Room 107, Building 11 Yueshanju, No. 189 Yanshan Avenue Pukou District Nanjing, Jiangsu Province PRC	American
Mr. Wu Di (吳笛)	1606, Unit 2 Building 8, Jiangyu Cheng No. 56 Wanshou Road Dingshan Street, Pukou District Nanjing, Jiangsu Province PRC	Chinese
Non-executive Directors		
Ms. Jia Zhongxin (賈中新)	19B, Building 12, Bihai Yuntian Qiaocheng East Road, Futian District Shenzhen, Guangdong Province PRC	Chinese
Dr. Yi Hua (易華)	Room 201, No. 2, Lane 830 Huamu Road, Pudong New Area Shanghai PRC	Chinese
Independent non-executive Directors		
Ms. Chui Hoi Yam (徐海音)	House 92-1, Phase 1 Lilai Garden Yutianxia, Tianzhu district Shunyi District Beijing PRC	Chinese
Ms. Zheng Zhelan (鄭哲蘭)	Room 803, Unit 2 Building 1, Huaxin Cheng No. 38 Bashan Road, Jianye District Nanjing, Jiangsu Province PRC	Chinese
Mr. Li Shu Pai (李書泮)	Flat H 10/F Koon Wong Mansion 2-18 Yuen Long On Ning Road Yuen Long Hong Kong	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

SUPERVISORS

Ms. Zhao Weili (趙衛麗)	Room 301, Building 23 No. 8, Yongqiang Road Jiangbei New Area Nanjing, Jiangsu Province PRC	Chinese
Mr. Mei Jianghua (梅江華)	Room 502, No. 68, Lane 1077 Beiai Road, Pudong New Area Shanghai PRC	Chinese
Ms. Pang Yajing (龐亞京)	Room 801, Building 02 Block 14, Tianruncheng Pukou District Nanjing, Jiangsu Province PRC	Chinese

For details with respect to our Directors and Supervisors, please see the section “Directors, Supervisors and Senior Management” in this document.

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

(In no particular order)

CITIC Securities (Hong Kong) Limited

18/F, Pacific Place, 88 Queensway
Hong Kong

Huatai Financial Holdings (Hong Kong) Limited

62nd Floor, The Center, 99 Queen’s Road
Central, Hong Kong

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

Legal Advisors to the Company

As to Hong Kong and U.S. laws:

O'Melveny & Myers

31/F, AIA Central
1 Connaught Road Central
Hong Kong

as to PRC law:

Jia Yuan Law Offices

F408 Ocean Plaza
158 Fuxing Men Nei Street
Xicheng District
Beijing, PRC

**Legal Advisors to the Joint Sponsors
and [REDACTED]**

As to Hong Kong and U.S. laws:

Sidley Austin

39/F, Two Int'l Finance Centre
No. 8 Finance Street
Central, Hong Kong

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

as to PRC law:

Jingtian & Gongcheng

34/F, Tower 3, China Central Place
77 Jianguo Road
Beijing
PRC

Auditors and Reporting Accountants

Ernst & Young

Certified Public Accountants
Registered Public Interest Entity Auditor
27/F, One Taikoo Place
979 King’s Road
Quarry Bay, Hong Kong

Industry Consultant

**Frost & Sullivan (Beijing) Inc., Shanghai
Branch Co.**

2504 Wheelock Square
1717 Nanjing Xi Lu
Jing’an District
Shanghai
PRC

[REDACTED]

CORPORATE INFORMATION

Registered Office	Floor 3, Building 9, Accelerator Phase 2 Biotech and Pharmaceutical Valley Jiangbei New Area, Nanjing Jiangsu Province PRC
Headquarters and Principal Place of Business in the PRC	Floor 3, Building 9, Accelerator Phase 2 Biotech and Pharmaceutical Valley Jiangbei New Area, Nanjing Jiangsu Province PRC
Principal Place of Business in Hong Kong	Room 2609, China Resources Building 26 Harbour Road, Wanchai Hong Kong
Company Website	www.transthera.com <i>(Information contained on this website does not form part of this document)</i>
Joint Company Secretaries	Ms. Feng Jie (馮潔) Floor 3, Building 9, Accelerator Phase 2 Biotech and Pharmaceutical Valley Jiangbei New Area, Nanjing Jiangsu Province PRC Ms. Wong Tik (黃荻) <i>(Member of Hong Kong Institute of Certificate Public Accountants)</i> Room 2609, China Resources Building 26 Harbour Road, Wanchai Hong Kong
Authorized Representatives	Mr. Wu Di (吳笛) 1606, Unit 2 Building 8, Jiangyu Cheng No. 56 Wanshou Road Dingshan Street, Pukou District Nanjing, Jiangsu Province PRC Ms. Wong Tik (黃荻) Room 2609, China Resources Building 26 Harbour Road, Wanchai Hong Kong

CORPORATE INFORMATION

Audit Committee	Mr. Li Shu Pai (李書滸) (Chairman) Ms. Zheng Zhelan (鄭哲蘭) Ms. Jia Zhongxin (賈中新)
Remuneration and Appraisal Committee	Ms. Zheng Zhelan (鄭哲蘭) (Chairman) Ms. Chui Hoi Yam (徐海音) Ms. Jia Zhongxin (賈中新)
Nomination Committee	Ms. Chui Hoi Yam (徐海音) (Chairman) Ms. Zheng Zhelan (鄭哲蘭) Dr. Frank Wu (吳永謙)
Strategy Committee	Dr. Frank Wu (吳永謙) (Chairman) Ms. Chui Hoi Yam (徐海音) Ms. Jia Zhongxin (賈中新)
Compliance Advisor	Central China International Capital Limited Suites 1505-1508, Two Exchange Square 8 Connaught Place, Central Hong Kong

[REDACTED]

Principal Banks	Bank of China Nanjing Gaoxin sub branch Room 101, Building 2 No. 31 Gaoxin Road New and High-tech Industrial Development Zone Pukou, Nanjing, Jiangsu Province PRC Bank of Nanjing Building A, Zhongdan Park Phase I No. 3 Longshan South Road New and High-tech Industrial Development Zone Nanjing, Jiangsu Province PRC
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INDUSTRY OVERVIEW

The information and statistics set out in this section and elsewhere in this document relating to the industry in which we operate were extracted from the Frost & Sullivan Report, which was commissioned by us, and from various official government publications and other publicly available publications. The information from official government sources and other publicly available publications has not been independently verified by us, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], any of their respective directors, employees, agents or advisers or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy, fairness and completeness. For a discussion of the risks relating to our industry, see “Risk Factors.”

SMALL MOLECULE ONCOLOGY TARGETED THERAPY

Overview

A small molecule drug is any organic compound drug with low molecular weight. Small molecule drugs have certain advantages as therapeutics: most can be administered orally and they can pass through cell membranes to reach intracellular targets. They can also be designed to engage biological targets by various modes of action and their distribution can further be tailored, for example, to allow for systemic exposure with or without brain penetration. In addition, small molecule drugs are less complex in structure, which simplifies CMC, manufacturing, delivery and storage, leading to relatively lower costs. As such, small molecule drugs remain the dominant drug modality for the treatment of cancer.

The field of cancer treatment has advanced rapidly in recent decades, progressing from surgery and radiotherapy, to chemotherapy and, more recently, to more advanced treatment options represented by targeted therapies and immunotherapies, with the aim to improve patient outcomes while mitigating systemic adverse effects. The market size of oncology drug is expected to increase from US\$205.1 billion in 2022 to US\$458.6 billion in 2030 globally. In China, driven by favorable policies, increasing affordability for patients and the launching of innovative targeted drugs, the market size of oncology drug is expected to increase from RMB233.6 billion in 2022 to RMB586.6 billion in 2030.

Targeted therapy, by targeting specific oncogenic pathways, can offer patients improved efficacy, reduced symptoms, and/or better quality of life compared with the conventional therapeutic options. In addition to being used as a monotherapy, small molecule targeted therapies have been approved and are being studied in clinical trials for use in combination with several types of therapies, including combination with chemotherapies, other targeted therapies and immunotherapies. The combination of targeted therapy and immunotherapy can generate synergic effects, reversing the immunosuppressive TME, improving the exposure of the targets, thereby leading to enhanced antitumor efficacy. Such combinations have been proven to incur better outcomes in clinical practice. For instance, in a preclinical study, the combination of an MTK inhibitor with an anti-PD-1 antibody induced both significant tumor regression and improved survival in mice with lung tumors. The MTK inhibitor monotherapy or anti-PD-1 antibody monotherapy alone could not achieve such effects.

INDUSTRY OVERVIEW

Therefore, small molecule drugs represent an important modality in cancer treatment. Globally, small molecule drugs occupied five positions in the top ten oncology drugs based on sales revenue in 2022. Similarly, in China, small molecule drugs also claimed five positions in the top ten oncology drugs based on sales revenue in 2022. As of the Latest Practicable Date, the FDA had approved 96 types of novel small molecule oncology targeted drugs, while the NMPA had approved 84 such drugs. From 2018 to 2023, one third of the oncology drugs approved by the FDA and the NMPA are small molecule targeted drugs.

Significant Unmet Medical Needs

- *Drug Resistance.* Despite the improved efficacy of small molecule oncology targeted therapies, one of the key concerns that arises in small molecule oncology targeted therapies is the frequent development of drug resistance of disease progression. Most cancer patients treated with small molecule targeted drugs develop drug resistance gradually, such as the ones targeting FGFR, BTK, EGFR, ALK, and NTRK. Nearly all CCA patients treated with FGFR inhibitors eventually develop drug resistance, emphasizing the urgent need for alternative treatment options in later stages of the disease. Metastatic prostate cancer is initially sensitive to AR antagonists, but eventually will develop resistance to AR antagonists due to lineage plasticity and other mechanisms. For HR+/HER2– breast cancer, after receiving the first-line treatment, including CDK4/6 inhibitors, most patients will eventually develop acquired drug resistance. Therefore, there are significant unmet needs for second-line treatment of these cancer patients.
- *Low Five-Year Survival Rates.* Currently, there is no direct assay for early detection of CCA. Hence, the CCA patients are normally diagnosed at the late stage of cancer with low survival rate. Characterized by its high malignancy, invasive nature, and rapid progression, CCA stands out with a five-year survival rate of approximately 10%, which is significantly lower than the five-year survival rate of all cancer types combined, which is 69% in the U.S.
- *Major Cancer Types with High Incidence and Mortality.* In 2023, breast and prostate cancers ranked as the top two cancers in terms of incidence in the U.S., accounting for the highest number of new cancer cases. Similarly, in China, breast cancer and prostate cancer also ranked among the top ten cancers in terms of incidence, occupying the sixth and ninth positions, respectively. Moreover, breast cancer and prostate cancer were among the top five causes of cancer-related mortality in the U.S. in 2023, with breast cancer ranking fourth and prostate cancer ranking fifth. In China, breast cancer ranked the seventh in terms of mortality.

INDUSTRY OVERVIEW

MTK Inhibitor

A tyrosine kinase is an enzyme that can transfer a phosphate group from ATP to the tyrosine residues of specific proteins inside a cell to produce cell signal transduction resulting in a range of cellular processes. The family of tyrosine kinases encompasses the receptor tyrosine kinase proteins, which contain a transmembrane domain and the non-receptor tyrosine kinases that do not possess transmembrane domains. MTK inhibitor exerts its antitumor activity by simultaneously targeting a wide range of kinases that involved in multiple signaling pathways. MTK inhibitor can potentially overcome drug-resistance mechanisms such as bypass effects generated by single-target therapies, and has advantages in rescue treatment following the failure of single-target treatment. The sales revenues of two blockbuster original MTK inhibitors, cabozantinib (traded by CABOMETYX & COMETRIQ) and lenvatinib (traded by Lenvima), were US\$1.40 billion and US\$1.84 billion in 2022, respectively.

Compared to highly selective kinase inhibitors, MTK inhibitors offer several advantages. They exert antitumor effects by targeting a wide range of kinases simultaneously, enabling them to modulate multiple signaling pathways concurrently. Unlike highly selective kinase inhibitors, MTK inhibitors can address heterogeneous cancers or cancers lacking biomarkers, providing clinical benefits to patients who typically cannot be treated with highly selective kinase inhibitors, such as CCA, mCRPC, HR+/HER2– breast cancer, or BTC. Moreover, MTK inhibitors, by regulating multiple pathways simultaneously, are believed to help overcome drug resistance mechanisms such as bypass effects caused by single-target drugs. Additionally, because a single MTK inhibitor can have multiple functions, it can effectively reduce drug-drug interactions compared to combination therapy involving multiple drugs. The administration of a single drug is also convenient for patients to follow the instruction, and thus enhances patient compliance.

However, developing MTK inhibitors poses challenges due to their multifaceted targeting. Designing MTK inhibitors is complex, making them difficult to drug. Safety concerns are a major issue with MTK inhibitors. Given their extensive inhibition of various kinase targets, off-target side effects are more likely to occur. Furthermore, both desired and undesired targets can be affected by MTK inhibitors, and achieving an effective dose for inhibiting multiple targets without excessive toxicity can be challenging. Therefore, many MTK inhibitors cannot proceed beyond Phase I trial, because they failed to show a favorable balance between the antitumor efficacy and safety. As such, developing MTK inhibitors requires significant expertise and experience in drug development due to these complexities.

INDUSTRY OVERVIEW

Competitive Landscape

As of the Latest Practicable Date, there was one MTK inhibitor targeting FGFR approved by the FDA, which is erdafitinib. As of the Latest Practicable Date, there were three MTK inhibitors targeting FGFR, as well as one or more of JAK, Aurora, and VEGFR at clinical stage. Tinengotinib is a unique MTK inhibitor targeting FGFR/VEGFR, JAK and Aurora, which allows it to be efficacious in CCA, mCRPC, and HR+/HER2– breast cancer. No other MTK inhibitor has demonstrated the same target combination and applications, and thus such drug profile of Tinengotinib is without competing drug candidate.

Global Competitive Landscape of MTK inhibitors Targeting FGFR/VEGFR with JAK or Aurora at Clinical Stage

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date*	Study Locations
Tinengotinib	FGFR, VEGFR, JAK, Aurora	TransThera	Phase III	FGFR-altered advanced or metastatic CCA with prior chemotherapy and FGFR inhibitor treatment	2023-07-17	U.S., South Korea, United Kingdom, eight countries in EU and Taiwan
			Phase II			
			Phase I/II	mCRPC	2024-06-13	U.S.
			Phase I/II	HER2-negative breast cancer, mCRPC, gastric cancer and other solid tumor	2021-02-08	U.S.
			Phase I/II		2021-11-08	China
			Phase I/II		Combination with atezolizumab in the treatment of biliary tract cancer	2022-02-23
AL8326	AURKB, VEGFR, FGFR	Advenchen	Phase III	Small cell lung cancer	2023-10-20	China
MAX-40279-01	FGFR, HPK1, FLT3, VEGF, PDGF, JAK	MaxiNovel Technology Co., Ltd	Phase II	Small cell lung cancer	2022-05-05	U.S.
			Phase II	Advanced colorectal cancer	2021-11-29	China
			Phase II	Advanced gastric cancer and gastroesophageal junctional carcinoma	2022-02-16	China
			Phase I/II	Combination with KN-046 in the treatment of advanced and metastatic solid tumor	2022-04-11	China
			Phase I/II	Myelodysplastic syndrome, relapsed/refractory acute myeloid leukemia	2021-06-02	China

Source: CDE, ClinicalTrials.gov, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Major Indications of MTK Inhibitors

CCA

Biliary tract cancers are a common type of hepatobiliary cancer globally, typically consisting of CCAs and GBCs. CCA, also known as bile duct cancer, is a disease in which malignant cells form in the bile ducts, the branched tubes that connect the liver and gallbladder to the small intestine. Common signs of bile duct cancer include jaundice, fatigue and pain in the abdomen, and the risk factors of CCA usually point to a common role of chronic biliary inflammation in CCA development. Depending on their sites of origin, CCA can be categorized into intrahepatic and extrahepatic CCA, abbreviated as iCCA and eCCA, respectively, with the later further divided into perihilar and distal CCA, abbreviated as pCCA and dCCA, respectively. According to Frost & Sullivan, iCCA is sometimes misdiagnosed as hepatocellular carcinoma, especially when diagnosed using contrast-enhanced ultrasound, and the mis-diagnosis rate can be high. Almost all CCA patients developed acquired drug resistance after receiving treatment of an FGFR inhibitor.

The global CCA drug market size reached US\$1.3 billion in 2022, with a CAGR of 10.5% from 2018 to 2022. It is projected to grow to US\$3.1 billion in 2026, with a CAGR of 22.9% from 2022 to 2026, and further increase to US\$5.4 billion in 2030, with a CAGR of 15.1% from 2026 to 2030. China’s CCA drug market size reached RMB2.0 billion in 2022, with a CAGR of 8.3% from 2018 to 2022, and is expected to further grow to RMB5.5 billion and RMB10.6 billion in 2026 and 2030, respectively.

Globally, the incidence of CCA increased from 234.9 thousand in 2018 to 280.0 thousand in 2023, representing a CAGR of 3.6%. It is projected to increase to 310.7 thousand and 354.9 thousand in 2026 and 2030, respectively, representing a CAGR of 3.5% from 2023 to 2026 and a CAGR of 3.4% from 2026 to 2030. The incidence of CCA in China increased from 92.2 thousand in 2018 to 104.1 thousand in 2023, representing a CAGR of 2.5%. The number is expected to reach 111.6 thousand and 121.6 thousand in 2026 and 2030, respectively, representing a CAGR of 2.4% from 2023 to 2026 and a CAGR of 2.2% from 2026 to 2030. The following charts set forth the incidence of CCA globally and in China from 2018 to 2030:

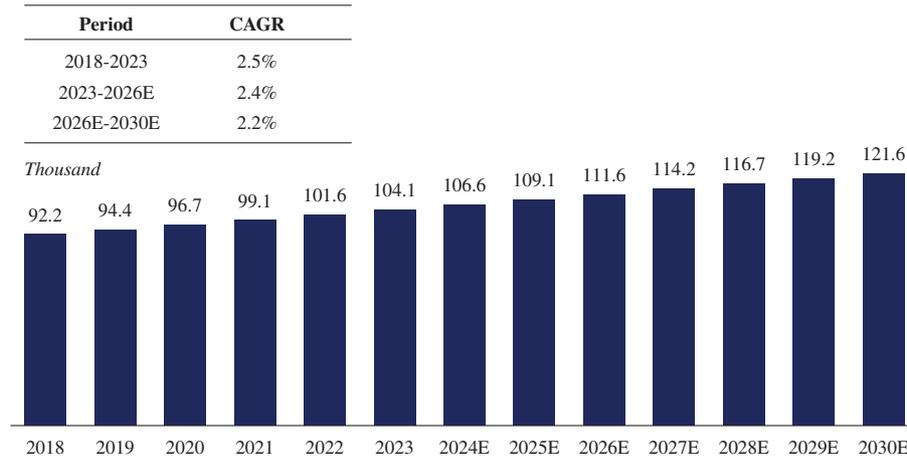
Global Incidence of CCA, 2018-2030E



Source: IARC, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Incidence of CCA in China, 2018-2030E



Source: NCCR, Frost & Sullivan Analysis

CCA is an aggressive type of tumor that can progress rapidly and become fatal due to invasion across all body areas if treatment is not administered at an early stage. Currently, CCA is considered incurable unless fully resected during early-stage through surgery. Nevertheless, CCA is frequently diagnosed at an advanced, unresectable stage because of the late presentation of obvious clinical symptoms of the disease and the lack of effective screening modalities. As such, in the U.S., the five-year survival rate for CCA is approximately 10%, which is lower than the five-year survival rate of all cancer types combined at 69%.

Current Treatment and Limitations

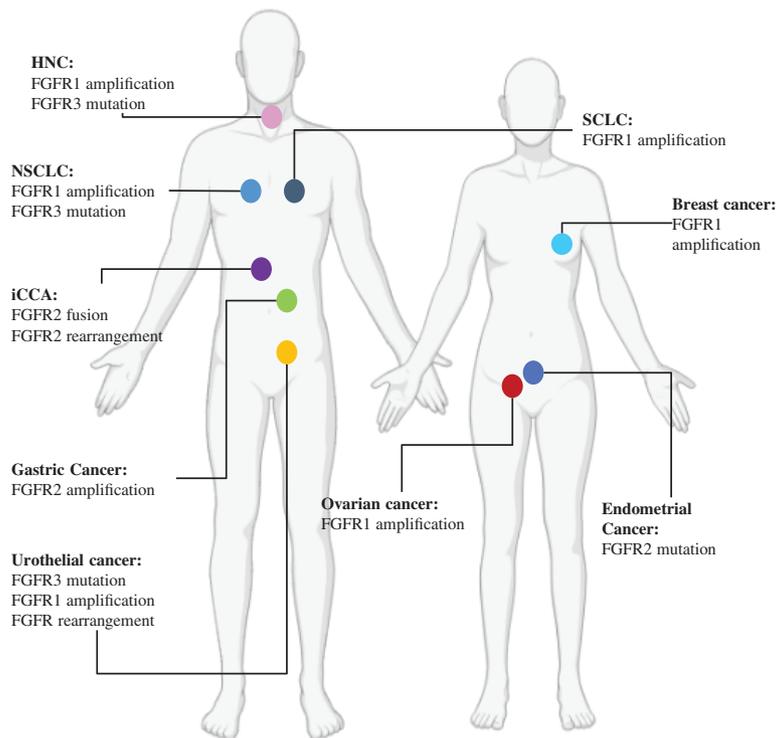
In the U.S. and China, surgery is the preferred choice for eligible patients in all types of CCA, facilitated by neo-adjuvant therapy or other pre-operative procedures to achieve surgical eligibility. Liver transplant was also considered an ideal treatment option for CCA. However, due to difficulty in finding well-matched organs, the treatment was no longer a preferred treatment. For late stage CCA with advanced/metastatic disease, immune checkpoint inhibitor in combination with chemotherapy of gemcitabine and cisplatin is currently the preferred treatment in the first-line setting. Targeted therapies are useful when patients qualify for genetic testing of FGFR2, NTRK, MSI-H/dMMR, and IDH1, providing more precise treatment options. The safety and efficacy of FGFR inhibitors (pemigatinib and futibatinib) approved for the second-line treatment of advanced/metastatic CCA have been validated in early studies. In particular, in the U.S. and China, the pricing (cost) of pemigatinib is US\$19,759 and RMB66,547 per 21-day treatment cycle, respectively, while the pricing (cost) of futibatinib is US\$27,492 per month in the U.S. However, there is no recommended treatment for CCA in the third-line setting.

INDUSTRY OVERVIEW

FGFR Inhibitor

FGFR is a family of highly homologous receptors that includes four subtypes, FGFR 1 to 4. The FGFR signals regulate a wide range of fundamental biological processes, including tissue development and regeneration, and their dysfunction is thought to be one of the causes of cancer development. FGFR alteration is prevalent in solid tumor patients, accounting for approximately 7.1% of all solid tumor patients. FGFR alteration was observed in multiple cancers, including urothelial cancer, CCA, endometrial cancer and breast cancer.

FGFR alterations include (1) gene amplification, referring to an increase in the number of copies of a gene without proportional increase in other genes; (2) gene point mutation, referring to a change in single nucleotide of DNA; and (3) gene fusion and rearrangement, referring to chromosomal abnormality that hybridizes two or more genes. For example, FGFR1 amplification can be observed in breast cancer, while FGFR2 fusion or rearrangement can be found in iCCA. The following diagram exemplifies FGFR alterations in certain solid tumor patients:



Abbreviations: HNC=head and neck cancer, NSCLC=non-small cell lung cancer, SCLC=small cell lung cancer, iCCA=intrahepatic cholangiocarcinoma.

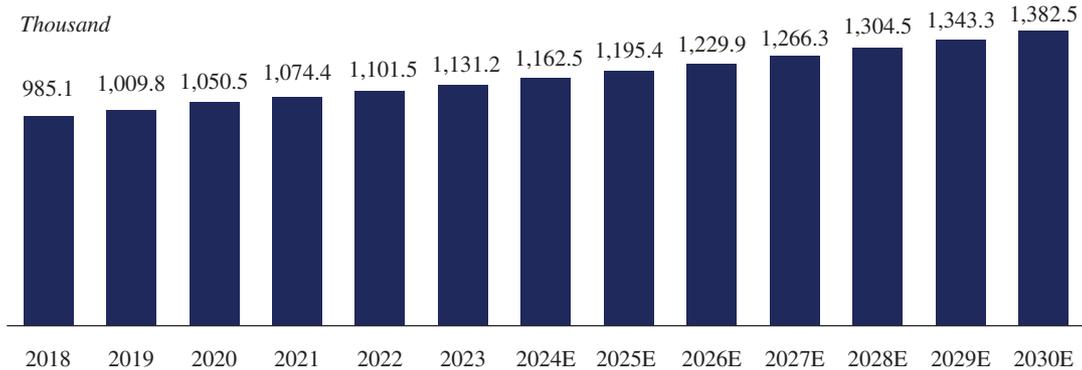
Source: Literature Review, Frost & Sullivan Analysis

The annual global incidence of major tumor types with FGFR alteration grew from 985.1 thousand in 2018 to 1,131.2 thousand in 2023, representing a CAGR of 2.8% from 2018 to 2023. It is expected to grow to 1,229.9 thousand in 2026 and 1,382.5 thousand in 2030, with a CAGR of 2.8% from 2023 to 2026 and a CAGR of 3.0% from 2026 to 2030. The annual incidence of major tumor types with FGFR alteration in China grew from 379.2 thousand in 2018 to 430.2 thousand in 2023, representing a CAGR of 2.6% from 2018 to 2023. The number is expected to grow to 462.4 thousand in 2026 and 504.7 thousand in 2030, with a CAGR of 2.4% from 2023 to 2026 and a CAGR of 2.2% from 2026 to 2030. These major tumor types include urothelial cancer, CCA, endometrium cancer, gastric cancer, breast cancer, and colorectal cancer.

INDUSTRY OVERVIEW

Global Incidence of Major Tumor Types with FGFR Alteration, 2018-2030E

Period	CAGR
2018-2023	2.8%
2023-2026E	2.8%
2026E-2030E	3.0%

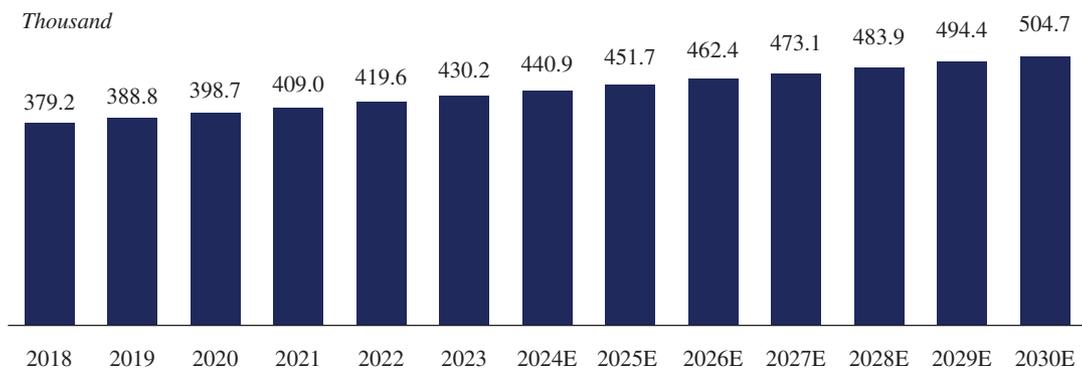


Note: One article, “The FGFR Landscape in Cancer: Analysis of 4,853 Tumors by Next-Generation Sequencing,” analyzed frequencies of FGFR aberrations in 4,853 solid tumors, including more than 15 types of cancer, such as urothelial cancer (32%), breast cancer (18%), endometrial cancer (13%), gastric cancer (7%), and colorectal cancer (4.4%). Another article, “Cholangiocarcinoma With FGFR Genetic Aberrations: A Unique Clinical Phenotype” mentioned around 25.2% of CCA patients are identified with FGFR aberrations. The global incidence of major tumor types with FGFR alteration is calculated based on these data.

Source: IARC, Frost & Sullivan Analysis

Incidence of Major Tumor Types with FGFR Alteration in China, 2018-2030E

Period	CAGR
2018-2023	2.6%
2023-2026E	2.4%
2026E-2030E	2.2%



Note: One article, “Landscape of FGF/FGFR Alterations in 12,372 Chinese Cancer Patients,” analyzed frequencies of FGFR aberrations in 12,372 solid tumors, including 20 types of cancer, such as urothelial cancer (30.5%), endometrium cancer (16.9%), gastric cancer (13.3%), breast cancer (13.2%), and colorectal cancer (10.2%). Another article, “Cholangiocarcinoma With FGFR Genetic Aberrations: A Unique Clinical Phenotype,” mentioned around 25.2% of CCA patients are identified with FGFR aberrations. The incidence of major tumor types with FGFR alteration in China is calculated based on these data.

Source: NCCR, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Drug Resistance to Existing FGFR Inhibitors

After receiving FGFR inhibitor treatment, acquired resistance will develop due to alterations of target genes (including mutation, amplification, and signal activation) generated gradually during the treatment process, leading to cancer relapse and progression. For acquired resistance, point mutations, gene fusion, and rearrangement lead to conformational changes on targets (such as proteins), which diminish the affinity between ligand and receptor. The amplification of target-encoding gene copy number results in an increase in target quantity and restoration of the tumor signaling pathway, leading to the reduction or even elimination of drug efficacy. Restoration of the tumor signaling cascade can also be achieved by mutation-driven activation of downstream or bypass signaling pathways, thereby causing tumor progression and drug resistance.

FGFR alteration is the main driver of drug resistance in various cancers, including but not limited to CCA, breast cancer, urothelial cancer, and endometrial cancer. In fact, almost all patients previously treated with FGFR inhibitors may automatically develop acquired resistance to FGFR inhibitors. Therefore, drug resistance has emerged as a limiting factor to the efficacy of FGFR-targeted therapies. Specifically, for FGFR2 acquired drug resistance, it is mainly caused by polyclonal mutations at one or more of V564F, N549K, and C491S, any of which can lead to a reduction or loss of affinity between the inhibitor and FGFR2 at the binding site. Because CCA patients may harbor more than one of these mutations, it is challenging to develop effective therapies to address all the mutations simultaneously. For example, patients with metastatic CCA harboring FGFR2 alterations demonstrated disease progression after FGFR inhibitor treatment, such as pemigatinib.

Therefore, with the expanded application of existing FGFR inhibitors, there is an increasing demand for innovative FGFR inhibitors to address acquired resistance to FGFR inhibitors. Therefore, innovative therapies are in great demand to address these urgent unmet medical needs.

Competitive Landscape

As of the Latest Practicable Date, the FDA had approved three FGFR inhibitors for the treatment of CCA i.e. futibatinib, infigratinib and pemigatinib, and one FGFR inhibitor for the treatment of urothelial cancer, i.e. erdafitinib. On May 16, 2024, the FDA announced the final withdrawal of the approval of infigratinib for previously treated, unresectable locally advanced or metastatic CCA with a FGFR2 fusion or other rearrangement. The NMPA approved pemigatinib for the treatment of CCA. However, none of these approved drugs are capable of overcoming FGFR drug resistance.

As of the Latest Practicable Date, there were four FGFR inhibitors in clinical development globally for CCA that had progressed on prior FGFR inhibitor treatment, along with two FGFR inhibitors in clinical development for CCA that had progressed on prior FGFR inhibitor treatment in China. On a global scale, as of the Latest Practicable Date, Tinengotinib stood out as the only drug candidate in registrational stage for treating CCA that has progressed on the prior FGFR inhibitor treatment in China.

INDUSTRY OVERVIEW

Global Competitive Landscape of FGFR Inhibitors for CCA Progressed on Prior FGFR Inhibitor Treatment At Clinical Stage

Drug Name	Target	Company	Clinical Stage	Indications	First Posted Date	Study Locations
Tinengotinib	FGFR, VEGFR, JAK2, Aurora	TransThera	Phase III	FGFR-altered advanced or metastatic CCA with prior chemotherapy or FGFR inhibitor treatment	2023-07-17	U.S., South Korea, United Kingdom, eight countries in EU and Taiwan
			Phase II	FGFR-altered advanced or metastatic CCA with prior chemotherapy or FGFR inhibitor treatment	2023-09-22	China
RLY-4008	FGFR2	Relay Therapeutics, Inc.	Phase I/II	Unresectable or metastatic iCCA and other advanced solid tumors	2020-08-25	U.S., Australia, France, Germany and other countries and regions
TYRA-200	FGFR1/2/3	Tyra Biosciences, Inc.	Phase I	Unresectable locally advanced or metastatic iCCA and other advanced solid tumors with activating FGFR2 gene alterations	2023-12-07	U.S.
ABSK121-NX	FGFR1/2/3	Abbisko Therapeutics Co, Ltd	Phase I	Urothelial carcinoma, intrahepatic cholangiocarcinoma and other solid tumor	2022-11-25	U.S.
				Urothelial carcinoma, intrahepatic cholangiocarcinoma and other solid tumor	2023-04-19	China

Source: CDE, ClinicalTrials.gov, Frost & Sullivan Analysis

mCRPC

Prostate cancer is an epithelial malignant tumor that occurs in the prostate. It is the most common malignant tumor in the male genitourinary system, and it mostly occurs among people over 65 years of age. Prostate cancer progresses slowly and is usually asymptomatic at the early stage. If prostate cancer spreads beyond the prostate, it is called “metastatic”. Once metastasis or migration of prostate cancer occurs, the condition of the patients will get worse. mCRPC is a form of advanced prostate cancer. It is defined by disease progression despite ADT, and/or the appearance of new metastases. Testosterone measurement is important as androgens are the drivers of activity of the AR. Maintenance of castrate testosterone levels required in mCRPC is a key factor for intermittent and continuous ADT. For mCRPC, some prostate tumors are aggressive and have a tendency to metastasize to other organs because the tumor stops responding to hormone therapy, thus enhancing the refractory and lethal nature of the disease. mCRPC is the leading cause of death from prostate cancer. Patients with mCRPC have a poor prognosis and a five-year survival rate of less than 30% globally.

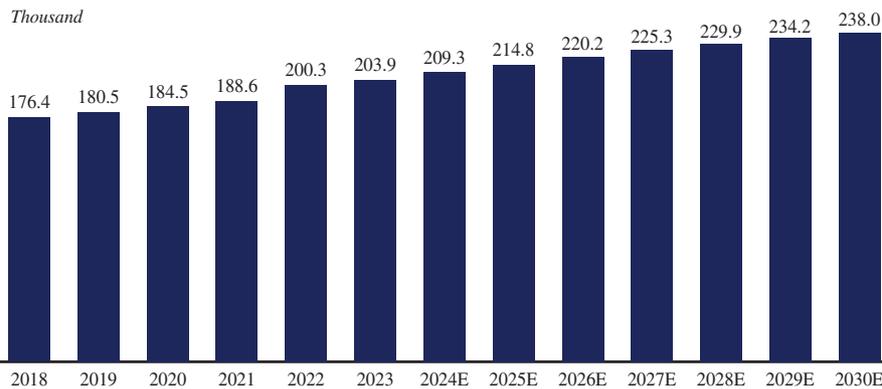
INDUSTRY OVERVIEW

The global prostate cancer drug market size reached US\$15.9 billion in 2022, with a CAGR of 7.9% from 2018 to 2022. It is expected to reach US\$23.5 billion in 2026, with a CAGR of 10.2% from 2022 to 2026, and further increase to US\$45.9 billion in 2030, with a CAGR of 18.2% from 2026 to 2030. China’s prostate cancer drug market size reached RMB8.2 billion in 2022, with a CAGR of 19.7% from 2018 to 2022. It is expected to increase to RMB24.2 billion in 2026 and RMB54.1 billion 2030, with respective CAGRs of 31.0% from 2022 to 2026 and 22.3% from 2026 to 2030.

With an aging population, the global incidence of mCRPC increased from 176.4 thousand in 2018 to 203.9 thousand in 2023. It is expected to grow to 220.2 thousand in 2026 and further to 238.0 thousand in 2030. In China, due to the change in dietary habit to high protein and high fat in recent years, the risks of having prostate cancer are increasing. Nevertheless, the diagnosis rate is relatively low due to the insufficient awareness and attention to this disease as well as no obvious specific symptoms in the early stage. The incidence of mCRPC in China increased from 42.8 thousand in 2018 to 50.5 thousand in 2023. The number is expected to grow to 57.3 thousand in 2026 and further reach 67.1 thousand in 2030.

Global Incidence of mCRPC, 2018-2030E

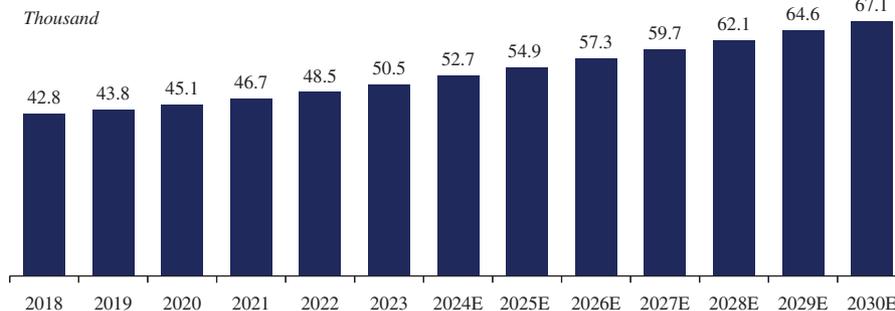
Period	CAGR
2018-2023	2.9%
2023-2026E	2.6%
2026E-2030E	2.0%



Source: IARC, Frost & Sullivan Analysis

Incidence of mCRPC in China, 2018-2030E

Period	CAGR
2018-2023	3.4%
2023-2026E	4.3%
2026E-2030E	4.1%

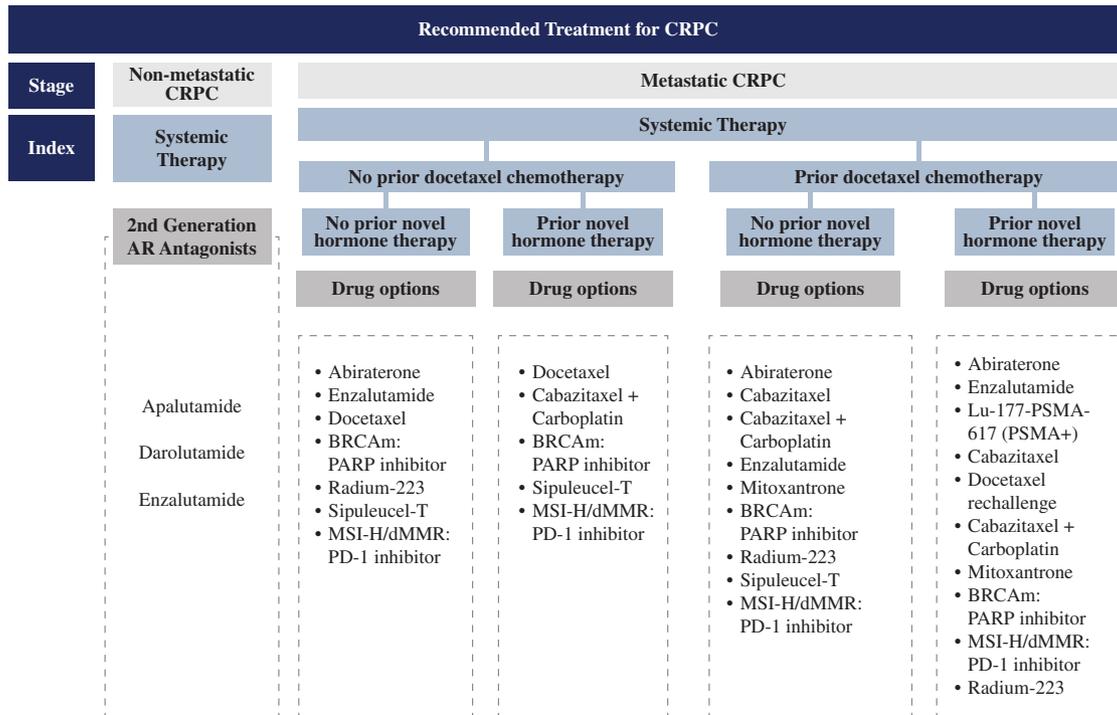


Source: NCCN, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Currently, in both U.S. and China, the main treatment options for mCRPC patients include, the second-generation AR antagonists (enzalutamide), androgen biosynthesis inhibitor (abiraterone), cytotoxic chemotherapy (docetaxel and prednisone), and immunotherapy (sipuleucel-T). To further enhance the therapeutic effects, future studies on mCRPC need to focus on a deeper understanding of the molecular mechanism of mCRPC, as well as the exploration of relevant targets in order to address the resistance issues.

Treatment Paradigm of CRPC in the U.S. and China



Source: CSCO2023, NCCN2024 V3, Frost & Sullivan analysis

HER2– Breast Cancer

Breast cancer is the most common cancer in women, with its incidence increasing year by year. Developed from breast tissue, breast cancer may present as a lump in the breast, a change in breast shape, dimpling of the skin, fluid coming from the nipple, a newly inverted nipple, or a red or scaly patch of skin. New cases of breast cancer around the world increased from 2,088.8 thousand to 2,408.0 thousand from 2018 to 2023. The number is expected to grow to 2,624.4 thousand in 2026 and further to 2,995.4 thousand in 2030. New cases of breast cancer in China increased from 321.1 thousand to 365.1 thousand from 2018 to 2023. The number is expected to grow to 390.3 thousand in 2026 and reach 421.9 thousand in 2030.

Breast cancer classification divides breast cancer into categories according to different gene expression and receptor status. Among all the different kinds of receptors in breast cancer cells, the three most important classifications are the ER and PR, and HER2. ER and PR are termed as HR. Cancer cells with none of these receptors are called basal-like or TNBC. HER2–breast cancer accounts for approximately 80% of the total breast cancer population globally, and TNBC, a subtype of HER2– breast cancer, accounts for approximately 15% of the total breast cancer population globally.

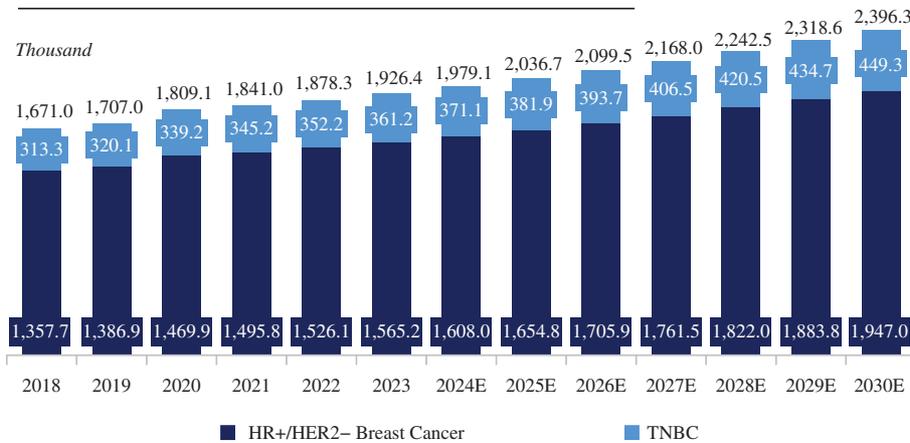
The global breast cancer drug market size reached US\$35.6 billion in 2022, with a CAGR of 7.4% from 2018 to 2022. It is expected to reach US\$48.2 billion in 2026 and US\$64.9 billion in 2030, with a CAGR of 7.9% from 2022 to 2026 and a CAGR of 7.7% from 2026 to 2030. China’s breast cancer drug market size reached RMB54.8 billion in 2022, with a CAGR of 8.1% from 2018 to 2022. The market size is expected to increase to RMB81.2 billion and RMB114.4 billion in 2026 and 2030, respectively.

INDUSTRY OVERVIEW

The global incidence of HER2– breast cancer increased from 1,671.1 thousand in 2018 to 1,926.4 thousand in 2023. It is projected to reach 2,099.5 thousand in 2026 and 2,396.3 thousand in 2030. The incidence of HER2– breast cancer in China rose from 256.9 thousand in 2018 to 292.1 thousand in 2023. It is projected to further increase to 312.2 thousand in 2026 and 337.5 thousand in 2030. The majority of the HER2– breast cancers are HR+/HER2– breast cancer, while TNBC represents a significant portion of the HER2– breast cancer cases and cannot be overlooked.

Global Incidence of HER2– Breast Cancer, 2018-2030E

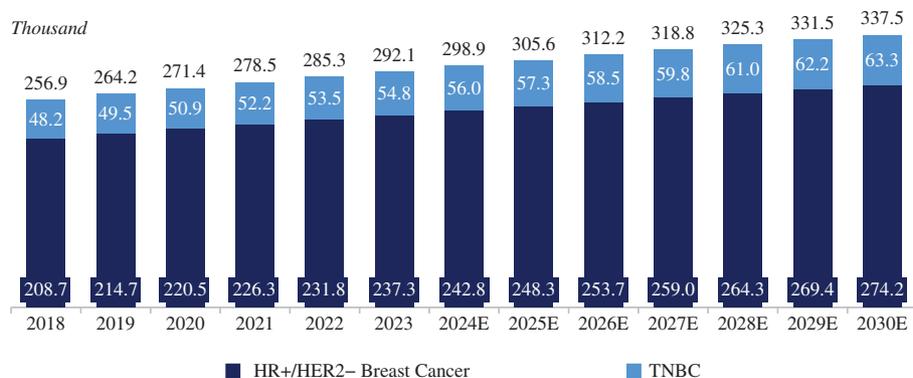
CAGR	HR+/HER2– Breast Cancer	TNBC	HER2– Breast Cancer
2018-2023	2.9%	2.9%	2.9%
2023-2026E	2.9%	2.9%	2.9%
2026E-2030E	3.4%	3.4%	3.4%



Source: NCCR, Frost & Sullivan Analysis

Incidence of HER2– Breast Cancer in China, 2018-2030E

CAGR	HR+/HER2– Breast Cancer	TNBC	HER2– Breast Cancer
2018-2023	2.6%	2.6%	2.6%
2023-2026E	2.2%	2.2%	2.2%
2026E-2030E	2.0%	2.0%	2.0%



Source: NCCR, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

In the U.S. and China, according to the treatment guidelines of breast cancer, the basic therapy of breast cancer is systemic therapies. Once disease progresses, multiple targeted drugs or non-specific drugs are available. For advanced HR+/HER2– breast cancer, hormone therapy and chemotherapy are the main treatments. AI combined with CDK4/6 inhibitors is recommended as the first-line standard treatment. When CDK4/6 inhibitors are not available, single-agent hormone therapy, such as fulvestrant, AI, and estrogen receptor modulators, is also feasible. For HR+/HER2– patients resistant to endocrine therapy, single-agent chemotherapy or combined chemotherapy is recommended. The main chemotherapy drugs include anthracyclines (doxorubicin or liposomal doxorubicin), taxanes (paclitaxel), anti-metabolites (capecitabine or gemcitabine), and microtubule inhibitors (vinorelbine or eribulin).

Treatment Paradigm of Advanced HR+/HER2– Breast Cancer in the U.S. and China

	Chemotherapy options: HER2- with visceral crisis or endocrine refractory	Systematic therapy options: HR+ with HER2- and no visceral crisis
Preferred options	<ul style="list-style-type: none"> • Anthracyclines • Taxanes • Anti-metabolites • Microtubule inhibitors 	<ul style="list-style-type: none"> • First-line options: <ul style="list-style-type: none"> • Aromatase inhibitor with CDK4/6 inhibitor • Fulvestrant with CDK4/6 inhibitor • Second-line and next-line options: <ul style="list-style-type: none"> • Fulvestrant with CDK4/6 inhibitor if CDK4/6 inhibitor not used before • PIK3CA inhibitor with Fulvestrant • Aromatase inhibitor with mTOR inhibitor • Aromatase inhibitor with HDAC inhibitor (CSCO recommends)
Other recommended	<ul style="list-style-type: none"> • Chemotherapy options 	<ul style="list-style-type: none"> • Aromatase inhibitor • Selective estrogen receptor down-regulator • Selective estrogen receptor modulator
Used in some cases	<ul style="list-style-type: none"> • Combination chemotherapy options 	<ul style="list-style-type: none"> • Progestogens • Estrogen • NTRK fusion-positive: NTRK inhibitor • MSI-H/dMMR: PD-1 inhibitor • TMB-H: PD-1 inhibitor • RET fusion-positive: RET inhibitor

In addition to patients initially diagnosed with TNBC, some HR+/HER2– breast cancers are found to be transformed into TNBC after receiving treatment of CDK4/6 inhibitor. For TNBC patients, chemotherapy is the current primary treatment option. In addition, for PD-L1-positive TNBC patients, the NCCN and CSCO guidelines recommend chemotherapy combined with PD-1 inhibitors. Besides, the ADC drugs, sacituzumab govitecan-hziy and T-DXd, are also recommended for the treatment of TNBC.

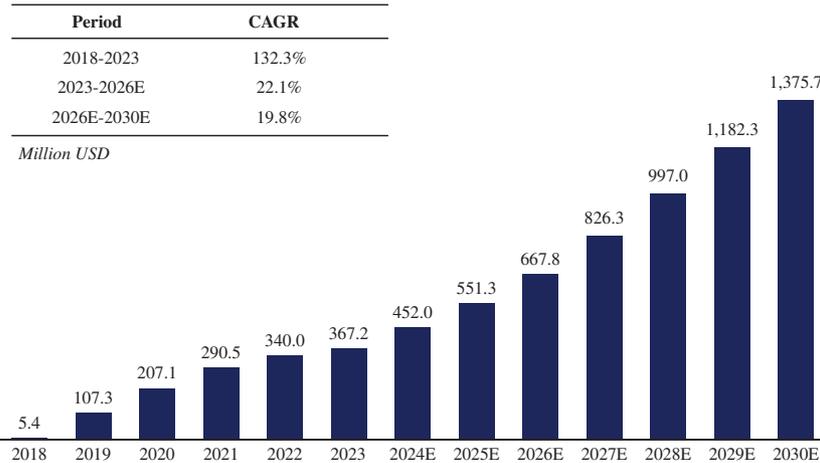
AXL/FLT3 Inhibitor

AXL, a member of the Tyro3 receptor tyrosine kinase family, represents an independent prognostic marker and therapeutic target in AML. AML cells induce expression and secretion of the AXL ligand Gas6 by bone marrow-derived stromal cells. Gas6 in turn mediates proliferation, survival, and chemoresistance of AXL-expressing AML cells. AXL inhibition is active in both FLT3 wild-type and mutated AML, improves clinically relevant endpoints, and its efficacy depends on presence of Gas6 and AXL.

INDUSTRY OVERVIEW

The global AXL/FLT3 Inhibitor market size reached US\$367.2 million in 2023, with a CAGR of 132.3% from 2018 to 2023. It is expected to reach US\$667.8 million in 2026 and US\$1,375.7 million in 2030, with a CAGR of 22.1% from 2023 to 2026 and a CAGR of 19.8% from 2026 to 2030.

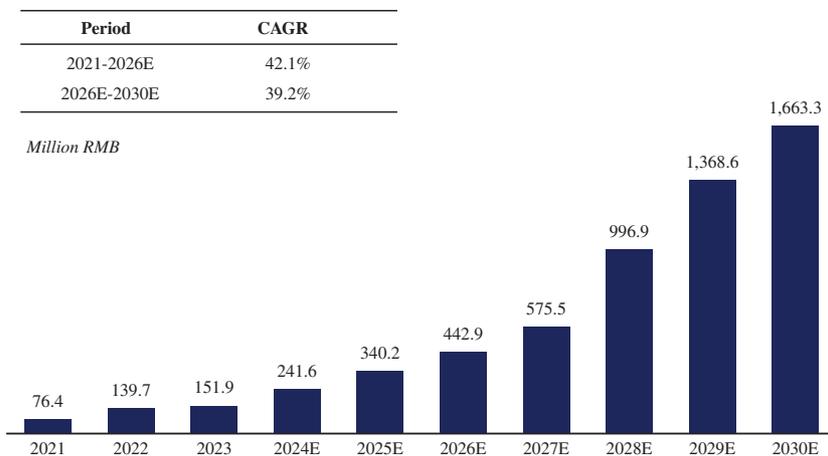
Historical and Forecasted Global AXL/FLT3 Inhibitor Market Size, 2018-2030E



Source: Frost & Sullivan Analysis

With the first AXL/FLT3 inhibitor, gilteritinib, approved by the NMPA in 2021, China’s AXL/FLT3 inhibitor market size is projected to reach RMB442.9 million in 2026, with a CAGR of 42.1% from 2021 to 2026. It is projected to increase to RMB1,663.3 million in 2030, with a CAGR of 39.2% from 2026 to 2030.

Historical and Forecasted China AXL/FLT3 Inhibitor Market Size, 2021-2030E



Source: Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Competitive Landscape

As of the Latest Practicable Date, there was only one AXL/FLT3 inhibitor, i.e. gilteritinib by Astellas Pharma, which was approved by the FDA in 2018 and the NMPA in 2021 for AML. There was no AXL inhibitor approved for the treatment of solid tumor. As of the Latest Practicable Date, there were six AXL inhibitors indicated for solid tumor at clinical stage globally, and three AXL inhibitors in the clinical stage indicated for solid tumor in China.

Global Competitive Landscape of AXL Inhibitors Indicated for Solid Tumor at Clinical Stage

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
BGB324	AXL	BerGenBio ASA/Merck Sharp & Dohme LLC	Phase II	Advanced adenocarcinoma of the lung	2017-06-12
XZB-0004/ SLC-391	AXL	SignalChem Lifesciences Corporation/Xuanzhu Biopharmaceutical Co., Ltd.	Phase I/II	Advanced or metastatic non-small cell lung cancer	2023-05-16
TT-00973	AXL/FLT3	TransThera	Phase I	Advanced solid tumor	2023-01-06
AB801	AXL	Arcus Biosciences, Inc.	Phase I	Advanced solid tumor	2023-11-07
FC084	AXL	FindCure Biosciences Co., Ltd.	Phase I	Advanced solid tumor	2024-01-30
TP-0903	AXL	Sumitomo Pharma Oncology, Inc.	Phase I	Advanced solid tumor	2016-04-06

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of AXL Inhibitors Indicated for Solid Tumor at Clinical Stage in China

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
TT-00973	AXL/FLT3	TransThera	Phase I	Solid tumor	2022-11-10
XZB-0004/ SLC-391	AXL	Xuanzhu Biopharmaceutical Co., Ltd./SignalChem Lifesciences Corporation	Phase I	Solid tumor	2023-02-24
FC084	AXL	FindCure Biosciences Co., Ltd.	Phase I	Solid tumor	2023-02-23

Source: CDE, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

BTK Inhibitor

BTK is a key component of the B-cell receptor signaling pathway and is an important regulator of cell proliferation and cell survival in various lymphomas. BTK inhibitors block B-cell receptor, or BCR, induced BTK activation and its downstream signaling, leading to growth inhibition and cell death in B-cells.

Covalent BTK inhibitors are BTK inhibitors that form covalent bond to BTK protein. It is irreversible due to the feature of existing a “war-head.” Noncovalent BTK inhibitors are reversible BTK inhibitors that bind to the BTK protein through other molecular interactions without forming a covalent bond. For instance, covalent BTK inhibitors can form a covalent bond with the C481 site of BTK. However, when C481S mutation occurs, they will not be able to maintain the covalent bond, leading to drug resistance. In contrast, noncovalent BTK inhibitors can bind to BTK without the facilitation of C481 residue, therefore are able to inhibit BTK even in the presence of C481S mutation, and then avoid drug resistance.

In addition to the high potency to overcome C481S mutation of drug acquired resistance, reversible BTK inhibitors, which do not have a reactive “war-head”, tend to have higher selectivity and potentially avoid off-target side effects.

	Covalent	Non-covalent
Definition	<ul style="list-style-type: none"> • BTK inhibitors that form covalent bond to BTK protein. • Irreversible due to the feature of covalent bond. 	<ul style="list-style-type: none"> • BTK inhibitors that bind to BTK protein with other molecular interactions such as hydrogen bond. • Reversible
Drug Resistance	<ul style="list-style-type: none"> • Covalent BTK inhibitors can form a covalent bond with the C481 site of BTK, however it was found that when C481S mutation occurs, the BTK inhibitor cannot maintain the covalent bond, leading to drug resistance. 	<ul style="list-style-type: none"> • Non-covalent BTK inhibitors do not bind with C481 residue, thereby can inhibit BTK even in the presence of C481S mutation.
Efficacy	<ul style="list-style-type: none"> • Due to the feature of covalent bonds, the stability of covalent bond is much higher than non-covalent molecular interaction. Therefore, covalent BTK inhibitors take rapid effect with lower IC₅₀ value. 	<ul style="list-style-type: none"> • By inhibiting B-cell activation and downstream survival signaling pathways, non-covalent agents inhibit the proliferation of B-cell tumors with high expression of BTK. Thus, these agents have respectable efficacy.
Adverse Effect	<ul style="list-style-type: none"> • As covalent binding are too stable that hardly to break, irreversible inhibition of multiple pathway lead to adverse effect. 	<ul style="list-style-type: none"> • Non-covalent BTK inhibitors have higher selectivity. Thus, it has better safety profiles compared with covalent agents.

Source: Frost & Sullivan Analysis

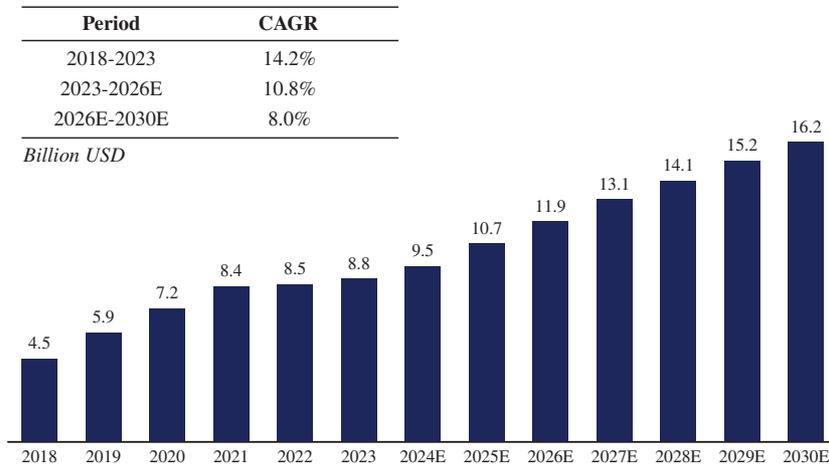
As of the Latest Practicable Date, except for pirtobrutinib, all BTK inhibitors approved by the FDA or the NMPA were covalent irreversible BTK inhibitors, which underscores the medical needs for noncovalent reversible BTK inhibitors, given the large medical needs.

INDUSTRY OVERVIEW

Market Size

The global BTK inhibitor market size increased from US\$4.5 billion in 2018 to US\$8.8 billion in 2023, with a CAGR of 14.2% from 2018 to 2023. It is expected to reach US\$11.9 billion in 2026 and US\$16.2 billion in 2030, with a CAGR of 10.8% from 2023 to 2026 and a CAGR of 8.0% from 2026 to 2030.

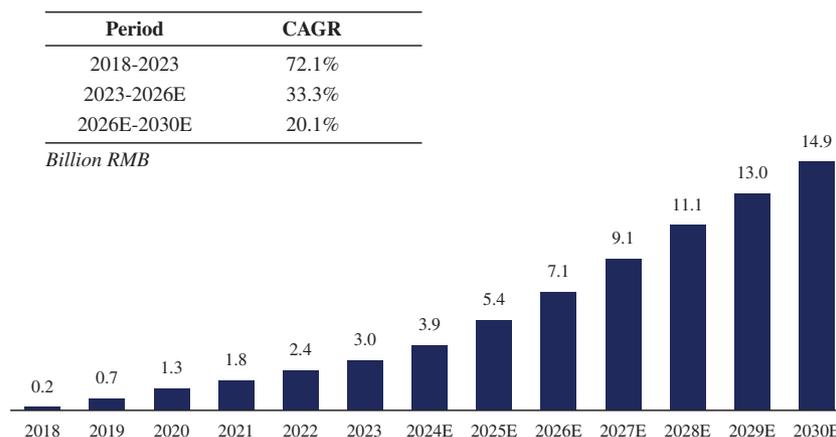
Historical and Forecasted Global BTK Inhibitor Market Size, 2018-2030E



Source: Frost & Sullivan Analysis

After the first BTK inhibitor, which was a covalent BTK inhibitor, was approved in China in 2017, the BTK inhibitor market in China increased rapidly. China’s BTK inhibitor market size reached RMB3.0 billion in 2023, with a CAGR of 72.1% from 2018 to 2023. It is expected to grow to RMB7.1 billion and further to RMB14.9 billion in 2026 and 2030, respectively, representing a CAGR of 33.3% from 2023 to 2026 and a CAGR of 20.1% from 2026 to 2030.

Historical and Forecasted China BTK Inhibitor Market Size, 2018-2030E



Source: Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Competitive Landscape

As of the Latest Practicable Date, there were four BTK inhibitors approved by the FDA, and four BTK inhibitors approved by the NMPA, among which only pirtobrutinib was a noncovalent reversible BTK inhibitor.

As of the Latest Practicable Date, there were six non-covalent reversible BTK inhibitors under development for the treatment of hematological malignancies globally. The following table illustrates the noncovalent reversible BTK inhibitors for cancer treatment that were at clinical stage globally as of the Latest Practicable Date:

Global Competitive Landscape of Noncovalent Reversible BTK Inhibitors for Cancer Treatment at Clinical Stage

Drug Name	Target	Molecular feature	Company	Clinical Stage	Indications	First Posted Date
ARQ-531	BTK	Noncovalent; Reversible	MSD	Phase III	CLL, SLL	2022-11-22
LP-168	BTK	Noncovalent; Reversible and Covalent; Irreversible	Lupeng Pharmaceutical Company LTD.	Phase II	MCL	2023-02-08
BN102/ AS-1763	BTK	Noncovalent; Reversible	BioNova Pharmaceuticals	Phase I/II	B-cell NHL	2022-05-09
TT-01488	BTK	Noncovalent; Reversible	TransThera	Phase I	B-cell lymphoma	2023-01-13
HMPL-760	BTK	Noncovalent; Reversible	HUTCHMED	Phase I	B-cell NHL	2022-01-13
MH048	BTK	Noncovalent; Reversible	Minghui Pharmaceutical Co., Ltd	Phase I	B-cell lymphoma	2020-12-30

Abbreviations: NHL=Non-Hodgkin Lymphoma

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

As of the Latest Practicable Date, there were eight non-covalent reversible BTK inhibitors under clinical development for the treatment of hematological malignancies in China. The following table illustrates the non-covalent reversible BTK inhibitors for cancer treatment that were at clinical stage in China as of the Latest Practicable Date:

Competitive Landscape of Noncovalent Reversible BTK Inhibitor for Cancer Treatment at Clinical Stage in China

Drug Name	Target	Molecular feature	Company	Clinical Stage	Indications	First Posted Date
LOXO-305	BTK	Noncovalent; Reversible	LOXO ONCOLOGY	Phase III	CLL, SLL	2022-08-08
ARQ-531	BTK	Noncovalent; Reversible	MSD	Phase III	CLL, SLL	2023-03-28
MH048	BTK	Noncovalent; Reversible	Minghui Pharmaceutical Co., Ltd	Phase II	B-cell lymphoma	2022-04-14
LP-168	BTK	Noncovalent; Reversible and Covalent; Irreversible	Lupeng Pharmaceutical Company Limited	Phase II	MCL	2023-01-12
HBW-3210	BTK	Noncovalent; Reversible	Hyperway Pharmaceuticals	Phase I/II	B-cell lymphoma	2023-10-09
HBW-3220	BTK	Noncovalent; Reversible	Hyperway Pharmaceuticals	Phase I/II	B-cell lymphoma	2022-05-20
TT-01488	BTK	Noncovalent; Reversible	TransThera	Phase I	B-cell lymphoma	2023-01-04
HMPL-760	BTK	Noncovalent; Reversible	HUTCHMED	Phase I	B-cell NHL	2021-12-15

Abbreviations: NHL=Non-Hodgkin Lymphoma

Source: CDE, Frost & Sullivan Analysis

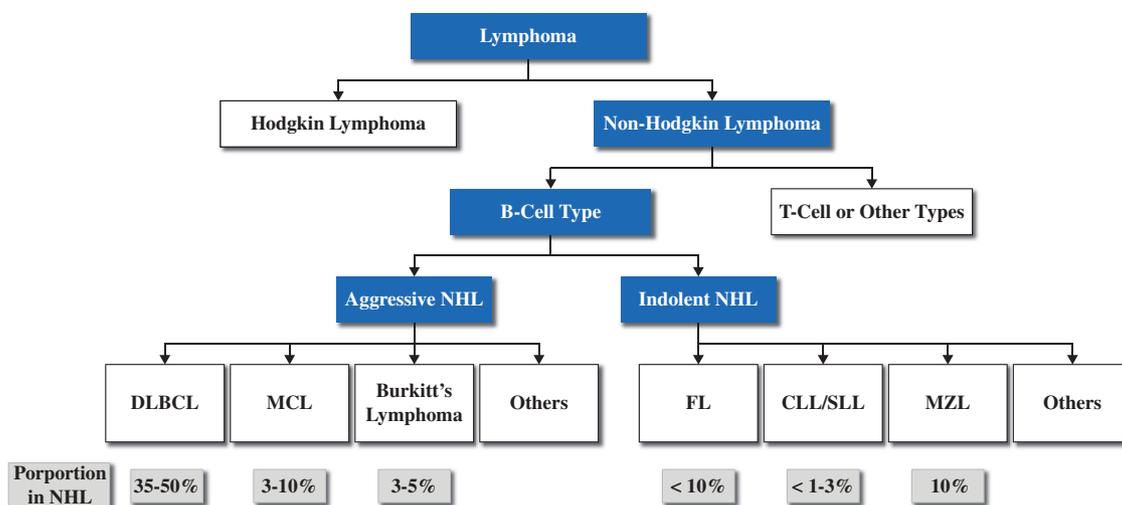
Major Indication

NHL

Lymphoma is a broad term for cancer that begins in cells of the lymph system. It can be categorized into two main categories: Hodgkin’s lymphomas and the NHL. The latter accounts for around 90% of lymphoma with various subtypes globally. The incidence of NHL around the world increased from 509.6 thousand in 2018 to 584.2 thousand in 2023. The number is expected to grow to 626.7 thousand and 679.2 thousand in 2026 and 2030, respectively, with a CAGR of 2.4% from 2023 to 2026 and a CAGR of 2.0% from 2026 to 2030. The incidence of NHL in China increased from 74.2 thousand in 2018 to 82.5 thousand in 2023. The number is expected to grow to 87.6 thousand and 94.0 thousand in 2026 and 2030, respectively, with a CAGR of 2.0% from 2023 to 2026 and a CAGR of 1.8% from 2026 to 2030.

CLL is a type of non-Hodgkin lymphoma. CLL cancer cells are found mostly in the blood and bone marrow, and it grows slowly. CLL is the most common type of leukemia in western countries, accounting for around 7% to 10% of NHL cases. MCL, on the other hand, is an aggressive, rare form of NHL that arises from cells originating in the “mantle zone.” The mantle zone is the outer ring of small lymphocytes surrounding the center of a lymphatic nodule. MCL accounts for roughly 3% to 10% of all NHL cases in China.

INDUSTRY OVERVIEW



Abbreviations: NHL=non-Hodgkin lymphomas; DLBCL=diffuse large B cell lymphoma; MCL=mantle cell lymphoma; FL=follicular lymphoma; CLL=chronic lymphocytic leukemia; SLL=small lymphocytic lymphoma; MZL=marginal zone lymphoma.

Note: The diagram demonstrates the proportion of different types of lymphoma in China.

Source: Literature Review, Frost & Sullivan Analysis

For NHL, targeted therapy is recommended if a patient is diagnosed as being potentially sensitive to such treatment. Otherwise, rituximab or lenalidomide can be recommended. For second- and later-line treatment, combination therapy involving rituximab or lenalidomide is still the recommended option. The development of BTK inhibitors changed the treatment paradigm for NHL. In clinical practice, BTK inhibitors significantly improved clinical activity in patients with relapsed/refractory disease and are now recommended as first-line treatments and also as second-line options for patients following chemoimmunotherapy.

SMALL MOLECULE NON-ONCOLOGY TARGETED THERAPY

S1P1

S1P is a lysophospholipid with a polar head-group and lipophilic tail, formed intracellularly via phosphorylation of sphingosine. S1P is a signaling lipid that serves as an essential regulator in inflammation, angiogenesis, and vascular permeability. The S1P1 receptor expresses on lymphocytes and plays a crucial role in the trafficking of lymphocytes from lymphoid organs. The S1P1 modulator can induce internalization and degradation of the S1P1, rendering B and T lymphocytes incapable of migrating from secondary lymphoid organs, which leads to a reduction in circulating lymphocytes in the blood. S1P1 is a prominent drug target for inflammatory diseases and has been clinically validated in multiple sclerosis and ulcerative colitis. Accumulating clinical evidence also supports its efficacy in other immunological disorders, such as UC and AD. However, the lack of selectivity on other S1P receptor subtypes may be associated with potentially adverse effects. Non-selective binding to other S1P receptor subtypes, particularly S1P2 and S1P3, may lead to adverse events, including vasoconstriction and an increase in blood pressure.

INDUSTRY OVERVIEW

Competitive Landscape

As of the Latest Practicable Date, there were three S1P receptor modulators approved by the NMPA, all of which were indicated for multiple sclerosis as illustrated below:

Competitive Landscape of S1P Receptor Modulators Approved by the NMPA

Drug Name	Brand Name	Target	Company	Molecular feature	Indications	Approval Date
Ozanimod	ZEPOSIA [®]	S1P1/5	Bristol Myers Squibb	Selective	Multiple sclerosis	2023-01-31
Siponimod	MAYZENT [®]	S1P1/5	Novartis	Selective	Multiple sclerosis	2020-05-07
Fingolimod	GILENYA [®]	S1P1/3/4/5	Novartis	Non-selective	Multiple sclerosis	2019-07-12

Source: NMPA, Frost & Sullivan Analysis

As of the Latest Practicable Date, there were six S1P receptor modulators in clinical development in China as illustrated below:

Competitive Landscape of S1P Receptor Modulators at Clinical Stage in China

Drug Name	Target	Company	Clinical Stage	Indications	First Posted Date
Etrasimod	S1P1/4/5	Everstar Therapeutics	Phase III	Ulcerative colitis	2019-12-02
TT-01688	S1P1	TransThera	Phase II	Atopic dermatitis	2022-06-23
			Phase I	Moderate and severe ulcerative colitis	2022-03-14
CBP-307	S1P1	Connect Biopharmaceutical Co., Ltd	Phase II	Ulcerative colitis	2018-08-16
HE009	S1P1	Helioeast Pharmaceutical Co., Ltd	Phase I	Systemic lupus erythematosus	2022-12-22
Ethoximod	S1P1	Institute of Materia Medica Chinese Academy of Medical Science	Phase I	Psoriasis	2022-09-13
Proximod	S1P1		Phase I	Rheumatoid arthritis	2022-01-20

Source: CDE, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

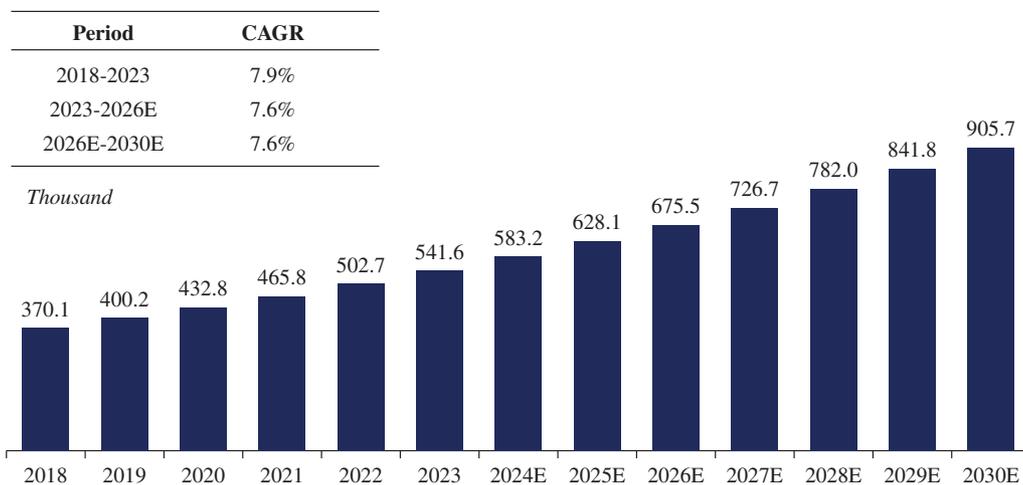
Major Indications

UC

IBD, are chronic immune-mediated inflammatory conditions of the gastrointestinal tract, which clinically include UC and CD. UC is a chronic immune-mediated inflammatory condition of the large intestine that is frequently associated with inflammation of the rectum but often extends proximally to involve additional areas of the colon. As a progressive disease with a chronic nature, UC inflicts not only physical but also psychological, economic, and social burdens on patients.

UC can occur in all ages, with the peak onset age ranging from 30 to 49. In China, the prevalence of UC increased from 370.1 thousand in 2018 to 541.6 thousand in 2023. The number is expected to grow to 675.5 thousand in 2026 with a CAGR of 7.6% from 2023 to 2026 and further grow to 905.7 thousand in 2030 with a CAGR of 7.6% from 2026 to 2030. Approximately 70% of Chinese UC patients experience a moderate to severe disease course.

Prevalence of UC in China, 2018-2030E



Source: Literature Review, Frost & Sullivan Analysis

Due to the large patient population, the UC drug market size in China is also expected to grow steadily in the coming years. In China, the treatment guidelines before 2020 recommended traditional chemical drug therapy for UC treatment, resulting in a relatively stable market size from 2018 to 2020. However, the market dynamics shifted significantly after 2020 with the introduction of innovative drugs, particularly biologics, leading to an expected market surge since 2021. As such, China’s UC drug market size reached RMB1.5 billion in 2022, with a CAGR of 8.3% from 2018 to 2022. The market size is expected to grow to RMB2.0 billion and RMB2.4 billion in 2026 and 2030, respectively.

INDUSTRY OVERVIEW

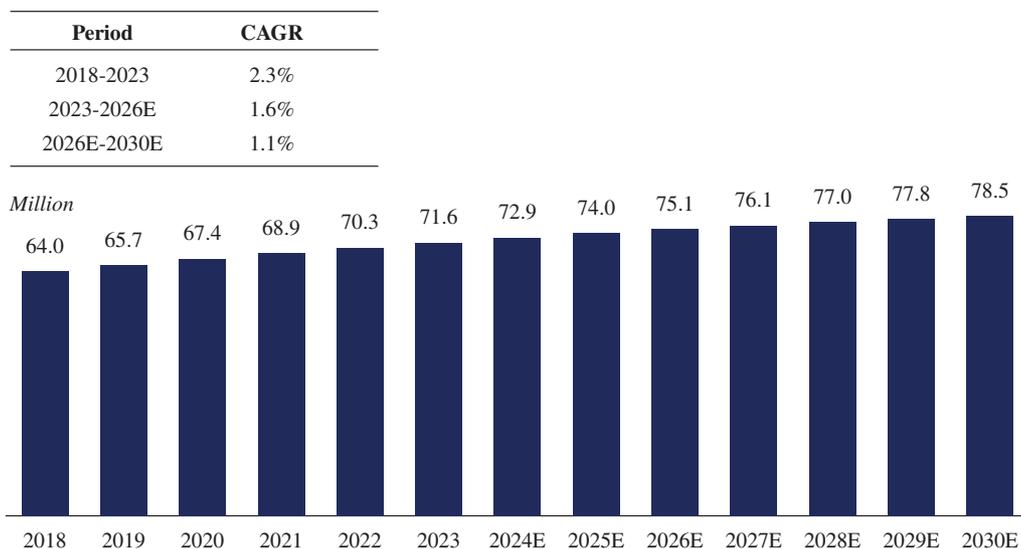
The treatment approach for UC can be categorized into two phases: active treatment and maintenance therapy. Mesalazine serves as the initial treatment for mild to moderate active UC. If Mesalazine fails to achieve adequate response, switching to oral systemic glucocorticoids or biologics is recommended to induce remission. In cases of moderate to severe active UC, oral or intravenous glucocorticoids are recommended. For patients with inadequate response to or intolerance of Mesalazine, a combination of immunosuppressive drugs, glucocorticoids, biologics, and small molecule inhibitors may be considered. For maintenance therapy in mild to moderate UC cases, Mesalazine is the primary choice. Immunosuppressive drugs, biologics and small molecule inhibitors are options for patients who do not respond to prior glucocorticoid therapy. In moderate to severe UC maintenance therapy, biologics and small molecule inhibitors are strongly recommended.

AD

AD is a serious, chronic, recurrent, immune-mediated skin disorder characterized by dry skin, pruritus or severe itching, rash, and relapsing lesions. AD is the most common type of eczema. AD has a multifactorial etiology involving immune and epidermal barrier components, which are influenced by genetic and environmental factors. Persistent underlying inflammation and barrier dysfunction are key drivers of eczematous lesions and pruritus, which are the hallmarks of AD.

In China, the prevalence of AD increased from 64.0 million in 2018 to 71.6 million in 2023. The number is expected to grow to 75.1 million in 2026 with a CAGR of 1.6% from 2023 to 2026 and further reach 78.5 million in 2030 with a CAGR of 1.1% from 2026 to 2030. Approximately 25% to 30% of AD patients experience a moderate or severe disease course in China.

Prevalence of AD in China, 2018-2030E



Source: Literature Review, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

In China, the AD market size increased from RMB3.3 billion in 2018 to RMB6.6 billion in 2022, with a CAGR of 18.5%, and is projected to increase to RMB18.8 billion and RMB31.1 billion in 2026 and 2030, respectively, with a CAGR of 30.0% from 2022 to 2026 and a CAGR of 13.5% from 2026 to 2030.

Several treatment options are available in China for AD, including basic therapies to protect the skin barrier (e.g. moisturizers), topical therapy, systemic therapy, traditional Chinese medicine and ultraviolet therapy. Topical therapy includes corticosteroids, calcineurin inhibitors (tacrolimus and pimecrolimus), and antimicrobial agents. Systemic therapy includes antihistamines (loratadine and cetirizine), systemic anti-infective drugs (erythromycin family and tetracycline family), immunosuppressants (cyclosporine and methotrexate), glucocorticoid and IL-4R α inhibitor. Safety concerns limit the long-term use of the current treatment options, particularly for children, due to the increased body surface area to mass ratio in children, which results in increased absorption and systemic exposure. In addition, the current treatment options have been reported to be associated with side effects, including application site burning and stinging. Therefore, there is a need to develop drugs with low side effects, low dosing frequency and high safety.

PDE9 Inhibitor

NP/cGMP signaling regulates cardiomyocyte growth, survival, and stress response, and its activation is cardioprotective. PDE9 catalyzes the hydrolysis of cGMP and negatively modulates cardiac NP/cGMP signaling. In human heart failure, particularly in HFpEF, PDE9 expression and activity are strongly enhanced in cardiomyocytes, blunting NP/cGMP signaling and making the heart more susceptible to failure, suggesting that PDE9 may play a critical role in NP/cGMP signaling in failing hearts.

In addition, PDE9 levels are associated with left ventricular filling pressure, left ventricle size as a marker of diastolic burden and right ventricular function in heart failure. Genetic or pharmacological inhibition of PDE9 increases NP/cGMP signaling and reverses preestablished heart disease in a number of heart failure animal models. PDE9 could serve as an attractive target for heart failure, especially for HFpEF. Entresto (LCZ696, a combination of angiotensin receptor blocker valsartan and neprilysin inhibitor sacubitril), a recent therapy approved by FDA for heart failure, increased the level of NP through neprilysin inhibition (blunting NP proteolysis) and showed good clinical efficacy in HFpEF, validating the efficacy of the pathway activation in heart failure. However, most of the recommended therapies for HFpEF are directed at symptoms, especially comorbidities, and risk factors that may worsen cardiovascular disease, rather than HFpEF itself. Therefore, there remains a large unmet medical need for patients with this condition.

Competitive Landscape

As of the Latest Practicable Date, there was no PDE9 inhibitor approved for commercialization globally or in China. As of the Latest Practicable Date, there were five PDE9 inhibitors in clinical trial globally, but only two illustrated below were developed for heart failure treatment.

INDUSTRY OVERVIEW

Global Competitive Landscape of PDE9 Inhibitors at Clinical Stage for the Treatment of Heart Failure

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
Tovinontrine	PDE9	Cardurion Pharmaceuticals, Inc.	Phase II	Heart failure	2024-01-22
TT-00920	PDE9	TransThera	Phase I	Heart failure	2022-05-02

Source: *ClinicalTrials.gov, Frost & Sullivan Analysis*

In China, TT-00920 was the only PDE9 inhibitor under clinical development for the treatment of chronic heart failure as of the Latest Practicable Date, which acted directly on cardiomyocytes to mechanistically synergize with current therapeutic approaches to form a novel and promising treatment regimen for both HF_rEF and HF_pEF.

Major Indication

Heart Failure

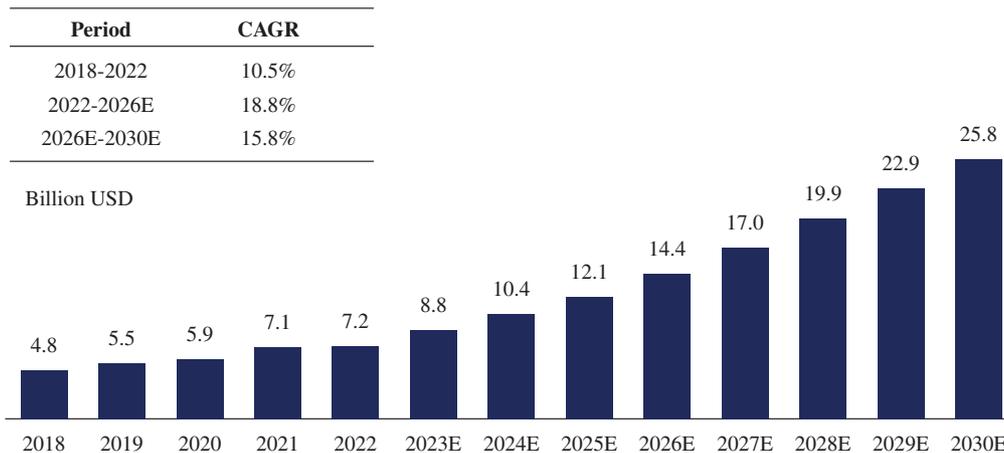
Heart failure, also as known as congestive heart failure, is a complex clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood. Heart failure is a common final stage of many heart diseases, and is also a disease with high prevalence and mortality. Although the treatment of heart failure has made continuous progress in recent years, the disease is still a fatal clinical disease.

The global prevalence of heart failure increased from 29.1 million in 2018 to 32.4 million in 2023, with a CAGR of 2.2%. It is expected to increase to 35.5 million in 2026, with a CAGR of 3.1% from 2023 to 2026, and is expected to further increase to 39.3 million in 2030, with a CAGR of 2.6% from 2026 to 2030. The prevalence of heart failure in China increased from 10.2 million in 2018 to 12.5 million in 2023, with a CAGR of 4.2%. It is expected to increase to 14.1 million in 2026, with a CAGR of 4.1% from 2023 to 2026, and is expected to further increase to 16.3 million by 2030, with a CAGR of 3.7% from 2026 to 2030.

The global heart failure drug market size reached US\$7.2 billion in 2022, with a CAGR of 10.5% from 2018 to 2022. The market size is expected to reach US\$14.4 billion in 2026 and US\$25.8 billion in 2030, with a CAGR of 18.8% from 2022 to 2026 and a CAGR of 15.8% from 2026 to 2030. China’s heart failure drug market size reached RMB6.2 billion in 2022, with a CAGR of 7.8% from 2018 to 2022. The market size is expected to grow to RMB11.5 billion and RMB28.6 billion in 2026 and 2030, respectively, with a CAGR of 16.8% from 2022 to 2026 and a CAGR of 25.7% from 2026 to 2030.

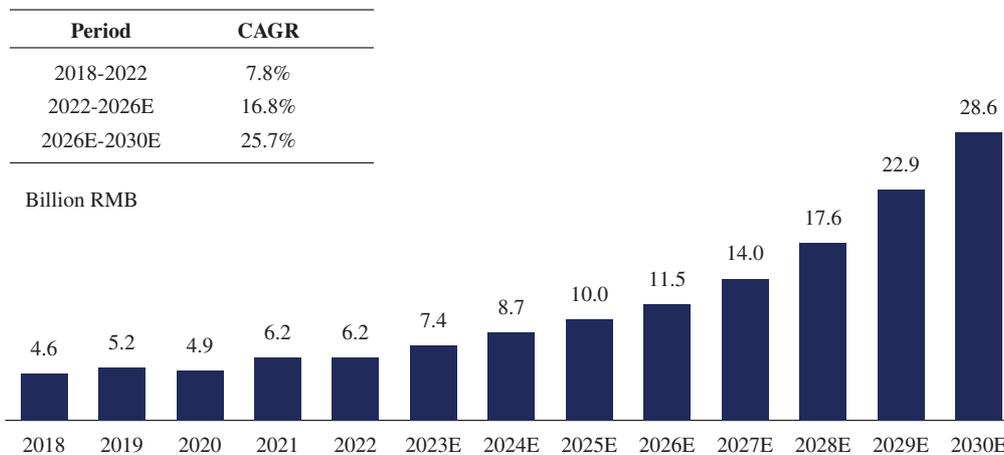
INDUSTRY OVERVIEW

Historical and Forecasted Global Heart Failure Drug Market Size, 2018-2030E



Source: Frost & Sullivan Analysis

Historical and Forecasted China Heart Failure Drug Market Size, 2018-2030E



Source: Frost & Sullivan Analysis

American College of Cardiology/American Heart Association Guideline for chronic heart failure divided patients with HF into two categories based on left ventricular ejection fraction: HFrEF and HFpEF, each has a unique pathophysiology. HFrEF accounts for around 50% of all heart failure patients around the world, while HFpEF accounts for the rest portion. Over the past few years, there had been significant advances in the pharmacological treatment of HFrEF, including the approval of Entresto (LCZ696), though long-lasting efforts are needed to further improve the outcomes and poor prognosis. On the other hand, the pathophysiology of HFpEF is not fully understood. For HFpEF patients, Entresto (LCZ696) is approved by the FDA. However the efficacy of Entresto (LCZ696) is very modest with respect to HFpEF. In general, treatments effective for HFrEF have shown disappointing treatment effects when used in patients with HFpEF. Thus, most of the recommended therapies for HFpEF are directed at symptoms, especially comorbidities, and risk factors that may worsen cardiovascular disease, rather than HFpEF itself. Although sotagliflozin has been approved for treating HFpEF, there remains a large unmet medical need for patients with this condition.

INDUSTRY OVERVIEW

Further, the prognosis for heart failure can only be improved when myocardial remodeling is controlled. However, most of the drugs currently approved for heart failure are neurohormonal modulators, and few directly target cardiomyocytes to improve primary cardiac pathology.

VAP-1 Inhibitor

VAP-1, also known as SSAO, catalyzes the oxidative conversion of endogenous primary amines to the corresponding cytotoxic aldehydes and hydrogen peroxide. VAP-1 is expressed in the human hepatic endothelium acting as a cell adhesion molecule and plays an important role in leukocyte adhesion and transmigration in the liver. This function is dependent on the amine oxidase enzyme activity of VAP-1. The level of its circulating soluble form (sVAP-1) increases during liver inflammation and is known to correlate with disease severity and the presence of fibrosis in NASH. Genetic or pharmacological inhibition of VAP-1 enzyme activity has shown reduction of oxidative stress and recruitment of inflammatory cells to the liver and also attenuation of fibrosis in multiple preclinical NASH models.

Competitive Landscape

As of the Latest Practicable Date, there was no VAP-1 inhibitor either approved by the FDA or the NMPA. There were seven VAP-1 inhibitors at clinical stage globally, but only three were developed for the treatment of NASH.

Global Competitive Landscape of VAP-1 Inhibitors at Clinical Stage for the Treatment of NASH

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
TT-01025	VAP-1	TransThera	Phase I	NASH	2021-01-29
Ecc0509	VAP-1	Eccanga Pty Ltd	Phase I	NASH	2021-08-19
TERN-201	VAP-1	Terns Pharmaceuticals Inc	Phase I	NASH	2021-05-21

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Meanwhile, as of the Latest Practicable Date, in China, only one VAP-1 inhibitor (TT-01025) was in clinical trial.

INDUSTRY OVERVIEW

Major Indication

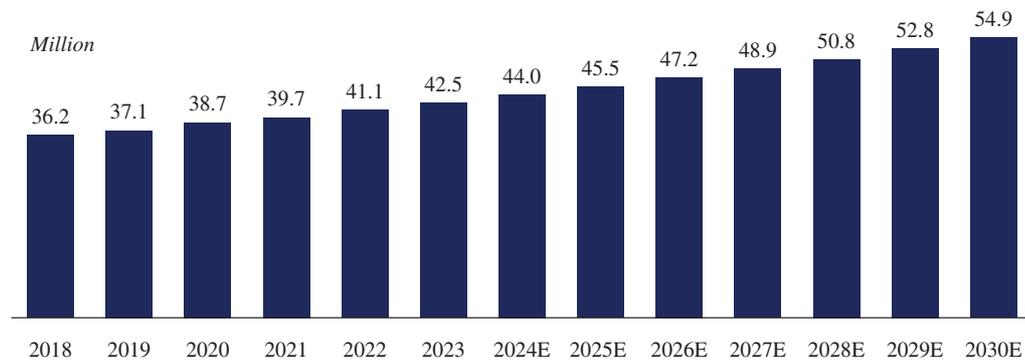
NASH

NASH is liver inflammation and damage caused by a buildup of fat in the liver. It is the more severe form of NAFLD, an umbrella term for a range of liver conditions affecting people who drink little to no alcohol. If left untreated, NASH can cause scarring of the liver, which leads to permanent scarring (cirrhosis) and liver cancer. NAFLD is characterized by steatosis of the liver, and NASH is a necro-inflammatory process whereby the liver cells become injured under steatosis.

The prevalence of NASH in China increased from 36.2 million in 2018 to 42.5 million in 2023. The number is expected to grow to 47.2 million in 2026 with a CAGR of 3.5% from 2023 to 2026, and further reach 54.9 million in 2030 with a CAGR of 3.9% from 2026 to 2030.

Prevalence of NASH in China, 2018-2030E

Period	CAGR
2018-2023	3.3%
2023-2026E	3.5%
2026E-2030E	3.9%



Source: Literature Review, Frost & Sullivan Analysis

China’s NASH drug market size reached RMB0.9 billion in 2022, with a CAGR of 8.4% from 2018 to 2022. The market size is expected to climb to RMB1.6 billion and RMB12.0 billion in 2026 and 2030, respectively, with a CAGR of 15.0% from 2022 to 2026 and a CAGR of 66.8% from 2026 to 2030.

In March 2024, the FDA approved Rezdiffra (resmetirom) for the treatment of adults with NASH with moderate to advanced liver scarring (fibrosis), to be used along with diet and exercise. Previously, patients with NASH who also have notable liver scarring did not have a medication that could directly address their liver damage. Rezdiffra’s approval will, for the first time, provide a treatment option for these patients, in addition to diet and exercise. In both the U.S. and China, the treatment of NASH can be divided into lifestyle intervention, drug intervention, and surgical intervention. The prevention and treatment of metabolic syndrome, type 2 diabetes mellitus, and other comorbidities are important. Despite the newly approved drug Rezdiffra, NASH treatment still focuses on a multi-mechanistic strategy of combination therapy, given the complexity in pathophysiology and the heterogeneous nature of the disease.

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Current drug intervention can only slow the accumulation of fat in liver tissue, which hardly resolve inflammation and have no consistently reliable effect on fibrosis. Given the high prevalence of NASH, the associated morbidity, the growing burden of end-stage liver disease, and limited availability of livers for organ transplantation, it is believed that identifying therapies that will slow the progress of, halt, or reverse NASH will address an unmet medical need.

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the small molecule drug market in China and the United States. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The contract sum to Frost & Sullivan is RMB1.8 million for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the results of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED]. We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the small molecule drug market for potential investors. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN CHINA

This section summarizes the principal PRC laws, rules and regulations that are relevant to our business.

MAJOR REGULATORY AUTHORITIES

The major regulatory authorities of China’s drug industry include the National Medical Products Administration (hereinafter referred to as the “NMPA”), National Health Commission (hereinafter referred to as the “NHC”) and National Healthcare Security Administration (hereinafter referred to as the “NHSA”).

NMPA

The NMPA is mainly responsible for the management of safety supervision, standards, registration, quality, post-marketing risks, and supervision and inspection of drugs, cosmetics and medical devices, as well as the supervision of external exchange and cooperation and guidance for the work of local drug supervision and management departments. In March 2018, the State Council Institutional Reform Proposal passed by the First Session of the Thirteenth NPC decided the China Food and Drug Administration shall cease to exist, and the NMPA was established to undertake the duties of the former China Food and Drug Administration (CFDA).

NHC

The NHC is mainly responsible for formulating national health policies, coordinating to deepen the reform of the medical and health system, organizing the formulation of a national essential drugs system, and supervising and managing medical services.

NHSA

The NHSA is mainly responsible for formulating and organizing the implementation of policies, plans and standards for medical insurance, maternity insurance, medical aid and other medical security systems, organizing the formulation and adjustment of prices and charging standards for drugs and medical services, and formulating and supervising the implementation of the bidding and procurement policies for drugs and medical consumables.

REGULATORY OVERVIEW

MAJOR REGULATORY LAWS AND REGULATIONS

Our business in the PRC is subject to a large number of laws and regulations and extensive government supervision. Such laws and regulations relate to R&D, registration, production, sales, labor, intellectual property rights, taxation and other areas of drugs.

Laws and Regulations in Relation to the Pharmaceutical Industry

Management and Classification of Drugs

The Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法》), which was amended on August 26, 2019 by the NPC Standing Committee and took effect on December 1, 2019, establishes a legal framework for the development, registration, marketing, production and operation of new drugs while conducting post-marketing management and supervising and managing the pricing, publicity, storage and supply of drugs. The NMPA is in charge of the supervision and management of drugs throughout the country, and the local medical products administration departments of provinces, autonomous regions and municipalities directly under the central government are responsible for the supervision and management of drugs within their respective administrative areas. The drug supervision and administration departments of the people’s governments of districted cities and counties are responsible for the drug supervision and management within their respective administrative areas. The relevant departments under the State Council and the relevant departments of the local people’s governments at or above the county level are responsible for the supervision and management of drugs within the scope of their respective functions and duties.

Compared with the Drug Administration Law revised in 2015, the changes in the Drug Administration Law currently in effect mainly focus on the following four aspects:

- Further optimize the drug management system and encourage drug innovation: An expert consultation system is established. The communication and exchange mechanism with registered applicants is completed. The review process is optimized. The review efficiency is improved. At the same time, regarding approval of clinical trials, the approval system is changed to implied license system; for clinical trial institutions, the certification management is adjusted to filing management, and priority review and approval are implemented. Green channels are established for drugs in short supply that are urgently needed in clinical settings, new drugs for the prevention and treatment of serious infectious diseases and orphan diseases, and drugs for children, subject to priority review and approval.
- Establish the system of drug marketing authorization holder: The marketing authorization holder is legally responsible for the safety, effectiveness and quality controllability of drugs that are either in the process of R&D, production and trading. Meanwhile, the marketing authorization holder is required to establish a quality assurance system and responsible for non-clinical research, clinical trial, production and management, post-marketing research, adverse reaction monitoring, reporting and handling.

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- Establish and improve the drug tracing system: Under the principle of “tracing based on one code for one item”, the marketing authorization holder is required to establish a drug tracing system so as to make drugs in minimum package unit traceable and verifiable. Information-based measures are taken to ensure the quality and safety of drug production and management, prevent fake and inferior drugs from entering into legal channels, and enable drug risk control and precise recall.
- The definition and scope of fake and inferior drugs are modified, more severe punishment is imposed on illegal acts such as production, operation and sale of fake and inferior drugs, and criminal responsibility will be investigated according to law for any act that violates the Drug Administration Law and constitutes a crime.

According to the Measures on Prescription Drugs and Over the Counter (OTC) Drugs Classification Management (Trial) (《處方藥與非處方藥分類管理辦法(試行)》) which were issued by the NMPA on June 18, 1999 and took effect on January 1, 2000, China conducts classification management of prescription drugs and OTC drugs according to their varieties, specifications, indications, doses and administration routes. Prescription drugs can be dispensed, purchased and used only based on the prescription issued by the certified medical practitioner or certified medical assistant practitioner. OTC drugs are divided into Class A and Class B and they both can be judged, purchased and used without the prescription issued by the certified medical practitioner or certified medical assistant practitioner. In particular, the manufacturers of prescription drugs and OTC drugs are required to obtain the Drug Manufacturing Enterprise License. The pharmaceutical wholesale enterprises distributing prescription drugs and OTC drugs, as well as pharmaceutical retail enterprises selling prescription drugs and Class A OTC drugs are required to obtain the Pharmaceutical Trading Enterprise License. Class B OTC drugs can be retailed by enterprises upon approval by the provincial drug regulatory departments or its authorized departments.

Non-Clinical Study and Animal Testing

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration and relevant activities shall be conducted in accordance with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》), which was promulgated on August 6, 2003 and revised on July 27, 2017 by the former CFDA. On April 16, 2007, the former CFDA issued the Administrative Measures for the Certification of Good Laboratory Practice for Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》), which became effective since July 1, 2023 after being last revised by the NMPA. It provides for the procedures for application and acceptance of Good Laboratory Practice certification by research institutions conducting non-clinical safety evaluation study for drugs, requirements for data review and on-site inspection, audit procedures and supervision and management.

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The experimental animals involved in drug research shall be studied, preserved, fed, supplied, applied and managed in accordance with the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》), which were promulgated by the State Scientific and Technological Commission on November 14, 1988 and were last amended and took effect on March 1, 2017. The Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) promulgated by the State Scientific and Technological Commission and the former State Bureau of Quality and Technical Supervision and coming into effect on December 11, 1997 initiate the establishment of a national experimental animal seed center and further clarifies the production, usage, testing and supervision of experimental animals. At the same time, according to the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) jointly promulgated by the Ministry of Education, the Ministry of Science and Technology and other ministries and commissions on December 5, 2001 and coming into effect on January 1, 2002, organizations and individuals performing experimentation on animals in China are required to obtain a certificate for use of experimental animals.

Clinical Trial Application

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) amended by the State Administration for Market Regulation on January 22, 2020 and coming into effect on July 1, 2020, drug clinical trials are divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial and bioequivalence test, of which Phase I clinical trial to Phase IV clinical trial shall be carried out upon submission of application materials as required and approval, and bioequivalence test shall be filed. Drug clinical trials shall be subject to review and approval by the Ethics Committee. A corresponding trial protocol shall be formulated for any approved drug clinical trial, and the trial may be carried out after review and approval by the Ethics Committee.

According to the Decision on Adjusting the Approval Procedures of the Administrative Approval Matters for Certain Drugs (《關於調整部分藥品行政審批事項審批程序的決定》), which was promulgated by the NMPA on March 17, 2017 and took effect on May 1, 2017, upon adjustment, drug clinical trial approval decision shall be made by the CDE in the name of the NMPA. According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) promulgated by the NMPA on July 24, 2018, if the applicant does not receive any negative or questioning opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

Clinical trials that have been approved and conducted in China and relevant information shall be registered on the website of the information platform in accordance with the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) which was issued by the former CFDA and came into effect on September 6, 2013.

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The Conduct of Clinical Trials

According to the provisions of the Drug Administration Law, drug clinical trials shall be conducted in clinical trial institutions that meet corresponding conditions, and drug clinical trial institutions shall be subject to record-keeping management. The conduct of drug clinical trials shall comply with ethical principles, with a clinical trial protocol developed, and be subject to review and approval by the Ethics Committee. The Ethics Committee shall establish an ethics review system to ensure that the ethics review process is independent, objective, and fair, and supervise the standard conduct of drug clinical trials. Before a clinical trial is conducted, details such as the clinical trial objective and risks shall be truthfully stated and explained to the trial subjects or their guardians, and an informed consent letter signed voluntarily by the trial subject or their guardian shall be obtained, and effective measures shall be taken to protect the lawful rights and interests of the trial subjects. Where safety issues or other risks are discovered during a drug clinical trial, the clinical trial sponsor shall promptly adjust the clinical trial protocol, suspend or terminate the clinical trial, and report to the drug regulatory departments under the State Council. If necessary, the drug regulatory departments under the State Council may order the sponsor to adjust the clinical trial protocol or suspend or end the clinical trial.

The Good Clinical Practice (《藥物臨床試驗質量管理規範》), which was revised by the NMPA and the NHC on April 23, 2020 and came into effect on July 1, 2020, specifies the quality standards for the whole process of drug clinical trials, including protocol design, organization, implementation, monitoring, auditing, recording, analysis, summarization and reporting. It further clarifies the responsibilities of the Ethics Committee to protect the rights and interests and safety of the trial subjects. The Committee shall review the clinical trial protocol, the qualifications of the investigators, the methods and information of recruiting the trial subjects according to the specific requirements, as well as the scientific and ethical nature of clinical trials. It also provides for the qualifications and requirements of the investigators and the clinical trial institutions, and the sponsors shall establish a quality management system for clinical trials which covers the whole process of clinical trial design, implementation, recording, evaluation, results reporting, filing and information acquisition.

International Multi-center Clinical Trials

On January 30, 2015, the former CFDA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》), which took effect on March 1, 2015, to provide guidance for, regulate and supervise the application, implementation and management of international multi-center clinical trials in China, and to encourage Chinese applicants to conduct international multi-center drug clinical trials as a way to speed up the internationalization of drug research and development in China. In accordance with the guidelines, an applicant may conduct clinical trials simultaneously in multiple centers in one or more regions under the same clinical trial protocol.

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Where the applicants plan to implement the international multi-center drug clinical trials in China, they shall comply with relevant laws and regulations, such as the Drug Administration Law, the Implementation Regulations for the Drug Administration Law (《藥品管理法實施條例》) and the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), observe the Good Clinical Practice of China, make reference to universal international principles such as International Conference on Harmonization-Good Clinical Practice, and abide by the laws and regulations of relevant countries.

On July 6, 2018, the NMPA promulgated the Technical Guiding Principles for the Acceptance of the Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》), which took effect on the same day. It provides that overseas clinical data can be used as clinical evaluation materials and be submitted for registration applications in China. Where the data of international multi-center drug clinical trials are used to apply for drug registration in China, at least two countries including China shall be involved. The Guiding Principles clearly outlines the basic principles and requirements for accepting data from overseas clinical trials, and specifies different levels of acceptance according to the quality of data and the practical situation. The Guiding Principles requires applicants to ensure the authenticity, integrity, accuracy and traceability of data from overseas clinical trials. In addition, the process in which overseas clinical trial data is generated must follow relevant requirements of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Clinical Value-Oriented Anti-tumor Drug Clinical Research and Development Guidelines issued by the CDE on November 19, 2021 (the “Guidelines”)

On November 19, 2021, the Center for Drug Evaluation issued the “Clinical Value-Oriented Anti-tumor Drug Clinical Research and Development Guidelines” (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》) with the purpose to better address the needs of patients and to promote the clinical value-oriented R&D of anti-tumor drugs. The Draft Rule discourages repetitive research and development of “me-too drugs” (drugs with identical mechanisms of actions) and disorderly waste.

According to the Guidelines, when clinical trials of innovative drugs are designed to choose controlled drugs, the best supportive treatment should be preferred over placebo. To be specific, if an indication already has the current best drug recommendation in the treatment guidelines, the new drug should be compared with the existing drug.

The Guidelines becomes effective on November 19, 2021, which positively impacts research, development and innovation activities within the pharmaceutical industry. As the Guidelines aim to select more high-quality first-in-class or best-in-class drugs, and we have been developing drug candidates that meet the potential patients’ medical needs, this new focus of regulatory policies promoting value-oriented research and development activities in China

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is in line with our development strategies and may further facilitate our clinical trials and studies. To the best knowledge of Directors, we are able to fully comply with the relevant requirements of the Guidelines and we believe we are well positioned to benefit from the Guidelines.

Collection and Approval of Human Genetic Resources

The Bio-security Law of the PRC (《中華人民共和國生物安全法》) promulgated by the Standing Committee of the National People’s Congress on October 17, 2020, and was implemented on April 15, 2021, provides that the State shall have sovereignty over the human genetic resources and biological resources of China. The Bio-security Law of the PRC further stipulates that the department of science and technology under the State Council shall be the competent authority for the approval or filing of using China’s human genetic resources.

The regulations of the People’s Republic of China on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) which became effective on July 1, 2019 and was revised on March 10, 2024, stipulates that any international cooperative scientific research conducted with China’s human genetic resources shall meet the conditions stipulated in the regulations, and both partners shall jointly submit an application for approval by the health department of the State Council. In the case that clinical institutions, for the purpose of obtaining permission for the marketing of relevant drugs and medical devices in China, conduct international cooperative clinical trials with China’s human genetic resources without exporting human genetic resource materials, no examination and approval is required. However, both partners, before conducting clinical trials, shall file the type, quantity and purpose of the human genetic resources to be used with the health department of the State Council.

The Ministry of Science and Technology issued the Detailed Rules for the Implementation of the Regulations on the Administration of Human Genetic Resources (Draft for Comments) (《人類遺傳資源管理條例實施細則(徵求意見稿)》) in March 2022 to solicit opinions from the public, aiming to further improve the management efficiency of human genetic resources in China. The Ministry of Science and Technology promulgated the Detailed Rules for the Implementation of the Regulations on the Administration of Human Genetic Resources (《人類遺傳資源管理條例實施細則》) on May 26, 2023, which became effective on July 1, 2023 and refines the specific regulatory rules of the regulations of the People’s Republic of China on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》). The promulgation of these rules further improves the overall framework and specific requirements for the supervision of human genetic resources in China and provides more detailed compliance guidelines for the industry to carry out activities using human genetic resources in China.

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Administration of Drug Registration

The Administrative Measures for Drug Registration shall apply to the activities of drug research, registration, supervision and management in China for the purpose of drug marketing. Drug registration refers to the procedure that a drug registration applicant (hereinafter referred to as the “applicant”) submits an application for drug clinical trial, drug marketing authorization, re-registration and other supplementary applications in accordance with legal procedures and relevant requirements, and the drug regulatory departments, based on laws and regulations and existing scientific knowledge, reviews the safety, effectiveness and quality controllability of relevant drugs, and decides whether to approve of the application. The applicant shall be a drug marketing authorization holder (hereinafter referred to as the “authorization holder”) after obtaining the drug registration certificate.

According to the Administrative Measures for Drug Registration, the NMPA shall be in charge of the administration of drug registration throughout the country; the CDE of the NMPA shall be responsible for the evaluation of clinical trial application, marketing authorization application, supplementary application and re-registration application of overseas produced drugs; the National Institutes for Food and Drug Control, Center for Food and Drug Inspection of NMPA and other specialized drug technical institutions shall be responsible for examination, verification, monitoring and evaluation of drug registration, preparation and service of certificate and corresponding information construction and management.

According to the Administrative Measures for Drug Registration, the applicant shall, before applying for drug marketing registration, complete relevant research on pharmacy, pharmacology and toxicology and drug clinical trial. When applying for drug registration, authentic, sufficient and reliable data, materials and samples shall be provided to prove the safety, effectiveness and quality controllability of relevant drug. If relevant drug passes comprehensive evaluation, the drug will be approved for marketing and a drug registration certificate will be issued. If relevant drug fails the comprehensive evaluation, the drug will not be approved for marketing. The validity period of the drug registration certificate is five years. During the validity period of the drug registration certificate, the authorization holder shall ensure the safety, effectiveness and quality controllability of the marketed drug on an on-going basis, and apply for drug re-registration six months before the expiration of the validity period.

Prioritized Examination and Approval for Registration of Drugs

The Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》), promulgated by the former CFDA on November 11, 2015 and taking effect on the same day, further optimizes the examination and approval procedures for generic drugs, modified new drugs and clinical trial applications. In particular, the examination and approval procedures are streamlined for applications for innovative drugs for HIV/AIDS, malignant tumors, serious infectious diseases and orphan diseases, and for simultaneous applications by the applicant in the EU and the U.S. for new drug clinical trials.

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On October 8, 2017, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council promulgated The Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), proposing to reform the management of clinical trials, provide support for clinical trials, and optimize clinical trial approval procedures, so as to promote industrial restructuring and technological innovation of the drugs and medical devices industry, increase industrial competitiveness and meet the clinical needs of the public. At the same time, the opinions call on speeding up the research and development of drugs and medical devices for orphan disease, and streamlining the examination and approval procedure for marketing. The opinions also support the clinical application of new drugs, and the prompt incorporation of new drugs into the reimbursement scope of basic medical insurance according to applicable provisions.

On May 17, 2018, the NMPA and the NHC published the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), to ensure further implementation of the working mechanism for prioritized drug review and approval. In respect of drugs for the prevention and treatment of life-threatening diseases for which no effective treatment is available, and drugs for orphan diseases, the CDE of the CFDA will establish a mechanism for communication and exchange with the applicant. The circular also requires providing more guidance for the research and development of drugs, and prioritizing and speeding up the registration application, review, examination and approval of drugs falling into the scope of prioritized review and approval.

On July 7, 2020, the NMPA promulgated Working Procedures for Review of Breakthrough Therapy Drugs (Interim) (《突破性治療藥物審評工作程序(試行)》), Working Procedures for Review and Approval of Applications for Conditional Approval of Drug Marketing (Interim) and Working Procedures for Priority Review (《藥品附條件批准上市申請審評審批工作程序(試行)》) and Approval of Drug Marketing Authorization (Interim) (《藥品上市許可優先審評審批工作程序(試行)》) to encourage the research and innovation of new drugs and to standardize the review and approval system of drugs. The Working Procedures for the Review of Breakthrough Therapy Designation Drugs (Trial) stipulates that during the clinical trial period, for innovative drugs or modified new drugs for the prevention and treatment of diseases that are life-threatening or severely affecting the quality of life and for which no effective prevention and treatment are available, or for innovative drugs or modified new drugs that are fully proved to have significant clinical advantage over existing treatment methods, the applicant can apply for breakthrough therapy designation drug procedure during Phase I and II clinical trials, but usually no later than the commencement of Phase III clinical trial. The Opinions on Prioritized Review and Approval to Encourage Drug Innovation promulgated by the former CFDA in December 2017 shall be repealed simultaneously.

The Administrative Measures for Drug Registration, revised and effective in 2020, specifies that the NMPA shall continue to reform, optimize and increase the efficiency of the review and approval system. Where applicable, the applicant may apply for breakthrough therapy designation drug procedure, conditional approval, prioritized review and approval or special examination and approval procedure for its drug registration.

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Drug Marketing Authorization Holder System

The Drug Administration Law, amended on August 26, 2019 and taking effect on December 1, 2019, formalizes the drug marketing authorization holder system and stipulates that the drug marketing authorization holder shall be responsible for the non-clinical research, clinical trial, production and management, post-marketing research, adverse reaction monitoring, reporting and handling of drugs. It also requires the drug marketing authorization holder to establish a drug quality assurance system, and assign ad hoc personnel to be independently responsible for the supervision and management of drug quality.

Drug Manufacturing License

According to the Drug Administration Law and the Regulation on the Management and Implementation of Drug, drug manufacturing activities are subject to the approval of drug regulatory departments of local people’s governments of provinces, autonomous regions or municipalities directly under the central government and a drug manufacturing license shall be obtained. No drugs shall be manufactured without a drug manufacturing license. The drug manufacturing license shall indicate the period of validity and the scope of manufacturing. The license shall have a validity period of five years. If it is necessary to renew the license after the expiration thereof, the license-holding enterprise shall, within six months before the license expires, apply for a new license in accordance with the provisions of the drug regulatory departments under the State Council. For those enterprises that manufacture drugs without a drug manufacturing license, their plants shall be ordered to close down, the illegally manufactured drugs and illegal income shall be confiscated, and a fine shall also be imposed.

Good Manufacturing Practice of Medical Products

Prior to December 1, 2019, according to the Administrative Measures for the Certification of Good Manufacturing Practices for Medical Products (《藥品生產質量管理規範認證管理辦法》) issued by the CFDA in August 2011, new drug manufacturing enterprises, or construction of new workshops or new production premise of drug manufacturing enterprises shall apply for the Good Manufacturing Practice Certification for Drugs (the “Drug GMP Certification”) with the pharmaceutical supervision and administration departments. Drug GMP Certification shall be issued to the applicant enterprises meeting the requirements of Good Manufacturing Practice for Pharmaceutical Products (the “Drug GMP”). According to the Announcement on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the People’s Republic of China (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》) promulgated by the NMPA on November 29, 2019 and the Drug Administration Law, the Drug GMP and the Good Supply Practice for Drugs (the “GSP”) certification have been cancelled since December 1, 2019, applications for Drug GMP and GSP certification are no longer accepted, and Drug GMP and GSP certification are no longer issued. The legal representative and principal person in charge of a drug manufacturing enterprise shall be fully responsible for the drug manufacturing activities of the enterprise.

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The Good Manufacturing Practice of Medical Products (《藥品生產質量管理規範》), revised by the former Ministry of Health on January 17, 2011 and implemented on March 1, 2011, requires enterprises to establish a GMP system for drugs, including a quality assurance system, a quality control system, a quality risk management system, and an organization and personnel management system. At the same time, enterprises shall set quality objectives that conform to the GMP requirements for drugs, and systematically apply all the requirements related to safety, effectiveness and controllable quality for drug registration to the entire process of drug manufacturing, control and product release, storage and shipment to ensure that the drugs manufactured are for intended use and meet the requirements for registration.

Contract Manufacturing of Drugs

Pursuant to the Drug Administration Law and the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) promulgated by the former CFDA on August 14, 2014 and taking effect on October 1, 2014, in the event a drug manufacturer that has obtained a drug marketing license is temporarily unqualified for manufacturing as a result of technology upgrade or is under capacity and is therefore unable to ensure market supply, it can entrust the manufacturing of that drug to another drug manufacturer. The purpose of the system of contract manufacturing of drugs is to make full use of existing manufacturing conditions, reduce overlapping investment and construction, optimize the allocation of resources, and promote the structural adjustment of the pharmaceutical industry. The NMPA shall be responsible for guiding, supervising and inspecting the review, approval, supervision and administration of the contract manufacturing of drugs nationwide. The local branches of NMPA of all provinces, autonomous regions and municipalities directly under the central government shall be responsible for the review, approval, supervision and administration of contract manufacturing of drugs.

Both the entrusting party and the entrusted party shall be drug manufacturers holding the GMP certification applicable to the contracted drugs. Both parties shall sign a written contract, including a quality agreement, to specify the rights and obligations of both parties, the quality responsibilities and relevant technical matters of both parties in terms of the management and quality control of contract manufacturing of drugs, and shall observe the relevant national laws and regulations on drug administration.

The Administrative Measures for Supervision of Drug Production (《藥品生產監督管理辦法》) (the “Revised Administrative Measures for Drug Production”) promulgated by the State Administration for Market Regulation on January 22, 2020 and became effective on July 1, 2020, further implementing the marketing authorization holder system for drugs as required by the Drug Administration Law. A drug marketing authorization holder who entrusts others to produce pharmaceutical preparations shall sign an entrustment agreement and a quality agreement with a qualified drug manufacturer, and apply for the drug production license by submitting the relevant agreements together with the application materials of the actual production site to the regulatory departments of drugs. Announcement of the NMPA on Strengthening the Supervision and Administration of Entrusted Production of Drug Marketing Authorization Holders issued by the NMPA on October 17, 2023 and became effective on October 17, 2023, further implemented the main responsibility for the quality and safety of drug production entrusted by the drug marketing authorization holders, and ensured the quality and safety of the drug safety production cycle.

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Drug Distribution Management

The former CFDA promulgated the Measures for the Supervision and Administration of Drug Circulation (《藥品流通監督管理辦法》) on December 8, 2006, which took effect on May 1, 2007 and provided detailed regulations on the purchase, storage, transportation and sales of drugs. A drug manufacturer may only sell drugs manufactured by itself and shall not sell drugs that it is entrusted to manufacture or are manufactured by others. The drug manufacturers and sellers shall be responsible for their drug purchases and sales, and shall bear legal liability for the drug purchases and sales conducted by their sales personnel or the offices established in their names. The storage and transportation of drugs shall comply with relevant requirements (such as refrigerated storage, anti-freezing, damp-proof, light avoidance and ventilation) as stipulated in the drug instructions and by the drug storage and maintenance systems, so as to ensure the quality of drugs.

Drug Operation Permit

According to the Drug Administration Law, a drug operation permit shall be obtained for drug wholesale activities upon approval by the drug regulatory departments of the local people's governments of the provinces, autonomous regions or municipalities directly under the central government, and a drug operation permit shall be obtained for drug retailing activities upon approval by the drug regulatory departments of the local people's governments above the county level. Those who do not have a drug operation permit shall not trade in drugs. The drug operation permit shall indicate the validity period and the business scope of drug operation, and is renewable upon expiry after re-examination. The Measures for the Quality Supervision and Administration of the Operation and Use of Medical Products (《藥品經營和使用質量監督管理辦法》) promulgated by the State Administration for Market Regulation on September 27, 2023 came into effect on January 1, 2024, and the Measures for the Administration of Drug Operation Permit (《藥品經營許可證管理辦法》) was simultaneously repealed. The Measures for the Quality Supervision and Administration of the Operation and Use of Medical Products stipulates the conditions, procedures, changes and supervision and administration of the drug operation permit.

Drug Technology Transfer

The Administrative Regulations for Technology Transfer Registration of Drugs (《藥品技術轉讓註冊管理規定》) issued by the former CFDA and being effective on August 19, 2009 standardizes the registration process of drug technology transfer and stipulated the application, evaluation, examination, approval and supervision of registration for drug technology transfer. The application for drug technology transfer shall be submitted to the provincial drug regulatory authority, and the ultimate approval decision shall be made by the NMPA based on the comprehensive opinions of the center for drug evaluation. A letter of approval and a drug approval number for the supplementary application shall be issued for eligible applications.

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As defined in the Administrative Regulations for Technology Transfer Registration of Drugs, the drug technology transfer refers to the process of transferring drug production technology to the drug production enterprise of the transferee, which in turn applies for drug registration. It is divided into new drug technology transfer and drug production technology transfer. For new drug technology transfer, all relevant technical materials such as production process, quality standards, etc. of the transferred varieties shall be transferred to the transferee, and the transferee shall be instructed to trial-produce quality samples of 3 consecutive production lots. Since the date of approval of the application for registration of new drug technology transfer, the transferee shall continue to complete the relevant requirements set forth in the original drug approval documents of the transferor, such as drug adverse reaction monitoring, Phase IV clinical trial, and other follow-up work. For drug production technology transfer, all materials and technologies such as drug prescription, production process, quality standards, etc. of the drugs involved shall be transferred to the transferee, and the transferee shall be instructed to complete trial production of samples, scale-up, verification & implementation of production process parameters, batch production, etc., and trial-produce quality samples of 3 consecutive production lots.

OTHER LAWS AND REGULATIONS

Product Liability and Protection of Consumer Rights and Interests

The product quality supervision department under the State Council shall be in charge of product quality supervision throughout the country. The relevant departments under the State Council shall be responsible for supervision over product quality within the scope of their respective functions and responsibilities. The quality of a product shall be subject to inspection and up to the standards. No sub-standard product shall be passed off as a product up to the standards. Industrial products that may endanger the human health and personal and property safety shall be in compliance with the national standards and industry standards concerning safeguarding human health and personal and property safety. In the absence of such national standards or industry standards, the product must meet the requirements for safeguarding human health and personal and property safety. It is prohibited to produce or sell any industrial products failing to meet the standards and requirements for safeguarding human health and personal and property safety. Producers or sellers shall be liable for compensation for their illegal acts (such as producing or selling defective, obsolete or invalid products, forging places of origin or quality marks, doping and adulterating, passing fake products as genuine, and taking shoddy and sub-standard products as qualified products). Penalties include confiscation of sales income, revocation of business license and imposition of fines. Where the circumstance is serious, criminal liabilities shall be pursued according to law. The producers or sellers shall be responsible for any personal or property damage due to product defects arising from their breach of contract.

According to the Product Quality Law of the People's Republic of China (《中華人民共和國產品質量法》) revised by the NPC Standing Committee and taking effect on December 29, 2018, producers and sellers shall establish a sound internal product quality control system and strictly adhere to a job responsibility system in relation to quality standards and quality liabilities together with implementing corresponding examination and inspection measures. Producers and sellers shall bear liability for product quality in accordance with this Law.

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According to the Civil Code of the People's Republic of China (《中華人民共和國民法典》) promulgated by the National People's Congress on May 8, 2020 and taking effect on January 1, 2021, In the event of damage to others arising from a defective product, the infringed may seek compensation from either the producer or seller of the said product. If the product defect is caused by the producer, the seller shall be entitled to seek reimbursement from the producer upon compensation. If the product defect is caused through the fault of the seller, the producer shall be entitled to seek reimbursement from the seller upon compensation. If a defect is found in a product after it has been put into circulation, the producer and the seller shall take remedial measures in a timely manner including stopping selling, alerts and recalls. In the event of more damage arising from a failure to take remedial measures in a timely manner or inadequate remedial measures, they shall bear tort liability. A patient may seek compensation from the drug marketing authorization holder, producer or medical institution for any damage arising from defects of drugs. If the said patient seeks compensation from the medical institution, the medical institution shall have the right to, after compensation, claim reimbursement from the drug marketing authorization holder and the producer liable for the damage.

Safety Production

According to the Production Safety Law of the People's Republic of China (《中華人民共和國安全生產法》) revised by the NPC Standing Committee on June 10, 2021 and will take effect on September 1, 2021, a production and business operation entity must (i) abide by this Law and other laws and regulations related to production safety, strengthen production safety management, and establish and improve a production safety responsibility system and production safety rules and regulations for all employees; (ii) increase the efforts to guarantee the input of funds, materials, technology and personnel in production safety, improve production safety conditions, and strengthen standardization and informatization of production safety; (iii) construct a dual prevention mechanism consisting of graded management and control of safety risks and examination and control of potential risks, improve the risk prevention and resolution mechanism, raise production safety levels and ensure production safety. The entities that do not have such conditions are not allowed to engage in production and business activities.

The major person-in-charge of an entity shall take charge of the overall work of the production safety of the entity concerned. Entities who have more than one hundred employees shall establish an administrative organ for production safety or have full-time personnel for the administration of production safety, and those who have less than one hundred employees shall have full-time or part-time personnel for the administration of production safety. The persons in charge of the production safety of entities shall conduct regular inspections over the production safety of the entities concerned by taking the peculiarities of business operation of the entities into consideration. The safety problems that are found out in the inspections shall be dealt with immediately; if they cannot deal with the problems, they shall report to the relevant persons-in-charge in good time. The persons-in-charge shall deal with such situation at once. Records shall be truthfully taken for the inspections and the handling of the problems. The entities and institutions shall educate and urge the employees thereof to observe strictly the regulations and rules thereof for production safety and the rules for safe operations, and shall inform truthfully the employees of the dangerous elements that exist in the site of operations and work positions, of the prevention measures and corresponding emergency measures for dealing with accidents. In addition, the entities shall provide labor protection articles that meet the national standards or industrial standards to the employees thereof, supervise and educate them to wear or use these articles according to the prescribed rules.

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Labor and Social Security

According to the Labor Law of the People's Republic of China (《中華人民共和國勞動法》), which was revised by the NPC Standing Committee and came into effect on December 29, 2018, the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》), which was revised by the NPC Standing Committee on December 28, 2012 and came into effect on July 1, 2013, and the Regulations on the Implementation of the Labor Contract Law of the People's Republic of China, which was issued by the State Council and came into effect on September 18, 2008, the employer shall strictly abide by national standards, provide relevant training for laborers, and guarantee that laborers enjoy labor right and fulfill labor obligations. The employer and the laborers shall sign a written labor contract. Labor contracts consist of fixed-term labor contract, open-ended labor contracts and labor contracts that expire upon completion of given jobs. The wages paid by the employers to the laborers shall not be lower than the local minimum wage standard.

According to the Social Insurance Law of the People's Republic of China (《中華人民共和國社會保險法》), which was revised by the NPC Standing Committee and took effect on December 29, 2018, the Regulations on Management of Housing Provident Funds (《住房公積金管理條例》), which was revised by the State Council and took effect on March 24, 2019 and the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) revised by the State Council and taking effect on March 24, 2019, the employers shall pay basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, basic medical insurance and housing provident funds for their employees according to the statutory payment base and proportion. If any employer fails to pay the relevant monies to the relevant local administrative authority on time and in full, it may be ordered to make up the shortage or be fined.

Intellectual Property Rights

Trademark

The Trademark Law of the People's Republic of China (《中華人民共和國商標法》) amended by the NPC Standing Committee on April 23, 2019 and taking effect on November 1, 2019, and the Regulations for the Implementation of the Trademark Law of the People's Republic of China (《中華人民共和國商標法實施條例》) amended on April 29, 2014 and taking effect on May 1, 2014 provide for the registration application, examination and approval, renewal, alteration, transfer, use and invalidation of trademarks, and protect the exclusive right of a trademark registrant to the relevant trademark. According to the above laws and regulations, the validity period of a registered trademark shall be ten years from the date the registration is approved. Where any registrant intends to continue to use the registered trademark after expiration of the validity period, he/she shall go through renewal formalities according to relevant regulations within 12 months before expiration of the validity period. If he/she fails to complete such formalities within such period, relevant registration can be

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extended for six months. The validity period for each renewal of registration shall be ten years from the expiration date of the last validity period of such trademark. Any trademark registrant may, by signing a trademark license contract, authorize other persons to use his/her registered trademark.

Patents

According to the Patent Law of People’s Republic of China (《中華人民共和國專利法》) last revised by the NPC Standing Committee on October 17, 2020 and taking effect on June 1, 2021, and the Rules for the Implementation of the Patent Law of the People’s Republic of China revised by the State Council on January 9, 2010 and December 11, 2023, and taking effect on January 20, 2024, the Patent Administration Department under the State Council is responsible for the administration of patent work throughout the country, uniformly accepts and reviews patent applications and grants patent rights according to law. The patent administration departments of the people’s governments of provinces, autonomous regions, and municipalities directly under the central government are responsible for patent administration in their respective administrative areas. Any invention or utility model for which patent right may be granted must possess novelty, inventiveness and practical applicability. A design for which the patent right is granted is not an existing design, and no application is filed by any entity or individual for any identical design with the Patent Administration Department under the State Council before the date of application and no identical design is recorded in the patent documentations announced after the date of application. The term of patent right for invention is 20 years, the term of patent right for utility model is ten years and the term of patent right for design is 15 years, all of which are calculated from the date of application. Any entity or individual exploiting the patent of another person shall conclude an exploitation license contract with the patentee and pay the patentee a fee for the exploitation of the patent. The licensee has no right to authorize any entity or individual other than that specified in the contract for exploitation to exploit the patent. Exploiting a patentee’s patent without the permission of the patentee points to the infringement upon the patent right of the patentee.

According to the Patent Law of the People’s Republic of China, for the purpose of public health, the Patent Administration Department under the State Council may grant a compulsory license to manufacture a drug which has been granted a patent right and to export it to the countries or regions specified in related international conventions in which the People’s Republic of China is a contracting member.

In addition, according to the Patent Law of the People’s Republic of China, in order to compensate the time spent on the marketing review and approval of a new drug, for the patent for invention related to a new drug of which the authorization for marketing in China has been obtained, the Patent Administration Department under the State Council shall, at the request of the patentee, award a compensation on the term of the patent. The compensated term shall not exceed five years, and the total effective term of patent right after the marketing authorization of the new drug shall not exceed 14 years. If, in the process of the drug marketing review and approval, a dispute arises between the applicant for drug marketing authorization and the relevant patentee or an interested party on account of the patent right related to the drug applied

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for registration, the relevant party may institute legal proceedings with the people’s court and request the court to make a judgment on whether the relevant technical solution for the drug applied for registration falls within the scope of protection of others’ drug patents. The drug regulatory departments under the State Council may, within the prescribed time limit, make a decision on whether to suspend the approval of the marketing of relevant drug based on the effective judgment of the people’s court.

On July 4, 2021, the NMPA and the China National Intellectual Property Administration issued and put into effect the Measures for the Implementation of the Early Resolution Mechanism of Drug Patent Disputes (Trial) (《藥品專利糾紛早期解決機制實施辦法(試行)》), and the drug patent linkage system will be officially and fully implemented in China. The system aims to link the marketing approval procedure for generic drugs to the patent protection of brand name drugs to offer relevant parties a way to resolve patent disputes during the marketing review and approval of related drugs. The Measures provide for platform construction and information disclosure system, patent right registration system, generic drug patent declaration system, judicial linkage and administrative linkage system, approval waiting period system, drug review and approval classification system and market exclusivity period system for first generic chemical drug which successfully challenge an originator drug patent. If the patentee or interested party has any objection to Type IV patent declaration, they may institute legal proceedings with the people’s court or request an administrative decision from the Patent Administration Department under the State Council regarding whether the relevant technical solution for the drug applied for registration falls within the scope of protection of relevant patent, so as to protect the legitimate rights and interests of the drug patentee and reduce the risk of patent infringement after the generic drugs go on the market.

Trade Secrets

According to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), promulgated by the Standing Committee of the National People’s Congress in September 1993, most recently amended on April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, businesses are prohibited from infringing others’ trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation of the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed

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to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Pursuant to the provisions of the Criminal Law of the PRC (《中華人民共和國刑法》), which was amended by the NPC Standing Committee on December 29, 2023 and came into effect on March 1, 2024, for obtaining business secrets from a business secret owner or the user authorized by a business secret owner (“obligee”) by stealing, bribery, fraud, coercion, electronic intrusion or other illegitimate means; disclosing, using, or allowing others to use the business secrets obtained from the obligee by means mentioned in the preceding paragraph; in violation of the confidentiality obligation or against the obligee’s requirements for keeping business secrets, disclosing, using, or allowing another person to use the business secrets he has, whoever commits any of the above-mentioned acts of infringing on business secrets and the consequences are serious shall be sentenced to fixed-term imprisonment of not more than three years and shall also, or shall only, be fined; if the consequences are especially serious, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than ten years and shall also be fined.

Domain Names

Pursuant to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology on August 24, 2017 and coming into effect on November 1, 2017, the establishment of any domain name root server and institutions for operating domain name root servers, managing the registration of domain names and providing domain name registration services within the territory of China shall be subject to the approval of the Ministry of Industry and Information Technology or communications administration departments of provinces, autonomous regions and municipalities directly under the central government.

Customs

According to the Customs Law of the PRC (《中華人民共和國海關法》) which was passed by the NPC Standing Committee on January 22, 1987 and last amended and came into effect on April 29, 2021, the Customs of the PRC is the state’s entry and exit customs supervision and administration authority. The Customs of the PRC is responsible for the supervision of the transport vehicles, goods, freight items, postal items and other items entering into and departing from the PRC and collecting tariff and other duties and charges and is in charge of detecting and suppressing smuggling, compiling customs statistics and handling other customs related issues. Where a consignee or consignor of import or export goods or a customs clearance enterprise needs to go through customs declaration procedures, they shall be subject to registration by the Customs in accordance with law. Customs clearance enterprises or customs clearance personnel shall not illegally broker customs clearance on behalf of others.

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According to the Provisions of the Customs of the People's Republic of China on the Administration of Filing of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》) on November 19, 2021 and implemented from January 1, 2022, the term "declaration entities" refers to the consignee or consignor of import and export goods registered with the Customs, as well as declaring entities. The filing of a customs declaration entity is valid for a long period of time, while the provisional filing is valid for one year, with application for re-filing to be made upon expiration.

Environmental Protection

According to the Law of the People's Republic of China on Assessment of Environment Impacts (《中華人民共和國環境影響評價法》) amended by the NPC Standing Committee on December 29, 2018 and coming into effect on the same day, the Management Regulations for the Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) amended by the State Council on July 16, 2017 and coming into effect on October 1, 2017 and the Interim Measures for Acceptance Inspections for Environmental Protection Purposes over Completed Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) promulgated by the former Ministry of Environmental Protection on November 20, 2017 and taking effect on the same day, enterprises planning construction projects shall provide environmental impact reports, environmental impact statements and environmental impact registration forms related to such projects. Such environmental impact reports and environmental impact statements must be approved by the competent environmental protection authorities prior to commencement of any construction project and the environmental impact registration forms shall be filed with the abovementioned authorities. Unless otherwise stipulated by laws and regulations, the enterprises that are required to submit the environmental impact reports and the environmental impact statements shall be responsible for the acceptance of the environmental protection facilities by themselves upon the completion of the construction project. Any construction project cannot be officially put into production or use until the corresponding environmental protection facilities have passed the acceptance test. The competent departments may conduct spot checks and supervision on the implementation of the environmental protection facilities.

Enterprises and other producers that discharge pollutants shall take measures to prevent and control pollution and damage to environment caused by waste gas, waste water, residue or dust produced in the course of production, construction or other activities. Enterprises or other producers and business operators that discharge pollutants shall establish a responsibility system for environmental protection and define the responsibilities of the person-in-charge and related personnel. The facilities for the prevention and control of pollution in construction projects must be designed, built and commissioned together with the principal part of the project. The facilities for the prevention and control of pollution shall meet the requirements of the approved environmental impact assessment documents and may not be dismantled or leave unused without authorization.

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According to the Catalogue of Classified Management of Pollutant Discharge Permits for Fixed Pollution Sources (2019) (《固定污染源排污許可分類管理名錄(2019年版)》) promulgated by the Ministry of Ecology and Environment on December 20, 2019 and coming into effect on the same day, key management, simplified management or registration management of pollutant discharge permits shall be implemented according to factors such as the amount of pollutant produced or discharged and the degree of impact on the environment of the enterprises discharging pollutants. Pollutant-discharging units qualified for registration management do not need to apply for pollutant-discharging permits, but should fill in a pollutant-discharging registration form on the national pollutant-discharging permit information management platform.

According to the Guidelines on the Registration of Discharge from Fixed Pollution Sources (Trial) (《固定污染源排污登記工作指南(試行)》) promulgated by the Ministry of Ecology and Environment on January 6, 2020 and becoming effective on the same day, enterprises that are not required by law to apply for a pollutant discharge permit should register their pollutant discharge in accordance with the guidelines.

Regulations on Taxation

Enterprise Income Tax

According to the Enterprise Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法》) amended by the NPC Standing Committee and becoming effective on December 29, 2018, and the Regulations on the Implementation of the Enterprise Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法實施條例》) amended by the State Council and becoming effective on April 23, 2019, an enterprise, which is established within the territory of PRC according to law or established as per the laws of a foreign country (region) but has an actual management office within the territory of PRC, is a resident enterprise. A resident enterprise shall pay enterprise income tax for the income derived from both inside and outside the PRC at a rate of 25%. An enterprise income tax preference shall be granted to industries and projects strongly supported and encouraged by the state; an enterprise income tax shall be levied on high-tech enterprises at a reduced rate of 15%.

Value-added Tax

Pursuant to the Provisional Regulations of the People's Republic of China on Value-added Tax (《中華人民共和國增值稅暫行條例》) amended by the State Council and becoming effective on November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the People's Republic of China on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》) amended by the Ministry of Finance on October 28, 2011, and becoming effective on November 1, 2011, all taxpayers engaging in sale of goods, provision of processing services, repairs and replacement services, sales services, intangible assets, real estate or importation of goods within the territory of PRC shall pay value-added

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tax. A tax rate of 17% shall apply for general taxpayers selling goods and services, leasing tangible movable assets or importing goods, while the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-added Tax Rates (《財政部、稅務總局關於調整增值稅稅率的通知》) which was promulgated by the Ministry of Finance and the State Taxation Administration on April 4, 2018 and coming into effect on May 1, 2018, the tax rates of 17% and 11% applicable to any taxpayer's VAT taxable sale or import of goods are adjusted to 16% and 10%, respectively. According to the Announcement on Relevant Policies for Deepening the Value-added Tax Reform (《關於深化增值稅改革有關政策的公告》) promulgated by the Ministry of Finance, the State Taxation Administration and the General Administration of Customs on March 20, 2019 and becoming effective on April 1, 2019, the value added tax rates were adjusted to 13% and 9%, respectively.

Regulations on Foreign Investment

On January 1, 2020, the Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法》) (hereinafter referred to as "Foreign Investment Law") promulgated by the National People's Congress on March 15, 2019 came into effect and the Law of the People Republic of China on Chinese-Foreign Equity Joint Ventures (《中華人民共和國中外合資經營企業法》), the Law of the People's Republic of China on Foreign-funded Enterprises (《中華人民共和國外資企業法》) and the Law of the People's Republic of China on Chinese-Foreign Contractual Joint Ventures (《中華人民共和國中外合作經營企業法》) were repealed. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partly funded by foreign investors. The organization form and structure and operating rules of foreign-invested enterprises are subject to the provisions of the Company Law of the People's Republic of China (《中華人民共和國公司法》), and other applicable laws. China has implemented a management system of pre-establishment national treatment plus a negative list for foreign investment and replaced the previous system of approval and filing for the establishment and change of foreign-invested enterprises. The pre-establishment national treatment refers to granting to foreign investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments; the negative list refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. The State provides national treatment to foreign investment beyond the negative list. The Foreign Investment Law, while strengthening the promotion and protection of investment, further standardizes the management of foreign investment and proposes the establishment of foreign investment information reporting system, which replaces the approval and filing system for foreign investment enterprises by the Ministry of Commerce. Foreign investment information reporting is subject to the Measures for Foreign Investment Information Reporting (《外商投資信息報告辦法》) jointly formulated by the Ministry of Commerce and the State Administration for Market Regulation and coming into effect on January 1, 2020. According to the Measures for Foreign Investment Information Reporting, foreign investors who directly or indirectly invest in China shall submit the investment information to competent departments

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for commerce through the enterprise registration system and the national enterprise credit information publicity system; the reporting formats are divided into initial report, change report, cancellation report, annual report, etc.

The investment of foreign investors and foreign-invested enterprises in China is subject to the Catalogue of Industries for Guiding Foreign Investment (《外商投資產業指導目錄》). According to the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2021) (《外商投資准入特別管理措施(負面清單(2021年版))》) and the Catalogue of Industries for Encouraging Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版))》) promulgated by the National Development and Reform Commission and the Ministry of Commerce on October 26, 2022 and coming into effect on January 1, 2023, foreign investment projects can be divided into three categories: encouraged, restricted and prohibited. Foreign-invested projects that are not listed in the Negative List are permitted foreign-invested projects.

As of the Latest Practicable Date, the business of the Company does not belong to any restricted or prohibited industries listed in the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2021).

Overseas Securities Offering and Listing by Domestic Enterprises

On February 17, 2023, the CSRC issued the Trial Measures for the Administration of Overseas Securities Offering and Listing by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) (the “Trial Measures for Administration”) and the 5 ancillary guidelines, which have come into effect since March 31, 2023. The trial measures comprehensively improve and reform the current regulatory system for overseas offering and listing of securities by domestic enterprises, and regulate the direct and indirect offering and listing of securities overseas by domestic enterprises through the adoption of a regulatory system based on filing. According to the Trial Measures for Administration, overseas listing and offering shall not be permitted under any of the following circumstances, where: (i) listing and financing is specifically prohibited by the laws, administrative regulations or relevant national regulations of the PRC; (ii) overseas offering and listing may endanger national security as determined by the relevant competent department of the State Council after examination in accordance with the laws; (iii) a domestic enterprise or its controlling shareholder or de facto controller has committed a criminal crime of corruption, bribery, embezzlement of property, misappropriation of property or disrupting the economic order of the socialist market in the last three years; (iv) a domestic enterprise is under investigation according to the laws for being suspected of crimes or major violations of laws and regulations and but no clear conclusion has been made; or (v) there is a major dispute over ownership of the equity interests held by the controlling shareholder or the shareholder controlled by the controlling shareholder or the de facto controller.

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On February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening Confidentiality and Archives Administration for Overseas Securities Offering and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the “Confidentiality Provisions”), which became effective from March 31, 2023. Pursuant to Confidentiality Provisions, a domestic enterprise must obtain approval from the competent departments with the authority to examine and approve, in accordance with the laws, and file a record with the administrative department for confidentiality at the same level, when providing or publicly disclosing, or providing or public disclosing through its overseas listed entities, documents and information involving secrets of the State and work secrets of the organizations of the State to relevant securities companies, securities service institutions, overseas regulatory authorities, and other entities and individuals. Domestic enterprises shall perform relevant procedures in compliance with the relevant provisions of the State when providing accounting files or copies of accounting files to relevant securities companies, securities service institutions, overseas regulatory authorities, and other entities and individuals. The working papers generated domestically by securities companies and securities service institutions, which provide services in respect of overseas offering and listing for domestic enterprises, shall be stored within the territory. Those that need to transmit working papers outbound shall go through examination and approval formalities in accordance with the relevant provisions of the State.

OVERVIEW OF LAWS AND REGULATIONS IN THE U.S.

This section summarizes the principal laws and regulations in the U.S. that are relevant to our business.

LAWS AND REGULATIONS IN RELATION TO NEW DRUG

U.S. Government Regulation of Drug and Biological Products

In the U.S., the FDA regulates drugs under the FDCA, its implementing regulations and biologics under the FDCA and the Public Health Service Act (the “PHSA”) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

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Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of IND must submit the results of the preclinical testing, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (“IRB”), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap.

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect, tolerability and safety of the product candidate.
- Phase II clinical trials involve studies on disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

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Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or BLA. Unless deferred or waived, NDAs or BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of an NDA or a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is GMP-compliant to assure the product's identity, strength, quality and purity. Before approving the NDA/BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA/BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the NDA/BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for

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example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the NDA/BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase IV clinical trials, to further assess a product's safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In the U.S., products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product, which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Expedited Development and Review Programs

Accelerated Approval

Under FDA's accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

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Breakthrough Designation

Another program available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of IND, and according to FAQs published by the FDA (current as of February 3, 2022), the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product’s marketing application, including by meeting with the sponsor throughout the product’s development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstance.

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We are a clinical demand-oriented, registrational clinical-stage biopharmaceutical company focusing on discovering and developing innovative small molecule therapies for oncology, inflammatory and cardiovascular diseases. Our Company was founded by two individuals, both being Independent Third Parties, in April 2014. Dr. Wu, our executive Director and the chairman of our Board, acquired 40% equity interest of our Company from the then shareholder of our Company in November 2016. For the details of the background and industry experience of Dr. Wu, please see the section headed “Directors, Supervisors and Senior Management” in this document.

BUSINESS DEVELOPMENT MILESTONES

The following table summarizes the key milestones in our business development:

Year	Milestone
2014	Our Company was incorporated in the PRC
2016	Dr. Wu acquired 40% equity interest of our Company from the then shareholder of our Company (with the remaining 60% equity interest of our Company held as to 22.94%, 19.13% and 17.93% by Nanjing Jiminrui, Nanjing Yipu and PharmaBlock, respectively) In December, we completed the Series A-1 Financing and raised RMB30 million
2017	In September, we completed our Series A-2 Financing and raised RMB30 million
2018	In September, we completed our Series B Financing and raised RMB100 million In September, we received IND approval from the FDA to conduct Phase I clinical trial for Tinengotinib in the U.S.
2019	In February, we received IND approval from the NMPA to conduct Phase I clinical trial for Tinengotinib in the PRC In November, Tinengotinib was granted “Orphan Drug” by the FDA to treat CCA In December, we received IND approval from the FDA to conduct Phase I clinical trial for TT-00920 in the U.S.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
2020	<p>In March, we completed our Series C-1 Financing and raised RMB220 million</p> <p>In July, we completed our Series C-2 Financing and Series C-3 Financing and raised RMB110 million</p> <p>In August, we entered into an exclusive license agreement to out-licensed TT-01025 to LG Chem globally excluding Greater China and Japan</p> <p>In October and December, we entered into two collaboration and license agreements with Teijin seeking collaboration with respect to the research of projects based upon certain existing hit/lead compounds discovered and controlled by Teijin</p> <p>In November, we received IND approval from the FDA to conduct Phase Ib/II clinical trial for Tinengotinib in the U.S.; we received IND approval from the NMPA to conduct Phase I clinical trial for TT-00920 in PRC; we received IND approval from the FDA to conduct Phase I clinical trial for TT-01025 in the U.S.</p>
2021	<p>In March, we entered into a master clinical supply agreement with Roche to explore the combination of Tinengotinib and atezolizumab for the treatment of patients in China with BTC</p> <p>In April, we completed our Series C+ Financing and raised approximately RMB330 million</p> <p>In May, we received IND approval from the NMPA to conduct Phase Ib/II clinical trial for Tinengotinib in PRC; we received IND approval from the NMPA to conduct Phase I clinical trial for TT-01025 in PRC in May</p> <p>In July, we completed our Series D Financing and raised approximately RMB642.7 million</p> <p>In August, the FDA granted Tinengotinib the fast track designation</p> <p>In September, TT-01025 initiated FIH in the PRC for the potential market of the PRC, which was sponsored by our Company</p>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
	<p>In October, Tinengotinib commenced the Phase II of clinical trial for indication of mCRPC in the U.S. for the potential global market, which was sponsored by our Company</p> <p>In November, we received IND approval of TT-01688 from the NMPA to conduct Phase Ib/II clinical trial for the treatment UC in the PRC; Tinengotinib enrolled the first patient for a CCA-focused Phase II study in the U.S.</p>
2022	<p>In January, TT-01488 received the FDA IND approval</p> <p>In April, TT-01688 received the NMPA IND approval and undertakes phase II clinical trial</p> <p>TT-01488 received the NMPA IND approval</p> <p>In August, TT-00973 received the NMPA IND approval for solid tumor</p>
2023	<p>In February, we completed our Series D+ Financing and raised RMB260 million</p> <p>In July, Tinengotinib received Breakthrough Therapy Designation from the NMPA</p> <p>In October, Tinengotinib obtained the IND approval from the TFDA for conducting registrational Phase III clinical trial</p> <p>In November, Tinengotinib initiated a pivotal Phase II clinical trial in China and obtained the IND approval from the MFDS for conducting registrational Phase III clinical trial</p> <p>In December, Tinengotinib initiated a Phase III registrational clinical trial in certain countries and regions outside China</p>
2024	<p>In February, Tinengotinib obtained the IND approval from the EMA for conducting registrational Phase III clinical trial in five European Union countries, i.e. Belgium, Germany, Italy, Spain, and Poland</p> <p>In March , Tinengotinib obtained the IND approval from the EMA for conducting registrational Phase III clinical trial in three European Union countries, i.e. France, Austria and Portugal</p> <p>In June, Tinengotinib obtained the IND approval from the MHRA for conducting registrational Phase III clinical trial in the United Kingdom</p>

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OUR SUBSIDIARIES

As of the Latest Practicable Date, we had two subsidiaries, details of which are set forth below:

<u>Subsidiaries</u>	<u>Date and place of incorporation</u>	<u>Issued share capital</u>	<u>Principal business activities</u>
TransThera HK	August 18, 2022; HK	HK\$10,000	Investment holding
TransThera US	September 19, 2022; U.S.	US\$5,000	Research and development of pharmaceutical products

CORPORATE DEVELOPMENT AND SHAREHOLDING CHANGES OF OUR COMPANY

Our business operations are conducted through our Company and two subsidiaries. The following sets forth the corporate history and shareholding changes of our Company.

Incorporation of Our Company

On April 15, 2014, our Company was established as a limited liability company under the laws of the PRC, with an initial registered capital of RMB10.0 million. Upon the establishment, our Company was owned as to 95% and 5% by Dr. Yang Minmin (楊民民) and Mr. Wu Xihan (吳希罕), respectively, both of whom are Independent Third Parties. Dr. Wu became acquainted with Mr. Wu Xihan, who was a director of PharmaBlock, through their mutual-friend Dr. Yang Minmin, the founder and chairman of the board of directors of PharmaBlock, and there is no other relationship between Dr. Wu and Mr. Wu Xihan. PharmaBlock is a joint stock limited liability company incorporated in the PRC which is listed on the Shenzhen Stock Exchange (stock code: 300725). As of the date of this document, there is no overlap of the members of management between our Company and PharmaBlock.

Subsequent Capital Changes and Equity Transfers

(a) 2015 Transfers

On February 8, 2015, the then shareholders of our Company, Dr. Yang Minmin and Mr. Wu Xihan, resolved to decrease the registered capital of our Company from RMB10.0 million to RMB2.0 million in proportion to their respective equity interest in our Company.

On April 1, 2015, each of Mr. Wu Xihan and Dr. Yang Minmin entered into an equity transfer agreement with Mr. Li Jin (李進) and PharmaBlock, both being the Independent Third Parties. Pursuant to the equity transfer agreements, Mr. Wu Xihan transferred his 5% equity interest in our Company to Mr. Li Jin at nil consideration given such registered capital had not

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been paid up at the time of the transfer and Dr. Yang Minmin transferred his 95% equity interest in our Company to PharmaBlock at the consideration of RMB1.35 million considering RMB0.55 million of the registered capital subscribed for by him had not been paid up at the time of the transfer.

Upon completion of the capital decrease and the equity transfers on July 7, 2015, our Company became owned as to 95% and 5% by PharmaBlock and Mr. Li Jin, respectively, with a registered capital of RMB2.0 million, of which RMB1.45 million was paid up.

(b) 2016 Transfers

Pursuant to an equity transfer agreement dated April 27, 2016 entered into by each of Mr. Li Jin and PharmaBlock with Mr. Wu Eqing (吳萼青), Dr. Wu’s father, Mr. Li Jin transferred his 4% equity interest in our Company and PharmaBlock transferred its 76% equity interest in our Company to Mr. Wu Eqing at the consideration of RMB80,000 and RMB1.52 million, respectively. The considerations were determined by the parties after arm’s length negotiations based on the then registered capital of our Company considering our Company was still at its early research and development stage. Upon the completion of the equity transfers on May 10, 2016, our Company was owned as to 80%, 19% and 1% by Mr. Wu Eqing, PharmaBlock and Mr. Li Jin, respectively, with a registered capital of RMB2.0 million, which was fully paid up subsequently in May 2016.

On September 14, 2016, Mr. Wu Eqing entered an equity transfer agreement with each of Nanjing Jiminrui and Nanjing Yipu. Pursuant to the equity transfer agreements, Mr. Wu Eqing transferred his 22.94% and 17.06% equity interest in our Company to Nanjing Jiminrui and Nanjing Yipu at the consideration of RMB458,800 and RMB341,200, respectively. On the same date, each of PharmaBlock and Mr. Li Jin entered into an equity transfer agreement with Nanjing Yipu, pursuant to which PharmaBlock transferred its 1.07% equity interest in our Company and Mr. Li Jin transferred his 1% equity interest in our Company to Nanjing Yipu at the consideration of RMB21,400 and RMB20,000, respectively. The abovementioned considerations were determined based on the then paid-up registered capital of our Company. Upon completion of the above equity transfers on September 29, 2016, our Company was owned as to 40.00%, 22.94%, 19.13% and 17.93% by Mr. Wu Eqing, Nanjing Jiminrui, Nanjing Yipu and PharmaBlock, respectively, with a registered capital of RMB2.0 million.

Nanjing Jiminrui is a limited partnership established under the laws of the PRC and is controlled by Dr. Wu as its general partner. As of the Latest Practicable Date, Mr. Wu Di (吳笛), an executive Director and vice president of our Company, was the only limited partner of Nanjing Jiminrui with 0.10% partnership interest. Nanjing Yipu is one of our Employee Incentive Platforms, which is a limited partnership established in the PRC and is also controlled by Dr. Wu as its sole general partner. For further details on Nanjing Yipu, please refer to the paragraph headed “Employee Incentive Schemes” in this section.

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Pursuant to an equity transfer agreement dated October 24, 2016 entered into between Dr. Wu, our executive Director and the chairman of our Board, and Mr. Wu Eqing, Mr. Wu Eqing transferred his 40% equity interest in our Company to Dr. Wu at the consideration of RMB0.8 million which was determined with reference to the paid-up registered capital. Upon the completion of the equity transfer, our Company was converted into a sino-foreign equity joint venture with limited liability. Upon completion of the equity transfer on November 18, 2016, our Company was owned as to 40.00%, 22.94%, 19.13% and 17.93% by Dr. Wu, Nanjing Jiminrui, Nanjing Yipu and PharmaBlock, respectively, with a registered capital of RMB2.0 million.

(c) Series A-1 Financing and Series A-2 Financing

Pursuant to a capital increase agreement dated August 17, 2016 entered into by and amongst our Company, Dr. Wu, PharmaBlock, Mr. Li Jin, Genecare Development and Shanghai Guohong Medical and Health Investment Center (Limited Partnership) (上海國弘醫療健康投資中心(有限合夥)) (“**Guohong Medical**”), Genecare Development and Guohong Medical subscribed for the increased registered capital of RMB257,336 at consideration of RMB30,000,000, respectively (the “**Series A-1 Financing**”). The then shareholders of our Company resolved to increase the registered capital of our Company from RMB2,000,000 to RMB2,257,336 on November 30, 2016.

The respective subscription amount and consideration for each subscriber were as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration	Corresponding equity interest in our Company (upon completion of the capital increase) (%)
		USD3,599,286.53 (equivalent to	
Genecare Development ⁽¹⁾	214,447.0	RMB25.0 million)	9.50
Guohong Medical ⁽¹⁾	42,889.0	RMB5.0 million	1.90
Total	257,336.0	RMB30.0 million	11.40

Note:

- (1) Both Genecare Development and Guohong Medical are our Pre-[REDACTED] Investors and the Independent Third Parties. Genecare Development became acquainted with our Company through Mr. Yang Minmin, the chairman and general manager of our Shareholder, PharmaBlock. Our Company became acquainted with Guohong Medical when Guohong Medical solicited us and expressed the interest in investing our Company in 2016.

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Upon completion of the capital increase on December 6, 2016, the shareholding structure of our Company was as follows:

Shareholders	Registered capital (RMB)	Equity interest (%)
Dr. Wu	800,000.0	35.44
Nanjing Jiminrui	458,800.0	20.32
Nanjing Yipu	382,600.0	16.96
PharmaBlock	358,600.0	15.88
Genecare Development	214,447.0	9.50
Guohong Medical	42,889.0	1.90
Total	2,257,336.0	100.00

Pursuant to the abovementioned capital increase agreement dated August 17, 2016, upon the achievement of relevant research and development of milestone as provided in the agreement, (i) the registered capital of our Company shall be increased from RMB2,257,336 to RMB2,450,822; and (ii) Genecare Development and Guohong Medical subscribed for the increased registered capital of RMB193,486 at the total consideration of RMB30.0 million (the “**Series A-2 Financing**”). In August 2017, the then shareholders of our Company approved such increase in the registered capital.

The respective subscription amount and consideration for each subscriber were as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration	Corresponding equity interest in our Company (upon completion of the capital increase) (%)
		USD3,808,263.45 (equivalent to	
Genecare Development	161,238.0	RMB25.0 million)	6.58
Guohong Medical	32,248.0	RMB5.0 million	1.32
Total	193,486.0	RMB30.0 million	7.89

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the capital increase on September 6, 2017, the shareholding of our Company was as follows:

Shareholders	Registered capital (RMB)	Equity interest (%)
Dr. Wu	800,000.0	32.64
Nanjing Jiminrui	458,800.0	18.72
Nanjing Yipu	382,600.0	15.61
PharmaBlock	358,600.0	14.63
Genecare Development	375,685.0	15.33
Guohong Medical	75,137.0	3.07
Total	2,450,822.0	100.00

(d) 2018 Capital Increase

On July 6, 2018, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB2,450,822 to RMB2,526,621. Nanjing Yipu subscribed the increased registered capital of RMB75,799 at the consideration of RMB75,799.

Upon completion of the capital increase on July 31, 2018, the shareholding of our Company was as follows:

Shareholders	Registered capital (RMB)	Equity interest (%)
Dr. Wu	800,000.0	31.66
Nanjing Jiminrui	458,800.0	18.16
Nanjing Yipu	458,399.0	18.14
PharmaBlock	358,600.0	14.19
Genecare Development	375,685.0	14.87
Guohong Medical	75,137.0	2.97
Total	2,526,621.0	100.00

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(e) Series B Financing

On August 7, 2018, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB2,526,621 to RMB2,887,567. Pursuant to a capital increase agreement dated August 9, 2018 entered into among our Company, Dr. Wu, Nanjing Jiminrui, Nanjing Yipu, PharmaBlock, GP Healthcare Capital Phase II, Nanjing Jingshi Venture Capital Center (Limited Partnership) (南京璟石創業投資中心(有限合夥)) (“**Nanjing Jingshi**”), Genecare Development and Guohong Medical, GP Healthcare Capital Phase II, Nanjing Jingshi, Genecare Development and Guohong Medical subscribed for the increased registered capital of RMB360,946 at a total consideration of RMB100 million (the “**Series B Financing**”).

The respective subscription amount and consideration for each subscriber in the Series B Financing were as follows:

Subscribers	Registered capital subscribed for <i>(RMB)</i>	Consideration	Corresponding equity interest in our Company (upon completion of the capital increase) <i>(%)</i>
GP Healthcare Capital Phase II ⁽¹⁾	180,473.0	RMB50.0 million	6.25
Nanjing Jingshi ⁽²⁾	72,189.0	RMB20.0 million USD2,918,048.67 (equivalent to	2.50
Genecare Development	72,189.0	RMB20.0 million)	2.50
Guohong Medical	36,095.0	RMB10.0 million	1.25
Total	360,946.0	RMB100.0 million	12.50

Notes:

- (1) GP Healthcare Capital Phase II is our Pre-[REDACTED] Investor and an Independent Third Party. It became acquainted with our Company through our then financial advisor, Shanghai Huijia Investment Consulting Co., Ltd. (上海慧嘉投資顧問有限公司) (“**Shanghai Huijia**”).
- (2) The registered capital of RMB72,189 and the obligation of Nanjing Jingshi to pay for the consideration of RMB20 million were transferred to Nanjing InnoMed Innovation & Entrepreneurship Investment Partnership (Limited Partnership) (南京鷹盟創新創業投資合夥企業(有限合夥)) (“**Nanjing InnoMed**”) pursuant to an equity transfer agreement dated April 11, 2019 between Nanjing Jingshi and Nanjing InnoMed. Nanjing InnoMed is a Pre-[REDACTED] Investor and an Independent Third Party. Nanjing InnoMed became acquainted with our Company through our then financial advisor, Shanghai Huijia.

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Upon completion of the capital increase on September 11, 2018, the shareholding structure of our Company was as follows:

Shareholders	Registered capital (RMB)	Equity interest (%)
Dr. Wu	800,000.0	27.71
Nanjing Jiminrui	458,800.0	15.89
Nanjing Yipu	458,399.0	15.87
PharmaBlock	358,600.0	12.42
Genecare Development	447,874.0	15.51
Guohong Medical	111,232.0	3.85
GP Healthcare Capital Phase II	180,473.0	6.25
Nanjing Jingshi ⁽¹⁾	72,189.0	2.50
Total	2,887,567.0	100.00

Note:

- (1) Pursuant to an equity transfer agreement dated April 11, 2019 between Nanjing Jingshi and Nanjing InnoMed, Nanjing Jingshi transferred its unpaid registered capital of our Company of RMB72,189 (representing 2.50% equity interest in our Company) to Nanjing InnoMed at nil consideration. Upon completion of the transfer on May 16, 2019, Nanjing InnoMed became a shareholder with 2.50% equity interest in our Company.

(f) Series C-1 Financing

On March 3, 2020, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB2,887,567 to RMB3,609,458. Pursuant to an investment agreement dated March 3, 2020 entered into among our Company, Dr. Wu, Nanjing Jiminrui, Nanjing Yipu, PharmaBlock, Genecare Development, Guohong Medical, GP Healthcare Capital Phase II, Nanjing InnoMed, FIIF II, Nanjing Zijin Advanced Manufacture Industry Equity Investment Center (Limited Partnership) (南京紫金先進製造產業股權投資中心(有限合夥)) (“**Nanjing Zijin**”), Nanjing Jiangbei Medical Innovation Industry Fund (Limited Partnership) (南京江北醫療創新產業基金(有限合夥)) (“**Jiangbei Fund**”) and Nanjing Qiruiyoukang Venture Capital Partnership (Limited Partnership) (南京其瑞佑康創業投資合夥企業(有限合夥)) (formerly known as Nanjing Qiruiyoukang Technology Development Investment Partnership (Limited Partnership) (南京其瑞佑康科技發展投資合夥企業(有限合夥))) (“**Nanjing Qiruiyoukang**”), FIIF II, Nanjing Zijin, Jiangbei Fund and Nanjing Qiruiyoukang subscribed the increased registered capital of RMB721,891 at a total consideration of RMB220 million (the “**Series C-1 Financing**”).

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The respective subscription amount and consideration for each subscriber in the Series C-1 Financing were as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration (RMB'000)	Corresponding equity interest in our Company (upon completion of the capital increase) (%)
FIIF II ⁽¹⁾	393,759.0	120,000.0	10.91
Nanjing Zijin ⁽¹⁾	131,253.0	40,000.0	3.64
Jiangbei Fund ⁽¹⁾	164,066.0	50,000.0	4.54
Nanjing Qiruiyoukang ⁽¹⁾	32,813.0	10,000.0	0.91
Total	721,891.0	220,000.0	20.00

Note:

- (1) FIIF II, Nanjing Zijin, Jiangbei Fund and Nanjing Qiruiyoukang are all our Pre-[REDACTED] Investors and the Independent Third Parties. Jiangbei Fund and Nanjing Qiruiyoukang became acquainted with our Company when our Company resided in Jiangbei New Area of Nanjing City. FIIF II and Nanjing Zijin became acquainted with our Company through GP Healthcare Capital Phase II, one of our Shareholders and Pre-[REDACTED] Investors in Series B Financing.

Upon completion of the capital increase on March 16, 2020, the shareholding structure of our Company was as follows:

Shareholders	Registered capital (RMB)	Equity interest (%)
Dr. Wu	800,000.0	22.16
Nanjing Jiminrui	458,800.0	12.71
Nanjing Yipu	458,399.0	12.70
PharmaBlock	358,600.0	9.94
Genecare Development	447,874.0	12.41
Guohong Medical	111,232.0	3.08
GP Healthcare Capital Phase II	180,473.0	5.00
Nanjing InnoMed	72,189.0	2.00
FIIF II	393,759.0	10.91
Nanjing Zijin	131,253.0	3.64
Jiangbei Fund	164,066.0	4.55
Nanjing Qiruiyoukang	32,813.0	0.91
Total	3,609,458.0	100.00

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(g) Series C-2 Financing and Series C-3 Financing

On July 22, 2020, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB3,609,458 to RMB3,806,338. On July 22, 2020, the then shareholders of our Company further resolved to increase the registered capital of our Company from RMB3,806,338 to RMB3,970,404. Pursuant to an investment agreement dated May 20, 2020 entered into among our Company, the then shareholders of our Company, Zhangjiagang Guohong Jiyuan Investment Partnership (Limited Partnership) (張家港國弘紀元投資合夥企業(有限合夥)) (“**Guohong Jiyuan**”), Nanjing Ennovation Raylight Venture Capital Partnership (Limited Partnership) (南京恩然瑞光創業投資合夥企業(有限合夥)) (formerly known as Nanjing Ennovation Raylight Healthcare Investment Partnership (Limited Partnership) (南京恩然瑞光健康產業投資合夥企業(有限合夥))) (“**Ennovation Raylight**”) and Parkway Limited, Guohong Jiyuan, Ennovation Raylight, GP Healthcare Capital Phase II and Parkway Limited subscribed the increased registered capital of RMB196,880 at a total consideration of RMB60 million (the “**Series C-2 Financing**”). Pursuant to an investment agreement entered into among our Company, the then shareholders of our Company, Guohong Jiyuan, Ennovation Raylight, Eastern Handson Holdings Limited (“**Eastern Handson**”) (which agreed to subscribed the registered capital of our Company in replacement of Parkway Limited) and SDICVC Ningbo Fund on July 22, 2020, SDICVC Ningbo Fund subscribed the increased registered capital of RMB164,066 at a total consideration of RMB50 million (the “**Series C-3 Financing**”).

The respective subscription amount and consideration for each subscriber in the Series C-2 Financing and Series C-3 Financing were as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration	Corresponding equity interest in our Company (upon completion of the capital increase) (%)
Guohong Jiyuan ⁽¹⁾	65,627.0	RMB20.0 million	1.65
Ennovation Raylight ⁽¹⁾	54,142.0	RMB16.5 million	1.36
GP Healthcare Capital Phase II ⁽¹⁾	54,142.0	RMB16.5 million USD1,027,610 (equivalent to	1.36
Eastern Handson ⁽¹⁾⁽²⁾	22,969.0	RMB7.0 million)	0.58
SDICVC Ningbo Fund ⁽¹⁾	164,066.0	RMB50.0 million	4.13
Total	360,946.0	RMB110.0 million	9.09

Notes:

- (1) Guohong Jiyuan, Ennovation Raylight, GP Healthcare Capital Phase II, Eastern Handson and SDICVC Ningbo Fund are our Pre-[REDACTED] Investors and the Independent Third Parties. Except for Guohong Jiyuan which was introduced by our Shareholder, PharmaBlock, the rest of the Pre-[REDACTED] Investors of Series C-2 Financing and Series C-3 Financing became acquainted with our Company through our then financial advisor, Shanghai Huijia.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (2) Due to the outbreak of COVID-19, it was more time consuming for Parkway Limited, a company incorporated in the British Virgin Islands, to complete the relevant notary and filings required for subscription of registered capital of our Company as compared to Eastern Handson, a company incorporated in Hong Kong. In the interest of time, our Company, the then shareholders of our Company, Guohong Jiyuan, Ennovation Raylight, Parkway Limited and Eastern Handson entered into an agreement in July 2020, pursuant to which Eastern Handson subscribed for the registered capital of RMB22,969 of our Company in replacement of Parkway Limited.

Upon completion of the capital increase on July 28, 2020, the shareholding structure of our Company was as follows:

Shareholders	Registered capital (RMB)	Equity interest (%)
Dr. Wu	800,000.0	20.15
Nanjing Jiminrui	458,800.0	11.56
Nanjing Yipu	458,399.0	11.55
PharmaBlock	358,600.0	9.03
Genecare Development	447,874.0	11.28
Guohong Medical	111,232.0	2.80
GP Healthcare Capital Phase II	234,615.0	5.91
Nanjing InnoMed	72,189.0	1.82
FIIF II	393,759.0	9.92
Nanjing Zijin	131,253.0	3.31
Jiangbei Fund	164,066.0	4.13
Nanjing Qiruiyoukang	32,813.0	0.83
Guohong Jiyuan	65,627.0	1.65
Ennovation Raylight	54,142.0	1.36
Eastern Handson	22,969.0	0.58
SDICVC Ningbo Fund	164,066.0	4.13
Total	3,970,404.0	100.00

(h) January 2021 Capital Increase

On January 7, 2021, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB3,970,404 to RMB4,093,200. Nanjing Yipu subscribed the increased registered capital of RMB122,796 at the consideration of RMB122,796.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the capital increase on January 29, 2021, the shareholding of our Company was as follows:

Shareholders	Registered capital (RMB)	Equity interest (%)
Dr. Wu	800,000.0	19.54
Nanjing Jiminrui	458,800.0	11.21
Nanjing Yipu	581,195.0	14.20
PharmaBlock	358,600.0	8.76
Genecare Development	447,874.0	10.94
Guohong Medical	111,232.0	2.72
GP Healthcare Capital Phase II	234,615.0	5.73
Nanjing InnoMed	72,189.0	1.76
FIIF II	393,759.0	9.62
Nanjing Zijin	131,253.0	3.21
Jiangbei Fund	164,066.0	4.01
Nanjing Qiruiyoukang	32,813.0	0.80
Guohong Jiyuan	65,627.0	1.60
Ennovation Raylight	54,142.0	1.32
Eastern Handson	22,969.0	0.56
SDICVC Ningbo Fund	164,066.0	4.01
Total	4,093,200.0	100.00

(i) Series C+ Financing, April 2021 Transfer and April 2021 Capital Increase

On February 22, 2021, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB4,093,200 to RMB4,656,015. On the same date, our Company, the then shareholders of our Company, SDIC Greater Bay Area Fund, Shenzhen Linghui Cornerstone Equity Investment Fund Partnership (Limited Partnership) (深圳市領匯基石股權投資基金合夥企業(有限合夥)) (“**Shenzhen Linghui**”), Jingzhou Huikang Equity Investment Fund Partnership (Limited Partnership) (荊州慧康股權投資基金合夥企業(有限合夥)) (“**Jingzhou Huikang**”), Wuhu Xingrui Cornerstone Equity Investment Partnership (Limited Partnership) (蕪湖星睿基石股權投資合夥企業(有限合夥)) (“**Wuhu Xingrui**”) and CR Life Star Fund LLC (“**CR Life**”) entered into an investment agreement, pursuant to which SDIC Greater Bay Area Fund, Shenzhen Linghui, Jingzhou Huikang, Wuhu Xingrui, Nanjing Zijin, CR Life and Eastern Handson subscribed the increased registered capital of RMB562,815 for a total consideration of RMB330,000,001 (the “**Series C+ Financing**”).

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On the same date, the then shareholders of our Company further resolved to increase the registered capital of our Company from RMB4,656,015 to RMB4,800,015. Nanjing Yipu subscribed the increased registered capital of RMB144,000 at the consideration of RMB144,000 (“April 2021 Capital Increase”).

The respective subscription amount and consideration for each subscriber in the Series C+ Financing and the April 2021 Capital Increase were as follows:

Subscribers	Registered capital subscribed for (RMB)	Consideration	Corresponding equity interest in our Company (upon completion of the capital increase) (%)
SDIC Greater Bay Area Fund ⁽¹⁾	176,885.0	RMB103,714,286	3.69
Shenzhen Linghui ⁽¹⁾	118,995.0	RMB69,771,429	2.48
Jingzhou Huikang ⁽¹⁾	104,523.0	RMB61,285,714	2.18
Wuhu Xingrui ⁽¹⁾	73,970.0	RMB43,371,429	1.54
Nanjing Zijin	48,241.0	RMB28,285,714	1.01
		USD2,914,175.93 (equivalent to	
CR Life ⁽¹⁾	32,161.0	RMB18,857,143) USD726,295 (equivalent to	0.67
Eastern Handson	8,040.0	RMB4,714,286)	0.17
Nanjing Yipu	144,000.0	RMB144,000	3.00
Total	706,815.0	RMB330,144,001	14.73

Note:

- (1) SDIC Greater Bay Area Fund, Shenzhen Linghui, Jingzhou Huikang, Wuhu Xingrui and CR Life are all our Pre-[REDACTED] Investors and the Independent Third Parties. All of them became acquainted with our Company through our then financial advisor, Shanghai Huijia.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

On February 22, 2021, Dr. Wu, Nanjing Yipu and SDIC Greater Bay Area Fund entered into an equity transfer agreement, pursuant to which, Dr. Wu transferred registered capital of our Company of RMB7,504 and Nanjing Yipu transferred registered capital of our Company of RMB3,216 to SDIC Greater Bay Area Fund at the considerations of RMB4,400,000 and RMB1,885,714, respectively. On the same date, Dr. Wu, Nanjing Yipu, Shenzhen Linghui, Wuhu Xingrui, Jingzhou Huikang, Nanjing Zijin, CR Life and Eastern Handson entered into an equity transfer agreement. Pursuant to the above equity transfer agreements, the following equity transfers were made (“**April 2021 Transfer**”):

Transferor	Transferee	Registered capital transferred <i>(RMB)</i>	Corresponding equity interest in our Company (upon completion of the capital increase and equity transfers) <i>(%)</i>	Consideration <i>(RMB)</i>
Dr. Wu	SDIC Greater Bay Area Fund	7,504	0.16	4,400,000.0
	Shenzhen Linghui	5,048	0.11	2,960,000.0
	Jingzhou Huikang	4,435	0.09	2,600,000.0
	Wuhu Xingrui	2,407	0.05	1,411,429.0
	Nanjing Zijin	2,047	0.04	1,200,000.0
	CR Life	1,949	0.04	1,142,857.0
	Eastern Handson	487	0.01	285,714.0
Nanjing Yipu	SDIC Greater Bay Area Fund	3,216	0.07	1,885,714.0
	Shenzhen Linghui	2,164	0.05	1,268,571.0
	Jingzhou Huikang	1,901	0.04	1,114,286.0
	Wuhu Xingrui	2,076	0.04	1,217,143.0
	Nanjing Zijin	877	0.02	514,286.0
Total		<u>34,111</u>	<u>0.72</u>	<u>20,000,000</u>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the capital increase and equity transfers on April 26, 2021, the shareholding of our Company was as follows:

Shareholders	Registered capital (RMB)	Equity interest (%)
Dr. Wu	776,123.0	16.17
Nanjing Jiminrui	458,800.0	9.56
Nanjing Yipu	714,962.0	14.90
PharmaBlock	358,600.0	7.47
Genecare Development	447,874.0	9.33
Guohong Medical	111,232.0	2.32
GP Healthcare Capital Phase II	234,615.0	4.89
Nanjing InnoMed	72,189.0	1.50
FIIF II	393,759.0	8.20
Nanjing Zijin	182,418.0	3.80
Jiangbei Fund	164,066.0	3.42
Nanjing Qiruiyoukang	32,813.0	0.68
Guohong Jiyuan	65,627.0	1.37
Ennovation Raylight	54,142.0	1.13
Eastern Handson	31,496.0	0.66
SDICVC Ningbo Fund	164,066.0	3.42
SDIC Greater Bay Area Fund	187,605.0	3.91
Shenzhen Linghui	126,207.0	2.63
Jingzhou Huikang	110,858.0	2.31
Wuhu Xingrui	78,453.0	1.63
CR Life	34,110.0	0.71
Total	4,800,015.0	100.00

(j) Joint-stock Reform

Pursuant to the shareholders’ resolutions on June 16, 2021 and the promoters’ agreement dated June 17, 2021, the then existing Shareholders of our Company agreed to convert our Company into a joint stock limited liability company with a registered capital of RMB168,000,000. Pursuant to the promoters’ agreement, the net asset value of our Company as of April 30, 2021 amounted to RMB533,474,015.55, of which (i) RMB168,000,000 has been converted into 168,000,000 Shares of RMB1.0 par value each, which were subscribed by and issued to the then Shareholders of our Company in proportion to their respective equity interest in our Company at the ratio of 1:34.9999; and (ii) the remaining amount of RMB365,474,015.55 was converted to capital reserve of our Company. Upon the completion of registration with the Nanjing Administration for Market Regulation (南京市市場監督管理局) on July 2, 2021, our Company was converted into a joint stock company with limited liability and renamed as TransThera Sciences (Nanjing), Inc. (藥捷安康(南京)科技股份有限公司).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon the completion of the joint-stock reform on July 2, 2021, the shareholding of our Company was as follows:

Shareholders	Number of Shares	Equity interest (%)
Dr. Wu	27,164,220	16.17
Nanjing Yipu	25,023,593	14.90
Nanjing Jiminrui	16,057,950	9.56
Genecare Development	15,675,541	9.33
FIIF II	13,781,522	8.20
PharmaBlock	12,550,961	7.47
GP Healthcare Capital Phase II	8,211,499	4.89
SDIC Greater Bay Area Fund	6,566,154	3.91
Nanjing Zijin	6,384,610	3.80
Jiangbei Fund	5,742,292	3.42
SDICVC Ningbo Fund	5,742,292	3.42
Shenzhen Linghui	4,417,231	2.63
Guohong Medical	3,893,108	2.32
Jingzhou Huikang	3,880,018	2.31
Wuhu Xingrui	2,745,846	1.63
Nanjing InnoMed	2,526,607	1.50
Guohong Jiyuan	2,296,938	1.37
Ennovation Raylight	1,894,964	1.13
CR Life	1,193,846	0.71
Nanjing Qiruiyoukang	1,148,451	0.68
Eastern Handson	1,102,357	0.66
Total	168,000,000	100.00

(k) July 2021 Capital Increase

On July 8, 2021, the then shareholders of our Company resolved to increase the share capital of our Company from 168,000,000 Shares to 174,046,111 Shares with registered capital of our Company increased from RMB168,000,000 to RMB174,046,111. Nanjing Yipu subscribed for 6,046,111 Shares at the consideration of RMB6,046,111.

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Upon completion of the capital increase on July 9, 2021, the shareholding of our Company was as follows:

Shareholders	Number of Shares	Equity interest (%)
Nanjing Yipu	31,069,704	17.85
Dr. Wu	27,164,220	15.61
Nanjing Jiminrui	16,057,950	9.23
Genecare Development	15,675,541	9.01
FIIF II	13,781,522	7.92
PharmaBlock	12,550,961	7.21
GP Healthcare Capital Phase II	8,211,499	4.72
SDIC Greater Bay Area Fund	6,566,154	3.77
Nanjing Zijin	6,384,610	3.67
Jiangbei Fund	5,742,292	3.30
SDICVC Ningbo Fund	5,742,292	3.30
Shenzhen Linghui	4,417,231	2.54
Guohong Medical	3,893,108	2.24
Jingzhou Huikang	3,880,018	2.23
Wuhu Xingrui	2,745,846	1.58
Nanjing InnoMed	2,526,607	1.45
Guohong Jiyuan	2,296,938	1.32
Ennovation Raylight	1,894,964	1.09
CR Life	1,193,846	0.69
Nanjing Qiruiyoukang	1,148,451	0.66
Eastern Handson	1,102,357	0.63
Total	174,046,111	100.00

(l) Series D Financing

On July 16, 2021, the then shareholders of our Company resolved to increase the share capital of our Company from 174,046,111 Shares to 204,383,017 Shares with registered capital of our Company increased from RMB174,046,111 to RMB204,383,017. Pursuant to an investment agreement entered into among our Company, the then shareholders of our Company and seven Pre-[REDACTED] Investors (namely, CTT Biotech Investment Limited (“**CTT Biotech**”), Structural Reform Fund, Shenzhen Guotiao Merchants and Equity Investment Fund Partnership (Limited Partnership) (深圳國調招商併購股權投資基金合夥企業(有限合夥)) (“**Guotiao Merchants**”), GP Healthcare Capital Phase III, SIXTY DEGREE CAPITAL FUND II (INTERNATIONAL), L.P. (“**SIXTY DEGREE**”), Nanjing Lvyong Ruihua Medical Health Equity Investment Partnership (Limited Partnership) (南京綠涌瑞華醫健股權投資合夥企業(有

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限合夥)) (“**Lvyong Ruihua**”) and Nanjing Lingyi Cornerstone Equity Investment Partnership (Limited Partnership) (南京領益基石股權投資合夥企業(有限合夥)) (“**Nanjing Lingyi**”), the seven investors subscribed for 30,336,906 Shares at a total consideration of RMB642,672,000 (the “**Series D Financing**”).

The respective subscription amount and consideration for each investor in the Series D Financing were as follows:

Subscribers	Number of Shares subscribed for	Consideration	Corresponding equity interest in our Company (upon completion of the capital increase) (%)
		USD39,922,264.21 (equivalent to RMB258,836,000)	
CTT Biotech ⁽¹⁾ Structural Reform Fund ⁽²⁾	12,218,182	RMB194,127,000	5.98
Guotiao Merchants ⁽²⁾ GP Healthcare Capital Phase III ⁽¹⁾	9,163,636	RMB65,000,000	4.48
	1,527,273	RMB32,354,500 USD5,004,556.07 (equivalent to RMB32,354,500)	0.75
SIXTY DEGREE ⁽²⁾	1,527,273	RMB30,000,000	0.75
Lvyong Ruihua ⁽²⁾	1,416,130	RMB30,000,000	0.69
Nanjing Lingyi ⁽²⁾	1,416,130	RMB30,000,000	0.69
Total	30,336,906	RMB642,672,000	14.84

Notes:

- (1) On June 21, 2023, CTT Biotech transferred its entire equity interest in our Company (being 21,521,091 Shares, representing approximately 5.64% equity interest of our Company at the time of the transfer) to CPE Investment (Hong Kong) 2021 Limited (“**CPE Investment**”) at a consideration of USD35,921,505.50 (equivalent to RMB258,836,000). CPE Investment is a Pre-**[REDACTED]** Investor and an Independent Third Party. Both CCT Biotech and CPE Investment are under the common control of CPEChina Fund IV, L.P.
- (2) Structural Reform Fund, Guotiao Merchants, GP Healthcare Capital Phase III, SIXTY DEGREE, Lvyong Ruihua and Nanjing Lingyi are all our Pre-**[REDACTED]** Investors and the Independent Third Parties. All of them became acquainted with our Company through our then financial advisor, Shanghai Huijia.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the capital increase on July 16, 2021, the shareholding of our Company was as follows:

Shareholders	Number of Shares	Equity interest (%)
<i>Original Shareholders</i>		
Nanjing Yipu	31,069,704	15.20
Dr. Wu	27,164,220	13.29
Nanjing Jiminrui	16,057,950	7.86
PharmaBlock	12,550,961	6.14
<i>Pre-[REDACTED] Investors</i>		
GP Healthcare Capital Phase II	8,211,499	4.02
GP Healthcare Capital Phase III	1,527,273	0.75
Subtotal	<u>9,738,772</u>	<u>4.77</u>
SDIC Greater Bay Area Fund	6,566,154	3.21
SDICVC Ningbo Fund	5,742,292	2.81
Subtotal	<u>12,308,446</u>	<u>6.02</u>
Shenzhen Linghui	4,417,231	2.16
Wuhu Xingrui	2,745,846	1.34
Nanjing Lingyi	1,416,130	0.69
Subtotal	<u>8,579,207</u>	<u>4.19</u>
Guohong Medical	3,893,108	1.90
Guohong Jiyuan	2,296,938	1.12
Subtotal	<u>6,190,046</u>	<u>3.02</u>
Jingzhou Huikang	3,880,018	1.90
Guotiao Merchants	3,068,282	1.50
Subtotal	<u>6,948,300</u>	<u>3.40</u>
Ennovation Raylight	1,894,964	0.93
Nanjing Qiruiyoukang	1,148,451	0.56
Subtotal	<u>3,043,415</u>	<u>1.49</u>
Genecare Development	15,675,541	7.67
FIIF II	13,781,522	6.74
CTT Biotech	12,218,182	5.98
Structural Reform Fund	9,163,636	4.48
Nanjing Zijin	6,384,610	3.12
Jiangbei Fund	5,742,292	2.81
Nanjing InnoMed	2,526,607	1.24
SIXTY DEGREE	1,527,273	0.75
Lvyong Ruihua	1,416,130	0.69
CR Life	1,193,846	0.58
Eastern Handson	1,102,357	0.54
Total	<u><u>204,383,017</u></u>	<u><u>100.00</u></u>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(m) Capitalization of Capital Reserve

On October 17, 2022, the then shareholders of our Company resolved to increase the registered capital of our Company from RMB204,383,017 to RMB360,000,000 by way of capitalization of the capital reserve of our Company of RMB155,616,983 on the basis of 1.7614 Shares for one Share, representing a total increase of 155,616,983 Shares based on the total number of 204,383,017 Shares immediately before the capitalization. The capitalization was completed on October 27, 2022.

(n) Series D+ Financing and December 2022 Transfer

On December 9, 2022, December 29, 2022 and February 16, 2023, the then shareholders of our Company resolved to increase the share capital of our Company from 360,000,000 Shares to 381,616,633 Shares with the registered capital of our Company increased from RMB360,000,000 to RMB381,616,633. Pursuant to the investment agreement dated December 9, 2022 and the joinder agreements dated December 29, 2022 and February 16, 2023, 11 Pre-[REDACTED] Investors (namely, Shanghai Guoxin Investment Development Co., Ltd. (上海國鑫投資發展有限公司) (“**Shanghai Guoxin**”), Trinity Zhongzhi Phase II (Tianjin) Venture Capital Center (Limited Partnership) (三一眾志二期(天津)創業投資中心(有限合夥)) (“**Trinity Zhongzhi**”), Taixing Qichen Emerging Industry Venture Capital Fund Partnership (Limited Partnership) (泰興市啟辰新興產業創業投資基金合夥企業(有限合夥)) (“**Taixing Qichen**”), Nanjing Baiyide Equity Investment Partnership (Limited Partnership) (南京百益德股權投資合夥企業(有限合夥)) (“**Nanjing Baiyide**”), TIF Biomedical Fund II VCC (“**TIF Biomedical**”), Wuxi Ruitong Venture Capital Partnership (Limited Partnership) (無錫瑞桐創業投資合夥企業(有限合夥)) (“**Wuxi Ruitong**”), Jiangsu Zhongde Services Trade Industry Investment Fund (Limited Partnership) (江蘇中德服貿產業投資基金(有限合夥)) (“**Jiangsu Zhongde**”), Jiangsu Dunhe Venture Capital Partnership (Limited Partnership) (江蘇敦和創業投資合夥企業(有限合夥)) (“**Jiangsu Dunhe**”), Suzhou Dunxing Jucai Venture Capital Partnership (Limited Partnership) (蘇州敦行聚才創業投資合夥企業(有限合夥)) (“**Suzhou Dunxing**”), Nanjing Jiangbei New Area State-owned Assets Management Co., Ltd. (南京江北新區國有資產管理有限公司) (“**Jiangbei Assets Management**”) and BOC Capital Investment Holdings Co., Ltd. (中銀資本投資控股有限公司) (“**BOC Capital**”)) subscribed for 21,616,633 Shares at a total consideration of RMB260 million (the “**Series D+ Financing**”).

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The respective subscription amount and consideration for each investor in the Series D+ Financing were as follows:

Subscribers	Number of Shares subscribed for	Consideration <i>(RMB)</i>	Corresponding equity interest in our Company (upon completion of the capital increase) %
Shanghai Guoxin	8,314,088	100,000,000	2.18
Trinity Zhongzhi	2,718,707	32,700,000	0.71
Taixing Qichen	1,662,818	20,000,000	0.44
Nanjing Baiyide	1,662,818	20,000,000	0.44
Jiangbei Assets Management	1,662,818	20,000,000	0.44
BOC Capital	1,662,818	20,000,000	0.44
TIF Biomedical	1,438,338	17,300,000	0.38
Wuxi Ruitong	831,409	10,000,000	0.22
Jiangsu Zhongde	831,409	10,000,000	0.22
Jiangsu Dunhe	498,846	6,000,000	0.13
Suzhou Dunxing	332,564	4,000,000	0.09
Total	21,616,633	260,000,000	5.66

On December 30, 2022, Jiangbei Fund and Jiangbei Assets Management entered into an equity transfer agreement, pursuant to which, Jiangbei Fund transferred 2,494,222 Shares to Jiangbei Assets Management at the consideration of RMB30 million (“**December 2022 Transfer**”).

Upon the completion of the capital increase and equity transfer on February 17, 2023, the shareholding of our Company was as follows:

Shareholders	Number of Shares	Equity interest (%)
<i>Original Shareholders</i>		
Nanjing Yipu	54,726,152	14.34
Dr. Wu	47,847,024	12.54
Nanjing Jiminrui	28,284,453	7.41
PharmaBlock	22,107,247	5.79
<i>Pre-[REDACTED] Investors</i>		
GP Healthcare Capital Phase II	14,463,724	3.79
GP Healthcare Capital Phase III	2,690,136	0.70
Subtotal	17,153,860	4.49

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Shareholders	Number of Shares	Equity interest (%)
SDIC Greater Bay Area Fund	11,565,615	3.03
SDICVC Ningbo Fund	10,114,466	2.65
Subtotal	21,680,081	5.68
Shenzhen Linghui	7,780,505	2.04
Wuhu Xingrui	4,836,529	1.27
Nanjing Lingyi	2,494,369	0.65
Subtotal	15,111,403	3.96
Guohong Medical	6,857,315	1.80
Guohong Jiyuan	4,045,823	1.06
Subtotal	10,903,138	2.86
Jingzhou Huikang	6,834,259	1.79
Guotiao Merchants	5,404,468	1.42
Subtotal	12,238,727	3.21
Ennovation Raylight	3,337,787	0.87
Nanjing Qiruiyoukang	2,022,880	0.53
Subtotal	5,360,667	1.40
Taixing Qichen	1,662,818	0.44
Jiangsu Zhongde	831,409	0.22
Subtotal	2,494,227	0.66
Jiangsu Dunhe	498,846	0.13
Suzhou Duxing	332,564	0.09
Subtotal	831,410	0.22
TIF Biomedical	1,438,338	0.38
Trinity Zhongzhi	2,718,707	0.71
Subtotal	4,157,045	1.09
Genecare Development	27,610,879	7.24
FIIF II	24,274,756	6.36
CTT Biotech	21,521,091	5.64
Structural Reform Fund	16,140,817	4.23
Nanjing Zijin	11,245,844	2.95
Jiangbei Fund	7,620,244	2.00
Nanjing InnoMed	4,450,362	1.17
SIXTY DEGREE	2,690,136	0.70
Lvyong Ruihua	2,494,369	0.65
CR Life	2,102,838	0.55
Eastern Handson	1,941,690	0.51
Shanghai Guoxin	8,314,088	2.18
Nanjing Baiyide	1,662,818	0.44
Wuxi Ruitong	831,409	0.22
Jiangbei Assets Management	4,157,040	1.09
BOC Capital	1,662,818	0.44
Total	381,616,633	100.00

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

EMPLOYEE INCENTIVE SCHEMES

In recognition of the contributions of our employees and to incentivize them to further promote our development, Nanjing Yipu, Nanjing Yicheng and TT Therapeutics were established as our Employee Incentive Platforms.

Nanjing Yipu was established in the PRC as a limited partnership on August 29, 2016. Dr. Wu is the sole general partner of Nanjing Yipu and is responsible for the management of Nanjing Yipu. Thus, all management power and voting rights of Nanjing Yipu reside with Dr. Wu. As of the Latest Practicable Date, Nanjing Yipu had 21 limited partners including, Mr. Wu Di (an executive Director and vice president of our Company), Ms. Jia Zhongxin (a non-executive Director of our Company), Ms. Zhao Weili (a Supervisor of our Company), Ms. Pang Yajing (a Supervisor of our Company), Dr. Peng Peng (the vice president of project management of our Company), Dr. Sheng Zejuan (the vice president of biology department of our Company), Ms. Cui Songxi (the vice president of operations of our Company), Dr. Sun Caixia (clinical executive director of our Company), Nanjing Yicheng, TT Therapeutics, three former employees and eight existing employees of our Company.

Nanjing Yicheng was established in the PRC as a limited partnership on June 30, 2023. Dr. Wu is the sole general partner of Nanjing Yicheng and is responsible for the management of Nanjing Yicheng. Thus, all management power and voting rights of Nanjing Yicheng reside with Dr. Wu. As of the Latest Practicable Date, Nanjing Yicheng had 34 limited partners, including, Mr. Wu Di (an executive Director and vice president of our Company), Ms. Jia Zhongxin (a non-executive Director of our Company), Ms. Zhao Weili (a Supervisor of our Company), Ms. Pang Yajing (a Supervisor of our Company), Dr. Peng Peng (the vice president of project management of our Company), Dr. Sheng Zejuan (the vice president of biology department of our Company), Ms. Cui Songxi (the vice president of operations of our Company), Dr. Sun Caixia (clinical executive director of our Company), Ms. Feng Jie (secretary of the Board and joint company secretary of our Company) and 25 existing employees of our Company.

TT Therapeutics was incorporated under the laws of State of Delaware of the United States on October 26, 2022. As of the Latest Practicable Date, Dr. Wu was the sole member of TT Therapeutics.

For details of the Employee Incentive Schemes, see “Appendix VI – Statutory and General Information – Further Information about our Directors, Supervisors and Substantial Shareholders – 5. Employee Incentive Schemes”.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

PRE-[REDACTED] INVESTMENTS

Overview

Our Company obtained several rounds of investments from the Pre-[REDACTED] Investors through subscriptions for increased registered capital of our Company and/or through transfers by the then Shareholders. For further details, see the subsection headed “– Corporate Development and Shareholding Changes of Our Company – Subsequent Capital Changes and Equity Transfers” in this section.

Principal terms of the Pre-[REDACTED] Investments and Pre-[REDACTED] Investors’ Rights

The following table⁽¹⁾ summarizes the key terms of the Pre-[REDACTED] Investments to our Company made by the Pre-[REDACTED] Investors:

	Series A-1 Financing	Series A-2 Financing	Series B Financing	Series C-1 Financing	Series C-2 Financing	Series C-3 Financing	Series C+ Financing	Series D Financing	Series D+ Financing
Amount of consideration paid (RMB)	30,000,000	30,000,000	100,000,000	220,000,000	60,000,000	50,000,000	330,000,001	642,672,000	260,000,000
Date of payment of full consideration	January 13, 2017	October 16, 2017	February 1, 2019	April 2, 2020	September 29, 2020	July 27, 2020	April 29, 2021	July 26, 2021	February 17, 2023
Post-money valuation of our Company (RMB) (approximation)	263 million	380 million	800 million	1,100 million	1,160 million	1,210 million	2,730 million ⁽²⁾	4,329 million ⁽³⁾	4,590 million
Date of agreements	August 17, 2016	August 17, 2016	August 9, 2018	March 3, 2020	May 20, 2020	July 22, 2020	February 22, 2021	July 16, 2021	December 9, 2022; December 29, 2022; February 16, 2023
Cost per Share paid under the Pre-[REDACTED] Investments (RMB)	1.89	2.52	4.50	4.94	4.94	4.94	9.51	12.03	12.03
Discount to the [REDACTED] ⁽⁴⁾ (approximation)	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%
Basis of determination of the valuation and consideration	The valuation and consideration for each round of the Pre-[REDACTED] Investments were determined based on arm’s length negotiations between our Company and the Pre-[REDACTED] Investors after taking into consideration the timing of the investments and the business, operations and status of our business and operating entities.								

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	Series A-1 Financing	Series A-2 Financing	Series B Financing	Series C-1 Financing	Series C-2 Financing	Series C-3 Financing	Series C+ Financing	Series D Financing	Series D+ Financing
Lock-up Period	Pursuant to the applicable PRC law, all existing Shareholders (including the Pre-[REDACTED] Investors) could not dispose of any of the Shares held by them within 12 months following the [REDACTED] Date.								
Use of [REDACTED] from the Pre-[REDACTED] Investments	We utilized the [REDACTED] from the Pre-[REDACTED] Investments for the principal business of our Company, including but not limited to research and development activities, the growth and expansion of our Company’s business and general working capital purposes. As of the Latest Practicable Date, approximately 55.34% of the net [REDACTED] from the Pre-[REDACTED] Investments had been utilized.								
Strategic benefits to our Company brought by the Pre-[REDACTED] Investors	At the time of the Pre-[REDACTED] Investments, our Directors were of the view that our Company could benefit from the additional funds provided by the Pre-[REDACTED] Investors’ investments in our Company and the knowledge and experience of the Pre-[REDACTED] Investors.								

Notes:

- (1) The April 2021 Transfer is not included in the above table since the consideration of RMB20,000,000 was paid to Dr. Wu and Nanjing Yipu (instead of our Company) by the Pre-[REDACTED] Investors. The cost per Share of the April 2021 Transfer is RMB9.51 with the post-money valuation of our Company being approximately RMB2,730 million. Based on the indicative price of HK\$[REDACTED] (being the mid-point of the proposed range of the [REDACTED] as stated in this document) and the indicative exchange rate of HK\$1.00=RMB0.91199, the discount to the [REDACTED] of the April 2021 Transfer is approximately [REDACTED]%. For details of the April 2021 Transfer, please see “– Corporate Development and Shareholding Changes of our Company – Subsequent Capital Changes and Equity Transfers – (i) Series C+ Financing, April 2021 Transfer and April 2021 Capital Increase” in this section.

The December 2022 Transfer is not included in the above table since the consideration of RMB30,000,000 was paid to Jiangbei Fund (instead of our Company) by the Pre-[REDACTED] Investor. The cost per Share of the December 2022 Transfer is RMB12.03 with the post-money valuation of our Company being approximately RMB4,590 million. Based on the indicative price of HK\$[REDACTED] (being the mid-point of the proposed range of the [REDACTED] as stated in this document) and the indicative exchange rate of HK\$1.00=RMB0.91199, the discount to the [REDACTED] of the December 2022 Transfer is approximately [REDACTED]%. For details of the December 2022 Transfer, please see “– Corporate Development and Shareholding Changes of our Company – Subsequent Capital Changes and Equity Transfers – (n) Series D+ Financing and December 2022 Transfer” in this section.

- (2) The post-money valuation of our Company increased after Series C-3 Financing was primarily due to (i) our two collaboration and license agreements with Teijin seeking collaboration with respect to the research of projects based upon certain existing hit/lead compounds discovered and controlled by Teijin in October and December 2020; and (ii) IND approval from the FDA to conduct Phase Ib/II clinical trial for Tinengotinib in the U.S. in November 2020.
- (3) The post-money valuation of our Company increased after Series C+ Financing was primarily due to (i) IND approval from the NMPA to conduct Phase Ib/II clinical trial for Tinengotinib in the PRC; (ii) IND approval from the NMPA to conduct Phase I clinical trial for TT-01025 in the PRC; and (iii) IND approval from the NMPA to conduct Phase I clinical trial for TT-00434 in the PRC in May 2021.
- (4) The discount is based on the indicative price of HK\$[REDACTED] (being the mid-point of the indicative [REDACTED] range of as stated in this document) and the indicative exchange rate of HK\$1.00=RMB0.91199.

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Rights of the Pre-[REDACTED] Investors

Pursuant to a shareholders’ agreement and a supplemental shareholders’ agreement entered into among the Shareholders of our Company in December 2022 and in June 2024, the Pre-[REDACTED] Investors had been granted certain special rights, including, among others, pre-emptive right, right of first refusal and co-sale, drag-along right, preferred dividend right and information right and inspection right, all of which shall cease to be effective from the date immediately prior to the first filing of the [REDACTED] and be terminated upon [REDACTED] and shall automatically restored upon the earliest of (i) the withdrawal of the [REDACTED]; (ii) the [REDACTED] has been returned, rejected or vetoed by relevant exchange or authorities; or (iii) our Company fails to complete the [REDACTED] within 12 months after the first filing.

Information about the Pre-[REDACTED] Investors

Our Pre-[REDACTED] Investors include certain sophisticated investors. The background information of our Pre-[REDACTED] Investors is set out below.

- (a) **Genecare Development:** Genecare Development is a private company limited by shares incorporated under the laws of Hong Kong on September 18, 2007 and is principally engaged in investment holding. It is a wholly-owned subsidiary of Morningside Venture (I) Investments Limited (“**Morningside Venture (I)**”) which focuses on investment in life science sector including biopharmaceuticals, medical devices, diagnostics and healthcare services. Morningside Venture (I) is ultimately owned by a family trust established by Ms. Chan Tan Ching Fen. To the best knowledge of the Directors, Genecare Development is an Independent Third Party.
- (b) **FIIF II:** FIIF II is a limited partnership incorporated in the PRC. The general partner of FIIF II is CS Capital Co., Ltd. (國投招商投資管理有限公司) (“**CS CAPITAL**”). CS CAPITAL is an independent private equity fund manager. CS CAPITAL and its affiliates currently manage over RMB100 billion of capital from diversified limited partners, including financial institutions, social security fund, private enterprises, state-owned enterprises. CS CAPITAL focuses on four investment sectors: life science, intelligent NEV, smart manufacturing as well as information & communication technology. CS CAPITAL targets innovative medicine & medical devices in life science sector and has invested in many listed companies including Innovent Biologics, Inc. (信達生物) (01801.HK), CanSino Biologics Inc. (康希諾生物股份公司) (06185.HK and 688185.SH), Adlai Nortye Ltd. (阿諾醫藥集團有限公司) (NASDAQ: ANL) and Peijia Medical Limited (沛嘉醫療有限公司) (9996.HK). Thus, it is a sophisticated investor. To the best knowledge of our Directors, FIIF II is an Independent Third Party.

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- (c) **CPE Investment:** CPE Investment is a private company limited by shares incorporated under the laws of Hong Kong on February 17, 2021 and is a wholly-owned subsidiary of Cayenne Private Enterprise IV Limited which is controlled by CPEChina Fund IV, L.P. To the best knowledge of our Directors, CPE Investment is an Independent Third Party.
- (d) **Structural Reform Fund:** Structural Reform Fund is a joint stock limited liability company incorporated in the PRC on September 22, 2016. It is held by several state-owned enterprises and is ultimately controlled by the State-owned Assets Supervision and Administration Commission of the State Council (國務院國有資產監督管理委員會). It is mainly engaged in business activities including non-public fund raising, equity investment, project investment, capital management, investment consulting and enterprise management consulting. As of the Latest Practicable Date, Structural Reform Fund had assets under management of approximately RMB69.2 billion. Apart from the investment in our Company, Structural Reform Fund has invested in companies in healthcare and biotech industry, including but not limited to, Akeso, Inc. (康方生物科技(開曼)有限公司) (09926.HK), Transcenta Holding Limited (創勝集團醫藥有限公司) (6628.HK), JOINN Laboratories (China) Co., Ltd. (北京昭衍新藥研究中心股份有限公司) (6127.HK and 603127.SH) and InnoCare Pharma Limited (諾誠健華醫藥有限公司) (9969.HK). To the best knowledge of our Directors, Structural Reform Fund is an Independent Third Party.
- (e) **GP Healthcare Capital Phase II and GP Healthcare Capital Phase III:** Each of GP Healthcare Capital Phase II and GP Healthcare Capital Phase III is a limited partnership established under the laws of the PRC, the managing partner of which is GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理有限公司) (“**GP Healthcare Capital**”). As of the Latest Practicable Date, GP Healthcare Capital Phase II had 15 limited partners and the interest held by the limited partners in GP Healthcare Capital Phase II ranged from approximately 0.60% to 17.86%. As of the Latest Practicable Date, GP Healthcare Capital Phase III had 15 limited partners and the interest held by the limited partners in GP Healthcare Capital Phase III ranged from approximately 1.60% to 15.97% with Zhongtai Venture Capital (Shanghai) Co., Ltd. (中泰創業投資(上海)有限公司), (a wholly-owned subsidiary of ZHONGTAI SECURITIES CO., LTD. (中泰證券股份有限公司) (600918.SH)), and Shandong New Growth Drivers Investment Management Co., Ltd. (山東省新動能投資管理有限公司), (a company wholly owned by Shandong Provincial Department of Finance (山東省財政廳)), being the two limited partners each with 15.97% partnership interest in GP Healthcare Capital Phase III. GP Healthcare Capital focuses on equity investment in the medical and health industry with a management scale of over RMB2 billion. Since GP Healthcare Capital’s establishment in 2015, it has invested in more than 40 companies in the fields of biotechnology and pharmaceuticals, medical devices, IVD, and medical services, all of which are in a leading position in the industry, and thus a sophisticated investor. Apart from the investment in our Company, GP Healthcare Capital has invested in other companies, such as Laekna, Inc. (HK: 02105), Zylox-Tonbridge Medical Technology Co., Ltd. (歸創通橋醫療科技股份有限公司) (HK: 02190), Jenscare Scientific Co., Ltd. (寧波

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健世科技股份有限公司) (HK: 09877), Shanghai Yan’an Pharmaceutical Yangpu Holding Co., Ltd. (上海延安醫藥洋浦股份有限公司) (National Equities Exchange and Quotations: 839010) and Hangzhou Cell-gene Biotechnology Co., Ltd. (杭州賽基生物科技有限公司). To the best knowledge of our Directors, each of GP Healthcare Capital Phase II and GP Healthcare Capital Phase III is an Independent Third Party.

- (f) **SDIC Greater Bay Area Fund and SDICVC Ningbo Fund:** Each of SDIC Greater Bay Area Fund and SDICVC Ningbo Fund is a limited partnership established under the laws of the PRC. The general partner of SDIC Greater Bay Area Fund is SDIC (Guangdong) Venture Capital Management Co., Ltd (國投(廣東)創業投資管理有限公司), which is held as to 91% by SDIC Venture Capital Co., Ltd (國投創業投資管理有限公司) (“SDICVC”). The general partners of SDICVC Ningbo Fund are SDICVC and Veken Industrial Investment Management Co., Ltd (維科產業投資管理有限公司) with SDICVC as its executive partner and responsible for its management. As of the Latest Practicable Date, SDIC Greater Bay Area Fund had 15 limited partners and the interests held by the limited partners in SDIC Greater Bay Area Fund ranged from approximately 0.17% to 20.67%. As of the Latest Practicable Date, SDICVC Ningbo Fund had seven limited partners and the interests held by the limited partners in SDICVC Ningbo Fund ranged from 0.75% to 49% with Veken Holding Group Co., Ltd. (維科控股集團股份有限公司) being the only limited partner with more than one-third of the partnership interest in SDICVC Ningbo Fund. As of the Latest Practicable Date, SDIC Greater Bay Area Fund had assets under management of approximately RMB14.6 billion and SDICVC Ningbo Fund had assets under management of approximately RMB2 billion. SDICVC is a leading professional venture fund management institution with a focus on biotech, digital information, advanced manufacturing and material energy sections and has invested in over 40 biotech companies, including but not limited to, RemeGen Co., Ltd. (榮昌生物製藥(煙台)股份有限公司) (9995.HK), Keymed Biosciences Inc. (康諾亞生物醫藥科技有限公司) (2162.HK), Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (百奧賽圖(北京)醫藥科技股份有限公司) (2315.HK) and Yantai MabPlex International Biopharma Co., Ltd. (煙台邁百瑞國際生物醫藥股份有限公司). To the best knowledge of our Directors, each of SDIC Greater Bay Area Fund and SDICVC Ningbo Fund is an Independent Third Party.
- (g) **Nanjing Zijin:** Nanjing Zijin is a limited partnership established under the laws of the PRC on December 26, 2018. It is managed by its general partner, Nanjing Summit Equity Fund Management Co., Ltd. (南京峰嶺股權投資基金管理有限公司), an Independent Third Party. As of the Latest Practicable Date, Nanjing Zijin had five limited partners and the interests held by the limited partners in Nanjing Zijin ranged from approximately 0.4% to 50%. Nanjing Zijin is principally engaged in equity investment in non-publicly traded companies, non-publicly issued equity of listed companies, and related services. As of the Latest Practicable Date, it had assets under management of approximately RMB500 million. Apart from the investment in our Company, Nanjing Zijin has invested in other biotechnology

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companies, such as Jiangsu Vcare Pharmatech Co., Ltd. (江蘇威凱爾醫藥科技有限公司) and Nanjing Zenshine Pharmaceutical Technology Co., Ltd. (南京徵祥醫藥有限公司). To the best knowledge of our Directors, Nanjing Zijin is an Independent Third Party.

- (h) **Jiangbei Fund:** Jiangbei Fund is a limited partnership established under the laws of the PRC on November 7, 2018. It is managed by its general partner, Ningbo Zhirong Beta Investment Management Co., Ltd. (寧波志榮貝塔投資管理有限公司), a company controlled by Mr. Sun Jigang (孫冀剛), an Independent Third Party. As of the Latest Practicable Date, Jiangbei Fund had four limited partners and the interests held by the limited partners in Jiangbei Fund ranged from approximately 5.71% to 35.71% with Nanjing Beilian Venture Capital Co., Ltd (南京北聯創業投資有限公司), a company ultimately controlled by Nanjing Jiangbei New Area Industrial Investment Group Co., Ltd. (南京江北新區產業投資集團有限公司), being the only limited partner with more than one-third of the partnership interest in Jiangbei Fund. Jiangbei Fund is an investment fund with a focus on investments in innovative new drug development and medical devices sectors. As of the Latest Practicable Date, the paid-up capital of Jiangbei Fund is RMB307.3 million. Apart from the investment in our Company, it has invested in certain technology and biotechnology companies including Nanjing Dingnuo Biomedical Technology Co., Ltd. (南京鼎諾生物醫藥科技有限公司), Beijing Human Brain Cloud, Inc. (北京慧腦雲計算有限公司) and Nanjing Leads Biolabs Co., Ltd. (南京維立志博生物科技有限公司). To the best knowledge of our Directors, Jiangbei Fund is an Independent Third Party.
- (i) **Shenzhen Linghui, Wuhu Xingrui and Nanjing Lingyi:** Shenzhen Linghui is a limited partnership established under the laws of the PRC on June 25, 2018 and its general partner is Shenzhen Lingxin Cornerstone Equity Investment Fund Management Partnership (Limited Partnership) (深圳市領信基石股權投資基金管理合夥企業(有限合夥)), which is ultimately controlled by Mr. Zhang Wei (張維), an Independent Third Party. Wuhu Xingrui is a limited partnership established under the laws of the PRC on December 16, 2020. Nanjing Lingyi is a limited partnership established under the laws of the PRC on December 11, 2020. The general partner of Wuhu Xingrui and Nanjing Lingyi is Tibet Tianji Cornerstone Venture Capital Co., Ltd. (西藏天璣基石創業投資有限公司), which is also ultimately controlled by Mr. Zhang Wei (張維). As of the Latest Practicable Date, Shenzhen Linghui had 21 limited partners and the interests held by the limited partners in Shenzhen Linghui ranged from 0.13% to 25%. As of the Latest Practicable Date, Wuhu Xingrui had three limited partners and the interests held by the limited partners in Wuhu Xingrui ranged from approximately 2.13% to 74.47% with Mr. Zhang Feilian (張飛廉) being the only limited partner with more than one-third of the partnership interest in Wuhu Xingrui. As of the Latest Practicable Date, Nanjing Lingyi had six limited partners and the interests held by the limited partners in Nanjing Lingyi ranged from 5% to 23%. As of the Latest Practicable Date, Shenzhen Linghui, Wuhu Xingrui and Nanjing Lingyi had assets under management of approximately RMB4 billion, RMB47 million and RMB1 billion, respectively. Shenzhen Linghui, Wuhu Xingrui

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and Nanjing Lingyi are investment arms of Co-stone Venture Capital, a professional equity investment company dedicated to the equity investment in healthcare, technology, consumer services and media sectors, and its investment portfolios include Asymchem Laboratories (Tianjin) Co., Ltd. (凱萊英醫藥集團(天津)股份有限公司) (002821.SZ and 6821.HK), BrightGene Bio-Medical Technology Co., Ltd. (博瑞生物醫藥(蘇州)股份有限公司) (688166.SH), Dezhan Healthcare Company Limited (德展大健康股份有限公司) (000813.SZ) and Shenzhen New Industries Biomedical Engineering Co., Ltd. (深圳市新產業生物醫學工程股份有限公司) (300832.SZ). To the best knowledge of our Directors, each of Shenzhen Linghui, Wuhu Xingrui and Nanjing Lingyi is an Independent Third Party.

- (j) **Guohong Medical and Guohong Jiyuan:** Each of Guohong Medical and Guohong Jiyuan is a limited partnership established under the laws of the PRC and is managed by its general partner, Shanghai Grandyangtze Capital Co., Ltd. (上海長江國弘投資管理有限公司), which is ultimately controlled by Mr. Li Chunyi (李春義), an Independent Third Party. As of the Latest Practicable Date, Guohong Medical had 14 limited partners and the interests held by the limited partners in Guohong Medical ranged from approximately 2.40% to 32.21% with Hainan Jiahui Industrial Development Partnership (Limited Partnership) (海南嘉穗實業發展合夥企業(有限合夥)) being the largest limited partner. As of the Latest Practicable Date, Guohong Jiyuan had 16 limited partners and interests held by the limited partners in Guohong Jiyuan ranged from approximately 0.93% to 33.33% with Hainan Jiasui Industrial Development Partnership (Limited Partnership) (海南嘉穗實業發展合夥企業(有限合夥)) being the only limited partner with one-third of the partnership interest in Guohong Jiyuan. As of the Latest Practicable Date, Guohong Medical and Guohong Jiyuan had assets under management of approximately RMB208 million and RMB409 million, respectively. Shanghai Grandyangtze Capital Co., Ltd. (上海長江國弘投資管理有限公司) has investment experience in biotech and healthcare industry and its investment portfolios include Shandong Buchang Pharmaceuticals Co., Ltd. (山東步長製藥股份有限公司) (603858.SH), PharmaBlock Sciences (Nanjing), Inc. (南京藥石科技股份有限公司) (300725.SZ), Shanghai Haoyuan Chemexpress Co., Ltd. (上海皓元醫藥股份有限公司) (688131.SH), and Shanghai HeartCare Medical Technology Corporation Limited (上海心瑋醫療科技股份有限公司) (6609.HK). To the best knowledge of the Directors, each of Guohong Medical and Guohong Jiyuan is an Independent Third Party.

- (k) **Jingzhou Huikang and Guotiao Merchants:** Jingzhou Huikang is a limited partnership established under the laws of the PRC on February 28, 2018. Its general partner is Jingzhou China Merchants Huide Capital Management Co., Ltd. (荊州招商慧德資本管理有限責任公司) which is held as to 90% by China Merchants Capital Management Co., Ltd. (招商局資本管理有限責任公司) (“**CMC Management**”). Guotiao Merchants is a limited partnership established under the laws of the PRC on January 25, 2017. Its general partner is Shenzhen Merchants Huihe Equity Investment Fund Management Co., Ltd. (深圳市招商慧合股權投資基金管理有限公 司), which is held as to 100% by CMC Management. As of the Latest Practicable

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Date, Jingzhou Huikang had seven limited partners and the interests held by the limited partners in Jingzhou Huikang ranged from approximately 0.22% to 28.36%. As of the Latest Practicable Date, Guotiao Merchants had five limited partners and the interests held by the limited partners in Guotiao Merchants ranged from approximately 0.03% to 75.81% with Structural Reform Fund being the only limited partner with more than one-third of the partnership interest in Guotiao Merchants. As of the Latest Practicable Date, each of Jingzhou Huikang and Guotiao Merchants had assets under management of approximately RMB2.15 billion and RMB12.08 billion, respectively. Apart from the investment in our Company, CMC Management has invested in other healthcare and biotechnology companies such as JD Health International Inc. (京東健康股份有限公司) (6618.HK), Asymchem Laboratories (Tianjin) Co., Ltd. (凱萊英醫藥集團(天津)股份有限公司) (002821.SZ and 6821.HK), Transcenta Holding Limited (創勝集團醫藥有限公司) (6628.HK) and Shenzhen ImmVira Co., Ltd. (深圳市亦諾微醫藥科技有限公司). To the best knowledge of our Directors, each of Jingzhou Huikang and Guotiao Merchants is an Independent Third Party.

- (1) **Nanjing InnoMed:** Nanjing InnoMed is a limited partnership established under the laws of the PRC on December 27, 2018. It is managed by Nanjing InnoMed Investment Management Center (Limited Partnership) (南京鷹盟投資管理中心(有限合夥)) and its ultimate beneficial owner is Mr. He Xing (何邢), an Independent Third Party. As of the Latest Practicable Date, it had 16 limited partners and the interests held by the limited partners in Nanjing InnoMed ranged from approximately 0.33% to 33.33% with Dr. Yang Minmin (楊民民) (the founder and chairman of the board of directors of PharmaBlock) being the limited partner with one-third of the partnership interest in Nanjing InnoMed. Nanjing InnoMed is an investment fund with a focus on investments in biotech and healthcare industry. As of March 31, 2024, it had assets under management of approximately RMB177 million. Apart from the investment in our Company, it has invested in other companies include Nanjing Saint Medical Technology Co., Ltd. (南京聖德醫療科技有限公司), Nanjing Novall Medical Co., Ltd. (南京諾令生物科技有限公司) and Nanjing Keluosi Biotechnology Co., Ltd. (南京科絡思生物科技有限公司). To the best knowledge of our Directors, Nanjing InnoMed is an Independent Third Party.

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- (m) **Ennovation Raylight and Nanjing Qiruiyoukang:** Ennovation Raylight is a limited partnership established under the laws of the PRC on August 16, 2017. Its general partner is Nanjing Ennovation Raylight Venture Management (Limited Partnership) (南京恩然瑞光投資管理中心(有限合夥)). Nanjing Qiruiyoukang is a limited partnership established under the laws of the PRC on September 17, 2018. Its general partner is Nanjing Jiakang Venture Capital Partnership (Limited Partnership) (南京佳康創業投資合夥企業(有限合夥)). The ultimate beneficial owner of both Ennovation Raylight and Nanjing Qiruiyoukang is Mr. Chen Renhai (陳仁海), an Independent Third Party. As of the Latest Practicable Date, Ennovation Raylight had seven limited partners and the interests held by the limited partners in Ennovation Raylight ranged from approximately 1.24% to 41.24% with Ms. Sun Qinghua (孫青華) being the only limited partner with more than one-third of the partnership interest in Ennovation Raylight. Ennovation Raylight focuses on investment in biotech companies. As of the Latest Practicable Date, the paid-up capital of Ennovation Raylight is RMB242.5 million. Apart from the investment in our Company, it has invested in several companies, including, but not limited to Hangzhou LifeReal Biotechnology Ltd. (杭州遂真生物技術有限公司), Nanjing Leads Biolabs Co. Ltd. (南京維立志博生物科技股份有限公司), Bestudy (Shanghai) Medical Technology Co., Ltd. (百試達(上海)醫藥科技股份有限公司) and Zhejiang Syncozymes Bio-pharmaceutical Co., Ltd. (浙江尚科生物醫藥有限公司). As of the Latest Practicable Date, Nanjing Qiruiyoukang had two limited partners and the only limited partner with more than one-third of the partnership interest in Nanjing Qiruiyoukang was Nanjing Jiangbei New Area Technology Investment Group Co., Ltd. (南京江北新區科技投資集團有限公司). As of the Latest Practicable Date, the paid-up capital of Nanjing Qiruiyoukang is RMB 477.83 million. Apart from the investment in our Company, Nanjing Qiruiyoukang has invested in several companies, including, but not limited to InxMed Biotechnology (Nanjing) Co., Ltd. (應世生物科技(南京)有限公司), Nanjing Zenshine Pharmaceutical Technology Co., Ltd. (南京徵祥醫藥有限公司) and Nanjing Shineking Biotech Co., Ltd. (南京軒凱生物科技股份有限公司). To the best knowledge of our Directors, each of Ennovation Raylight and Nanjing Qiruiyoukang is an Independent Third Party.
- (n) **SIXTY DEGREE:** SIXTY DEGREE is a limited partnership established under the laws of Canada on September 2, 2020. Its general partner is SIXTY DEGREE CAPITAL FUND II GP INC. which is ultimately controlled by Mr. Jian Guo and Ms. Feng Zu. As of the Latest Practicable Date, SIXTY DEGREE has one limited partner, namely, Investment Talent Limited with 100% partnership interest and wholly owned by Mr. Chen Sung-Tse, an Independent Third Party. As of the Latest Practicable Date, it had assets under management of approximately USD136 million. SIXTY DEGREE is part of Sixty Degree Capital which aims to search for companies in biopharmaceuticals, healthcare and technology sectors and has made investment into various biotech investments in North America and Europe. To the best knowledge of our Directors, SIXTY DEGREE is an Independent Third Party.

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- (o) **Lvyong Ruihua:** Lvyong Ruihua is a limited partnership established under the laws of the PRC on July 1, 2021. Its general partner is Jiangsu Ruihua Venture Capital Management Co., Ltd. (江蘇瑞華創業投資管理有限公司) and its ultimate beneficial owner is Mr. Zhang Jianbin (張建斌), an Independent Third Party. As of the Latest Practicable Date, Lvyong Ruihua had five limited partners and the interests held by the limited partners in Lvyong Ruihua ranged from approximately 0.2% to 43.8% with Tibet Ruihua Business Management Co., Ltd. (西藏瑞華商業管理有限公司), a company ultimately controlled by Mr. Zhang Jianbin (張建斌), being the only limited partner with more than one-third of the partnership interest in Lvyong Ruihua. Lvyong Ruihua has a special focus on healthcare industry. As of the Latest Practicable Date, the paid-up capital of Lvyong Ruihua is RMB675 million. Apart from the investment in our Company, it has invested in various companies in healthcare and biotech industry, such as Shanghai Dingxin Gene Technology Co., Ltd. (上海鼎新基因科技有限公司), Jiangsu Kangrun Biotechnology Co., Ltd. (江蘇康潤生物科技股份有限公司) and Jiangsu Synthgene Biotechnology Co., Ltd. (江蘇申基生物科技股份有限公司). To the best knowledge of our Directors, Lvyong Ruihua is an Independent Third Party.
- (p) **CR Life:** CR Life is a limited liability company established under the laws of Cayman Islands on November 26, 2020. Its manager is Grand Eternity Limited, an Independent Third Party. As of June 25, 2024, the paid-up capital of CR Life is approximately USD52 million. Apart from the investment in our Company, it has invested in other biotech companies, such as Zhejiang Kanova Biopharma Co., Ltd. (浙江鑫康合生物醫藥科技有限公司). To the best knowledge of our Directors, CR Life is an Independent Third Party.
- (q) **Eastern Handson:** Eastern Handson is a private company limited by shares incorporated under the laws of Hong Kong on February 18, 2003 and is principally engaged in investment in biopharmaceutical industry with around USD20 million of assets under management as of the Latest Practicable Date. It is wholly owned by Ms. YIM CHI LIK (嚴自力), an Independent Third Party. To the best knowledge of our Directors, Eastern Handson is an Independent Third Party.
- (r) **Shanghai Guoxin:** Shanghai Guoxin is a company established under the laws of the PRC with limited liability on October 9, 2000. It is a wholly-owned subsidiary of Shanghai State-owned Assets Management Co., Ltd. (上海國有資產經營有限公司) which in turn is indirectly wholly owned by Shanghai State-owned Assets Supervision and Administration Commission (上海市國有資產監督管理委員會). To the best knowledge of our Directors, Shanghai Guoxin is an Independent Third Party.
- (s) **Trinity Zhongzhi and TIF Biomedical:** Trinity Zhongzhi is a limited partnership established under the laws of the PRC on August 27, 2021. The general partner of Trinity Zhongzhi is Sanyi Innovation (Beijing) Investment Management Co., Ltd. (三一創新(北京)投資管理有限公司) which is ultimately controlled by Mr. Yin

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Zheng (尹正). As of the Latest Practicable Date, Trinity Zhongzhi had eight limited partners and the interests held by the limited partners in Trinity Zhongzhi ranged from approximately 1.80% to 36.17% with Qiantong Technology Industrial Co., Ltd. (乾通科技實業有限公司) (“**Qiantong Technology**”) being the only limited partner with more than one-third of the partnership interest in Trinity Zhongzhi. Qiantong Technology was ultimately controlled by Lu Qingyun (蘆清雲). To the best knowledge of our Directors, Trinity Zhongzhi is an Independent Third Party. TIF Biomedical is a variable capital company incorporated under the laws of Singapore on May 7, 2021. As of the Latest Practicable Date, the fund manager of TIF Biomedical is Trinity Innovation BioVenture Singapore Pte. Ltd. which is ultimately controlled by Mr. Yin Zheng (尹正). To the best knowledge of our Directors, TIF Biomedical is an Independent Third Party.

- (t) **Taixing Qichen and Jiangsu Zhongde:** Taixing Qichen is a limited partnership established under the laws of the PRC on April 22, 2021. Jiangsu Zhongde is a limited partnership established under the laws of the PRC on April 30, 2020. The general partner of Taixing Qichen and Jiangsu Zhongde is Wuxi Guolian Financial Investment Qiyuan Private Equity Fund Management Co., Ltd. (無錫國聯金投啟源私募基金管理有限公司). As of the Latest Practicable Date, Taixing Qichen had two limited partners, being Taixing Jinjiang Investment Co., Ltd. (泰興市襟江投資有限公司) with 69% partnership interest in Taixing Qichen and Wuxi Innovation Investment Group Co., Ltd. (無錫市創新投資集團有限公司) with 30% partnership interest in Taixing Qichen. As of the Latest Practicable Date, Jiangsu Zhongde had 13 limited partners and the partnership interest held by the limited partners ranged from 0.14% to 16.97% with Wuxi Taihu Aisi Venture Capital Partnership (Limited Partnership) (無錫市太湖愛思創業投資合夥企業(有限合夥)) being the largest limited partner of Jiangsu Zhongde. To the best knowledge of our Directors, each of Taixing Qichen and Jiangsu Zhongde is an Independent Third Party.
- (u) **Nanjing Baiyide:** Nanjing Baiyide is a limited partnership established under the laws of the PRC on November 16, 2022. The general partner of Nanjing Baiyide is Shanghai Qilan Private Equity Fund Management Co., Ltd. (上海啟覽私募基金管理有限公司), a company owned by Li Haiyan (李海燕) and Kong Danjun (孔丹軍) as to 51% and 49%, respectively. As of the Latest Practicable Date, Nanjing Baiyide had four limited partners, namely Wang Kemiao (王克苗), Xu Jiangbo (徐江波), Wang Yi (王益) and Dai Zili (戴子傑) with approximately 49.52%, 22.93%, 13.76% and 13.76% partnership interest in Nanjing Baiyide, respectively. To the best knowledge of our Directors, Nanjing Baiyide is an Independent Third Party.
- (v) **Wuxi Ruitong:** Wuxi Ruitong is a limited partnership established under the laws of the PRC on December 13, 2021. The general partner of Wuxi Ruitong is Wuxi Xuanton Venture Capital Co., Ltd. (無錫市玄同創業投資有限公司), a company owned by Lin Zhuying (林柱英) and Wang Pengfei (王鵬飛) as to 60% and 40%, respectively. As of the Latest Practicable Date, Wuxi Ruitong had 10 limited partners and the partnership interest held by the limited partners ranged from

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

approximately 1.54% to 36.41% with Jiangsu Bailing New Material Technology Co., Ltd. (江蘇百鈴新材料科技有限公司) being the only limited partner with more than one-third partnership interest in Wuxi Ruitong. To the best knowledge of our Directors, Wuxi Ruitong is an Independent Third Party.

- (w) **Jingsu Dunhe and Suzhou Duxing:** Jiangsu Dunhe is a limited partnership established under the laws of the PRC on December 1, 2020. Suzhou Duxing is a limited partnership established under the laws of the PRC on April 15, 2020. The general partner of Jiangsu Dunhe is Suzhou Duxing Investment Management Co., Ltd. (蘇州敦行投資管理有限公司) which is ultimately controlled by Ma Yangguang (馬陽光). The general partner of Suzhou Duxing is Ma Yangguang (馬陽光). To the best knowledge of our Directors, each of Jiangsu Dunhe and Suzhou Duxing is an Independent Third Party.
- (x) **Jiangbei Assets Management:** Jiangbei Assets Management is a company established under the laws of the PRC with limited liability on December 30, 2004 and is wholly owned by Nanjing Jiangbei New Area Management Committee (China (Jiangsu) Pilot Free Trade Zone Nanjing Area Management Committee) (南京江北新區管理委員會(中國(江蘇)自由貿易試驗區南京片區管理委員會)). To the best knowledge of our Directors, Jiangbei Assets Management is an Independent Third Party.
- (y) **BOC Capital:** BOC Capital is a company established under the laws of the PRC with limited liability on March 20, 2019 and is a wholly-owned subsidiary of BOC International (China) Co., Ltd. (中銀國際證券股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 601696.SH). To the best knowledge of our Directors, BOC Capital is an Independent Third Party.

Compliance with the Guide

The Joint Sponsors confirm that the investments by the Pre-[REDACTED] Investors are in compliance with the guidance on pre-[REDACTED] investments in Chapter 4.2 of the Guide.

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[REDACTED]

The 95,230,960 Shares held by Nanjing Yipu, Nanjing Jiminrui, CPE Investment, Shanghai Guoxin, Jiangbei Fund, Jiangbei Assets Management, Ennovation Raylight, Nanjing Qiruiyoukang, Taixing Qichen, Nanjing Baiyide, BOC Capital and Jiangsu Zhongde, representing approximately 24.95% of our total issued Shares as of the Latest Practicable Date, or approximately [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), or approximately [REDACTED]% of our total issued Shares upon exercise of the [REDACTED] in full, will not be considered as part of the [REDACTED] for the purpose of Rule 8.08 of the Listing Rules as these Shares are Unlisted Shares which will not be converted into H Shares and [REDACTED] upon completion of the [REDACTED].

The 80,597,797 Unlisted Shares held by Dr. Wu, Nanjing Jiminrui and Nanjing Yipu, representing approximately 21.12% of our total issued Shares as of the Latest Practicable Date, or approximately [REDACTED] of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), or approximately [REDACTED] of our total issued Shares upon exercise of the [REDACTED] in full, will be converted into H Shares and listed upon completion of the [REDACTED]. As these Shares are held by our Controlling Shareholders who are core connected persons of our Company, the H Shares held by them will not be counted towards the [REDACTED] for the purpose of Rule 8.08 of the Listing Rules after the Listing.

The 205,787,876 Unlisted Shares held by Genecare Development, FIIF II, PharmaBlock, Structural Reform Fund, GP Healthcare Capital Phase II, SDIC Greater Bay Area Fund, Nanjing Zijin, SDICVC Ningbo Fund, Shenzhen Linghui, Jiangbei Fund, Guohong Medical, Jingzhou Huikang, Guotiao Merchants, Wuhu Xingrui, Nanjing InnoMed, Jiangbei Assets Management, Guohong Jiyuan, Ennovation Raylight, Trinity Zhongzhi, GP Healthcare Capital Phase III, SIXTY DEGREE, Lvyong Ruihua, Nanjing Lingyi, CR Life, Nanjing Qiruiyoukang, Eastern Handson, Nanjing Baiyide, TIF Biomedical, Wuxi Ruitong, Jiangsu Dunhe and Suzhou Dunxing, representing approximately 53.93% of our total issued Shares as of the Latest Practicable Date, or approximately [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), or approximately [REDACTED]% of our total issued Shares upon exercise of the [REDACTED] in full, are Unlisted Shares which will be converted into H Shares and [REDACTED] upon completion of the [REDACTED]. As these entities will not be core connected persons of our Company upon [REDACTED], are not accustomed to take instructions from core connected persons of our Company in relation to the acquisition, disposal, voting or other disposition of their Shares, and their acquisition of Shares were not financed directly or indirectly by core connected persons of our Company, the H Shares held by them will be counted towards the [REDACTED] for the purpose of Rule 8.08 of the Listing Rules after the [REDACTED].

Immediately upon [REDACTED], assuming that (i) [REDACTED] H Shares are allotted and [REDACTED] in the [REDACTED]; (ii) the [REDACTED] is not exercised; (iii) [REDACTED] Unlisted Shares will be converted to H Shares, and (iv) [REDACTED] Shares are issued and outstanding in the share capital of our Company upon completion of the [REDACTED], based on an [REDACTED] of HK\$[REDACTED] per H Share (being the mid-point of the indicative [REDACTED] range), [REDACTED] Shares, representing approximately [REDACTED]% of the total number of issued Shares of our Company will be counted towards the [REDACTED] and the Company will have a [REDACTED] of at least HK\$[REDACTED] held by the public. Therefore, our Company will be able to meet the minimum [REDACTED] requirements under Rules 8.08 and 18A.07 of the Listing Rules.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CAPITALIZATION OF OUR COMPANY

The table below is a summary of the capitalization of our Company as of the date of this document and the [REDACTED] (assuming the [REDACTED] is not exercised):

Shareholders	As of the date of this document		As of the [REDACTED] (assuming the [REDACTED] is not exercised)					
	Number of Unlisted Shares	Approximate percentage in total issued share capital (%)	Number of H Shares	Approximate ownership percentage in H Shares (%)	Number of Unlisted Shares	Approximate ownership percentage in Unlisted Shares (%)	Total number of Shares	Approximate ownership percentage in total issued share capital (%)
<i>Original Shareholders</i>								
Nanjing Yipu	54,726,152	14.34	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Wu	47,847,024	12.54	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Nanjing Jiminrui	28,284,453	7.41	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
PharmaBlock	22,107,247	5.79	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
<i>Pre-[REDACTED] Investors</i>								
GP Healthcare Capital Phase II	14,463,724	3.79	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GP Healthcare Capital Phase III	2,690,136	0.70	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	17,153,860	4.50	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
SDIC Greater Bay Area Fund								
SDICVC Ningbo Fund	11,565,615	3.03	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	21,680,081	5.68	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Shenzhen Linghui								
Wuhu Xingrui	7,780,505	2.04	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Nanjing Lingyi	4,836,529	1.27	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	15,111,403	3.96	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Guohong Medical								
Guohong Jiyuan	6,857,315	1.80	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	4,045,823	1.06	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Jingzhou Huikang								
Guotiao Merchants	6,834,259	1.79	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	5,404,468	1.42	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Ennovation Raylight								
Nanjing Qiruiyoukang	3,337,787	0.87	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	2,022,880	0.53	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Taixing Qichen								
Jiangsu Zhongde	1,662,818	0.44	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	831,409	0.22	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	2,494,227	0.65	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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Shareholders	As of the date of this document		As of the [REDACTED] (assuming the [REDACTED] is not exercised)					
	Number of Unlisted Shares	Approximate percentage in total issued share capital (%)	Number of H Shares	Approximate ownership percentage in H Shares (%)	Number of Unlisted Shares	Approximate ownership percentage in Unlisted Shares (%)	Total number of Shares	Approximate ownership percentage in total issued share capital (%)
Jiangsu Dunhe	498,846	0.13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Suzhou Dunxing	332,564	0.09	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	831,410	0.22	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
TIF Biomedical	1,438,338	0.38	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Trinity Zhongzhi	2,718,707	0.71	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Subtotal	4,157,045	1.09	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Genecare Development	27,610,879	7.24	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
FIIF II	24,274,756	6.36	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
CPE Investment	21,521,091	5.64	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Structural Reform Fund	16,140,817	4.23	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Nanjing Zijin	11,245,844	2.95	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Jiangbei Fund	7,620,244	2.00	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Nanjing InnoMed	4,450,362	1.17	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
SIXTY DEGREE	2,690,136	0.70	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Lvyong Ruihua	2,494,369	0.65	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
CR Life	2,102,838	0.55	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Eastern Handson	1,941,690	0.51	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Shanghai Guoxin	8,314,088	2.18	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Nanjing Baiyide	1,662,818	0.44	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Wuxi Ruitong	831,409	0.22	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Jiangbei Assets Management	4,157,040	1.09	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
BOC Capital	1,662,818	0.44	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Investors taking part in the [REDACTED]	-	-	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Total	381,616,633	100.00	[REDACTED]	100.00	[REDACTED]	100.00	[REDACTED]	100.00

PREVIOUS APPLICATION FOR [REDACTED]

We submitted an application for [REDACTED] of our H Shares on the the Main Board of Stock Exchange on August 25, 2021 (the “2021 HKEX [REDACTED] Application”). Having considered the prevailing market conditions at the relevant time, we ceased to proceed with the 2021 HKEX [REDACTED] Application upon the lapse of such application.

We may conduct an [REDACTED] and [REDACTED] of A shares at an appropriate time after the [REDACTED]. As of the Latest Practicable Date, we have not determined the size or the [REDACTED] venue of the contemplated A share [REDACTED], and have not submitted any application to any recognized stock exchange in the PRC for approval of A share [REDACTED]. There is no assurance that we will conduct an A share [REDACTED] in the future.

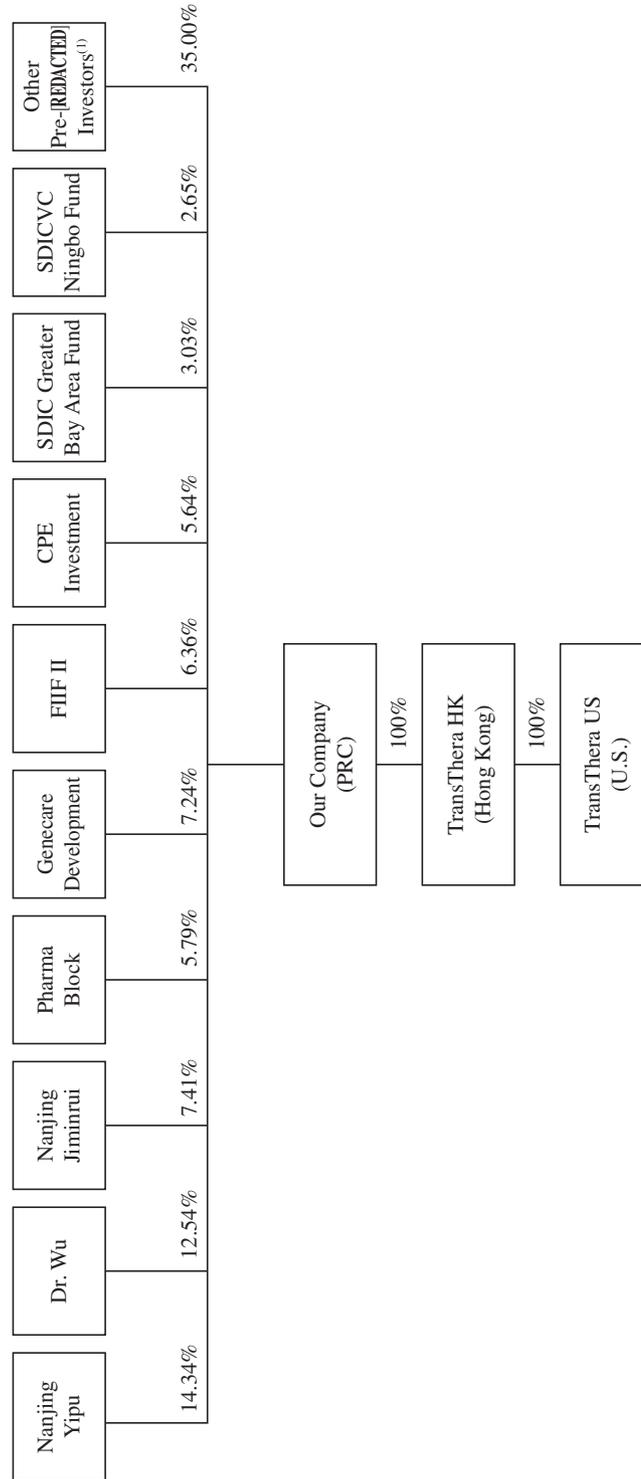
The Directors are of the view that there are no other matters relating to the 2021 HKEX [REDACTED] Application or the potential A share [REDACTED] that might affect our suitability for [REDACTED] on the Stock Exchange or need to be brought to the attention of the Stock Exchange and the potential investors.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR SHAREHOLDING AND CORPORATE STRUCTURE

Corporate Structure Immediately Before Completion of the [REDACTED]

The chart below sets out the shareholding structure of our Company immediately before completion of the [REDACTED]:



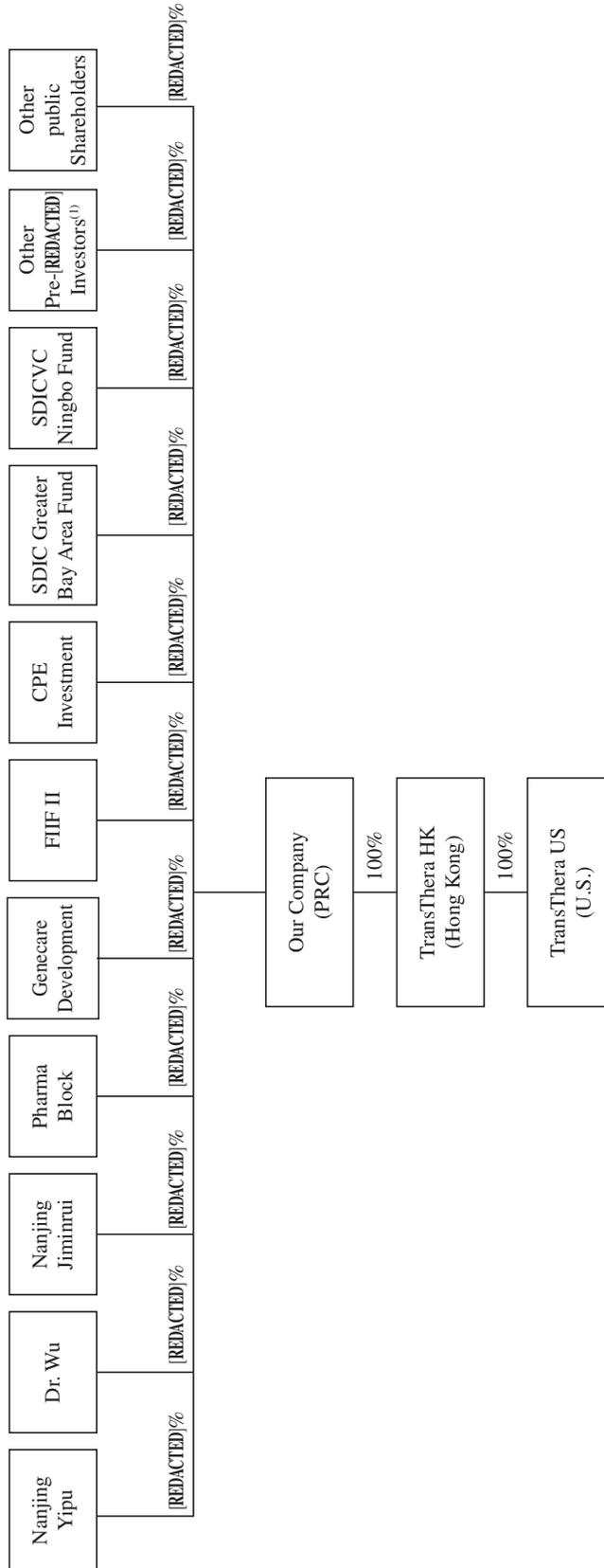
Note:

(1) For the details of the background information of the other Pre-[REDACTED] Investors, see “ – Pre-[REDACTED] Investments” above.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Corporate Structure Immediately After Completion of the [REDACTED]

The chart below sets out the shareholding structure of our Company immediately after completion of the [REDACTED] (assuming the [REDACTED] is not exercised):



Note:

(1) For the details of the background information of the other Pre-[REDACTED] Investors, see “– Pre-[REDACTED] Investments” above.

BUSINESS

OVERVIEW

We are a clinical demand-oriented, registrational clinical-stage biopharmaceutical company focusing on discovering and developing innovative small molecule therapies for oncology, inflammatory and cardiometabolic diseases. Our mission is to deliver innovative and differentiated treatment solutions to patients worldwide, guided by our core value of harnessing original technology as the driving force behind our business. Leveraging our fully-integrated in-house R&D system, we have built a pipeline of six clinical-stage product candidates and one preclinical product candidate, and we plan to continue expanding our pipeline. Further aided by in-depth study of translational medicine and drug design, we aim to develop first-in-class or best-in-class drug candidates strategically positioned to meet urgent clinical needs on a global scale.

Our mission and core value are best evident by our Core Product Tinengotinib (TT-00420), which was internally discovered through our thorough exploration of the foundational mechanisms of correlation between biological science and target diseases. As a registrational clinical-stage, potential first-in-class, potent MTK inhibitor primarily targeting three key pathways (namely, FGFR/VEGFR, JAK and Aurora kinases), Tinengotinib has the potential to address the unmet clinical needs in a variety of relapsed or refractory, drug-resistant solid tumors, including CCA, prostate cancer, breast cancer, BTC and pan-FGFR solid tumors. It was granted Breakthrough Therapy Designation by the NMPA and Fast-Track Designation by the FDA for the treatment of CCA. It was also granted Orphan Drug Designation by both the FDA for the treatment of CCA and by the EMA for the treatment of BTC. The encouraging clinical data of Tinengotinib have been published or presented orally at major international medical conferences such as the American Society of Clinical Oncology, the European Society of Medical Oncology, the San Antonio Breast Cancer Symposium, and American Association for Cancer Research.

- **CCA.** Tinengotinib is the world's first and the only investigational drug that has entered registrational stage to treat FGFR inhibitor relapsed or refractory CCA patients. We are currently conducting a Phase III multi-regional clinical trial across the U.S., South Korea, United Kingdom, eight countries in the EU and Taiwan. We are also conducting a Phase II pivotal trial in China under an accelerated approval protocol. We expect to launch Tinengotinib in China first after we receive the conditional marketing approval, followed by other regions.
- **mCRPC.** Tinengotinib is also the world's first and only investigational drug capable of simultaneously and effectively inhibiting the FGFR/JAK pathway with clinical evidence in the treatment of mCRPC. Further combination study to explore Tinengotinib and novel hormone therapies will be initiated to target mCRPC patients who have developed resistance to prior hormone therapy treatment.

BUSINESS

Except for the Core Product, we are also advancing multiple clinical programs in oncology, inflammatory and cardiometabolic diseases. In the field of oncology diseases, we are advancing two product candidates with best-in-class potential in their respective segments. TT-00973 is a potential best-in-class, novel AXL/FLT3 inhibitor, which has high activity in inhibiting the phosphorylation and activation of AXL in tumor cells, making it effective in the treatment of AXL overexpressing solid tumors. TT-01488 is a potential best-in-class, non-covalent, reversible BTK inhibitor, which can overcome acquired resistance to the front-line treatment of covalent BTK inhibitors in a variety of relapsed or refractory hematologic malignancies. In the field of inflammatory diseases, we are developing TT-01688, a highly selective oral S1P1 modulator primarily for UC and AD, in collaboration with LG Chem, and TT-01025, a potential best-in-class irreversible VAP-1 inhibitor for the treatment of NASH. In the cardiometabolic disease realm, we are developing TT-00920, a potential first-in-class, highly selective oral PDE9 inhibitor with a novel biological mechanism and strong disease relevance indicated for HF. Furthermore, we are also developing other novel preclinical stage drug candidates, including TT-02332, an internally discovered and developed NLRP3 inhibitor for metabolic and inflammatory diseases. The following chart illustrates our pipeline and summarizes the development status of our selected drug candidates in both the clinical stage and the preclinical stage as of the Latest Practicable Date:

BUSINESS

Drug Candidate	Target/Mechanism	Indication	Mono/Combo	Clinical Stage					Expected Upcoming Milestone	Rights Region		
				Preclinical	IND Enabling	Phase I	Phase II	Pivotal Phase II/Phase III				
Tinengotinib (TT-00420)	Unique MTK (FGFR/VEGFR/ JAK/Aurora)	CCA ¹	Mono	China	China	China	China	China	Complete the trial in 2H 2025	Global		
			Mono	MRCT ⁵	Complete patient enrollment in 2H 2026							
			Mono	U.S. ² , China ³	Complete the trial in Q4 2024							
		Combo (NHT)	mCRPC	U.S. ⁴ , China	Initiate the trial in 2H 2024 (US)/ 1H 2025 (China)							
		Mono	HER2- breast cancer	U.S. ² , China ³	Complete the trial in Q4 2024							
		Combo		U.S. ² , China ³	Clinical timeline TBD							
		Combo (PD-L1)	BTC	China ³	China ³	China ³	China ³	Complete the trial in Q4 2024				
		Mono	Pan-FGFR solid tumor	U.S. ² , China ³	Complete the trial in Q4 2024							
		TT-00973	AXL/FLT3	Solid tumor	Mono	China	China	China	China		Complete the trial in 1H 2026	Global
		TT-01488	Reversible BTK	CLL/MCL/WM	Mono	U.S., China	U.S., China	U.S., China	U.S., China		Obtain results from primary endpoint in 2H 2025	Global
TT-01688 TT-00920 TT-01025 TT-02332	S1P1 PDE9 VAP-1 NLRP3	UC AD	Mono	China	China	China	China	Complete the trial in 2H 2024	Greater China ⁶			
			Mono	China	China	China	China	Complete the trial in 2H 2024				
		Mono	HF	U.S., China	U.S., China	U.S., China	U.S., China	Clinical timeline TBD	Global			
		Mono	NASH	U.S., China	U.S., China	U.S., China	U.S., China	Clinical timeline TBD	Global			
		Mono	Metabolic/Inflammation	U.S., China	U.S., China	U.S., China	U.S., China	IND submission in the first half of 2025	Global			

★ Core Product

Abbreviations: CCA=cholangiocarcinoma; mCRPC=metastatic castration-resistant prostate cancer; HER2- breast cancer=human epidermal growth factor receptor 2 negative breast cancer; BTC=biliary tract carcinoma; CLL=chronic lymphocytic leukemia; NHT=novel hormone therapies; MCL=mantle-cell lymphoma; WM=waldenström’s macroglobulinemia; HF=heart failure, UC=ulcerative colitis; AD=atopic dermatitis; NASH=nonalcoholic steatohepatitis; MRCT=multi-regional clinical trial; TBD=to be determined; Q4=fourth quarter; 1H=first half; 2H=second half.

BUSINESS

Notes:

1. We received Breakthrough Therapy Designation for CCA from the NMPA in July 2023, and received Fast-Track Designation for CCA from the FDA in August 2021.
2. We are exploring these indications under the same trial protocol of one clinical trial (NCT04742959) conducted in the U.S.
3. We are exploring these indications under the same trial protocol of one clinical trial (CTR20212760) conducted in China.
4. This trial is an investigator-initiated trial.
5. We are currently conducting a Phase III multi-regional clinical trial (NCT05948475) of Tinengotinib monotherapy for the treatment of CCA across the U.S., South Korea, United Kingdom, eight countries in the EU and Taiwan.
6. We in-licensed exclusive rights from LG Chem to use, develop, manufacture, commercialize and otherwise exploit TT-01688 in Greater China. For more information, see “– Collaboration and License Agreements – License-in Agreement with LG Chem.”

BUSINESS

Leveraging our strong drug development expertise and business development capabilities, we adopt a global business strategy composed of global R&D positioning and collaboration activities. As of the Latest Practicable Date, we were developing our Core Product under IND approvals from the FDA, the NMPA, the EMA, the MHRA, the MFDS and the TFDA, and another five pipeline products under IND approvals from the NMPA and/or the FDA. We have established collaborations with world-renowned biopharmaceutical companies, including LG Chem (South Korea), Teijin (Japan), EA Pharmaceuticals (Japan), and F. Hoffmann-La Roche Ltd (Switzerland). Through these international collaborations, we have gained access to a spectrum of innovative technologies and international clinical development resources, positioning us for future global commercialization.

We have assembled a management team of industry executives with global vision and extensive experience in multinational pharmaceutical companies. Through our collective wisdom, we have built up a methodology platform, namely Adaptive Comprehensive Expandable (“ACE”) platform, which guides our innovative approach to small molecule drug discovery and development. We are faithful that clinically meaningful differentiations of our drug candidates are the key to future dominance in market competition. In addition, in-depth understanding of biology and mechanism of action will render additional clinical indication expansion and market broadening to amplify the return of investment. In order to support our ACE platform and innovation acumen, we have also established a fully integrated R&D platform, which integrates all the necessary capabilities to streamline our target-to-market timeline. This platform provides tangible and technological base to serve as firm pivot to our business. Combining the methodology ACE platform and the fully integrated R&D platform, we have continued to deliver a number of innovative products into clinical trials globally.

Our Core Product Tinengotinib (TT-00420)

Our Core Product Tinengotinib is a registrational clinical-stage, internally discovered and developed, potential first-in-class, unique MTK inhibitor indicated for certain relapsed or refractory, drug-resistant solid tumors. It mainly targets three key pathways, namely, FGFR/VEGFR, JAK and Aurora kinases. Driven by targeting one or a combination of pathways, Tinengotinib can target a wide range of cancer types. The unique binding mode with FGFR enables Tinengotinib to overcome polyclonal mutations, rendering it target FGFR-driven cancers (such as FGFR altered CCA and pan-FGFR solid tumor), and the distinct combination of the key pathways makes it capable of being efficacious in a broad range of cancer types (including prostate cancer, breast cancer and BTC).

As of the Latest Practicable Date, a total of eight self-sponsored clinical trials had been conducted or were being conducted for Tinengotinib globally, of which two clinical trials were conducted in healthy volunteers and six clinical trials were conducted in patients with solid tumors, including but not limited to CCA, prostate cancer, breast cancer and BTC. Up to the cut-off date of September 26, 2023, 350 patients with solid tumors were treated by Tinengotinib monotherapy, including 295 patients in the U.S. and 55 patients in China. The

BUSINESS

collective safety and tolerability data have demonstrated that Tinengotinib was well tolerated in patients with solid tumors. Tinengotinib also showed significant antitumor effects in a wide range of tumor types as a single agent or as a combination therapy. Specifically:

CCA

Tinengotinib is the world's first and the only investigational drug that has entered registrational stage to treat FGFR inhibitor relapsed or refractory CCA patients. FGFR inhibitors have been approved for the treatment of FGFR-altered CCA after chemotherapy. However, disease progression after FGFR inhibitors occurred in almost all patients. The absence of recommendations for subsequent treatment options in NCCN or CSCO guidelines has created an unmet medical need. Currently, there is no recommended choice for the third-line treatment of CCA. Patients are left to choose chemotherapy with unclear clinical benefits.

Researchers have reported that secondary polyclonal mutations in the FGFR2 kinase domain are a major prominent acquired resistance mechanism. In preclinical studies, Tinengotinib has shown high potency to a variety of FGFR2 kinase domain mutations both *in vitro* and *in vivo*. In a pooled analysis of clinical studies in the U.S., as of March 28, 2024, among 43 CCA patients who had progressed on prior FGFR inhibitors, after being treated with Tinengotinib and at least one tumor scan, the ORR was 30% (13/43), the DCR was 93% (40/43), and the median PFS was 6.0 months. The promising clinical data was also observed in the clinical trial conducted in the China. In China, two of three (66.7%) CCA patients who had progressed on prior FGFR inhibitors were treated with Tinengotinib and achieved PR. As of March 28, 2024, one patient lasted for more than 8 months, the other patient has lasted for 14 months, who is still on treatment. Results of Tinengotinib treating FGFR inhibitor relapsed or refractory CCA patients were presented at 2023 ESMO annual conference and 2024 ASCO GI annual conference as oral presentations and published as poster presentation at 2024 Cholangiocarcinoma Foundation annual conference. Two pivotal/registrational trials in China and certain other regions were initiated in November 2023 and December 2023, respectively.

mCRPC

Tinengotinib is also the world's first and the only investigational drug capable of simultaneously and effectively inhibiting the FGFR/JAK pathway with clinical evidence in the treatment of mCRPC. Currently, NHT, including enzalutamide, apalutamide and abiraterone, have been established as the standard of care for mCRPC patients. However, resistance will inevitably develop after a period of hormone therapy treatment. Recent academic discoveries have identified that activation of FGFR and JAK pathways will stimulate the cell state transformation from androgen sensitive cancer cells to neuroendocrine cancer cells and cause drug resistance. Simultaneous inhibition of FGFR and JAK pathways would be able to reverse the cell state transformation, or lineage plasticity, back to androgen sensitive cancer cells and re-sensitize to hormone therapies. In a pooled analysis of patients in the U.S. and China, Tinengotinib monotherapy has shown encouraging antitumor efficacy in heavily pre-treated mCRPC patients. According to our Phase I/II clinical trials of Tinengotinib as monotherapy in

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22 efficacy-evaluable heavily pre-treated mCRPC patients who are resistant to hormonal treatments, the preliminary efficacy observed in 13 patients with measurable lesions was promising, showing an ORR of 46% (6/13) and a DCR of 85% (11/13). 43% patients had prostate-specific antigen reduction of more than 50%. The median radiographic PFS was 5.6 months (N=22). The results have been published at 2024 ASCO GU annual conference. Further combination study to explore Tinengotinib and novel hormone therapies will be initiated to target mCRPC patients who have developed resistance to prior hormone therapy treatment.

Other Indications

- **Breast cancer.** Similar promising efficacy of Tinengotinib has also been observed in heavily pre-treated HR+/HER2– breast cancer patients and TNBC patients. In a pooled analysis of breast cancer patients in the U.S. and China, Tinengotinib monotherapy demonstrated an ORR of 50% (8/16) and a DCR of 88% (14/16) in patients who were originally diagnosed as HR+/HER2–. Notably, among the 16 patients, five transformed TNBC patients reached 60% ORR (3/5) and 100% DCR (5/5). One HR+/HER2– breast cancer patient has been on the treatment for over 20 months and reached confirmed complete response.
- **Biliary tract cancer.** Preclinical data demonstrated Tinengotinib was capable of modulating tumor microenvironment, indicating its potential to enhance the efficacy of immunotherapy. From our Phase Ib/II clinical trial, among nine efficacy-evaluable patients treated with Tinengotinib plus atezolizumab, the ORR and the DCR were 33% (3/9) and 78% (7/9), respectively. The combination therapy was generally safe and well tolerated. These encouraging data suggested Tinengotinib’s great potential in combination therapy with immunotherapies.
- **Pan-FGFR solid tumor.** Tinengotinib has unique binding mode to FGFR 1/2/3 kinase proteins, enabling it to be potent to key mutations within FGFR 1/2/3 kinase domains. This differentiated feature has brought good clinical responses to a variety of solid tumor patients with FGFR 1/2/3 alterations, especially point mutations. In a pooled retrospective analysis, 51 patients with documented or detected FGFR 1/2/3 mutations and measurable target lesions have been treated with Tinengotinib and demonstrated an ORR of 33% and a DCR of 88%. The median PFS reached 6.9 months.

BUSINESS

OUR COMPETITIVE STRENGTHS

Registrational Stage Tinengotinib Leading in Addressing Global Unmet Needs

Our Core Product Tinengotinib is a registrational clinical-stage, internally discovered and developed, potential first-in-class, unique MTK inhibitor indicated for certain relapsed or refractory, drug-resistant solid tumors, including CCA, mCRPC, HER2– breast cancer, BTC and pan-FGFR solid tumors. It mainly targets three key pathways, namely, FGFR/VEGFR, JAK and Aurora kinases. According to Frost & Sullivan, Tinengotinib is the world's first and the only investigational drug that has entered registrational stage to treat FGFR inhibitor relapsed or refractory CCA patients. Tinengotinib is also the world's first and the only investigational drug capable of simultaneously and effectively inhibiting the FGFR/JAK pathway with clinical evidence in the treatment of mCRPC. It was designed to address the limitations of the existing FGFR inhibitors and unmet clinical needs. Tinengotinib, which has a distinctive chemical scaffold with unique FGFR-binding mechanism that circumvents acquired resistance mechanisms, was internally discovered and developed by leveraging our deep understanding of the basic biology as well as our drug design capability.

CCA

For patients with unresectable advanced or metastatic CCA that have relapsed after prior systemic chemotherapy and FGFR inhibitor treatments, there is a global lack of effective therapies. The potential occurrence of multiple FGFR-acquired resistance mutations adds complexity to drug development, leading several U.S. biotechnology companies to withdraw from clinical development, underscoring the urgency for innovative treatments in this challenging clinical landscape. Tinengotinib, distinguished by its innovative mechanism and robust clinical evidence, is poised to address this market gap and stands as a global frontrunner in the treatment of advanced or metastatic CCA.

Advanced or metastatic CCA is a rare yet malignant cancer with limited treatment options. In the U.S., the five-year survival rate for CCA is approximately 10%, which is significantly lower than the five-year survival rate of all cancer types combined, which is 69%. For advanced CCA, surgical resection may become unfeasible due to cancer invasion. The standard first-line treatment is systemic chemotherapy, with a low median OS (approximately 12 months) and a low ORR of approximately 19%. If genetic testing reveals FGFR2 alterations, targeted therapies represented by FGFR inhibitors become the recommended choice for second-line treatment. However, drug-related adverse reactions pose challenges to medication compliance. Additionally, despite initial responses, almost all patients will experience disease progression after six to nine months of treatment. Currently, there is no recommended choice for the third-line treatment of CCA. Patients are left to choose chemotherapy with unclear clinical benefits. Literature data indicated a low ORR not exceeding 8%-10%, a median PFS of approximately three months, and a median OS of approximately six months, with poor tolerability.

BUSINESS

CCA patients on FGFR inhibitors typically develop multiple resistance mutations in the FGFR2 kinase domain. This necessitates the development of FGFR inhibitors that could simultaneously address all known resistance mutations. Therefore, molecular design of a compound for addressing FGFR inhibitor resistance faces significantly increased difficulty. Leveraging our extensive experience in drug design, we have internally discovered and developed Tinengotinib, which can overcome acquired resistance associated with FGFR inhibitors. Namely, Tinengotinib has the following characteristics that enable it to overcome FGFR inhibitor resistance:

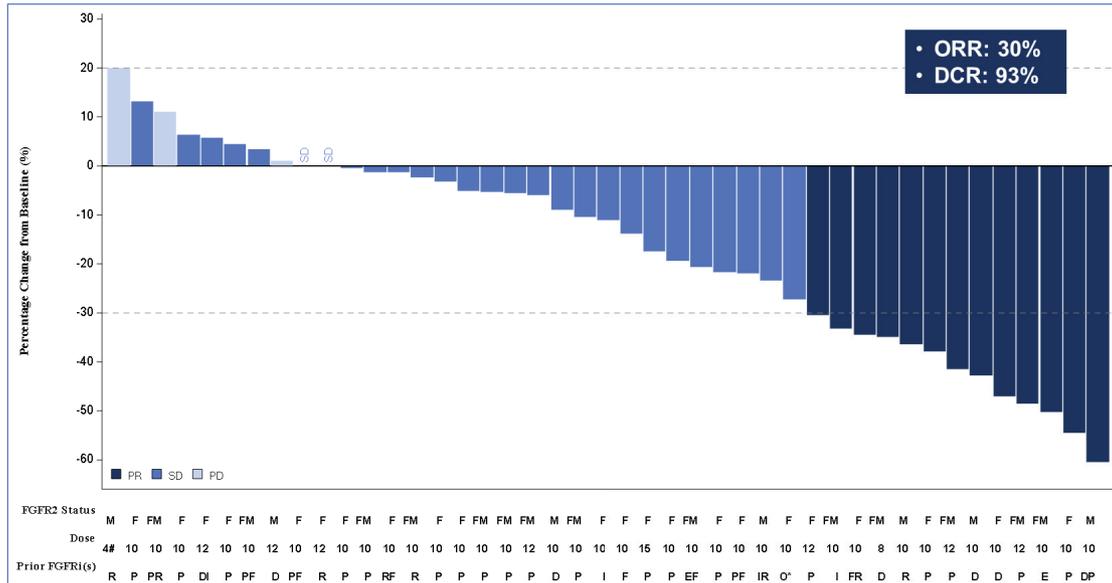
- Distinct Binding Mode: Tinengotinib binds to FGFR2 kinase domain through a unique binding mode other than existing FGFR inhibitors. Due to its smaller size, it does not extend to the hydrophobic pocket deeper within the FGFR2 kinase domain, making its binding to the FGFR2 kinase domain less likely to be affected by mutations of amino acids prone to contribute to acquired resistance.
- High Affinity: When binding to FGFR2 kinase domain, Tinengotinib forms three hydrogen bonds with the amino acid residues in the hinge region of FGFR2 kinase, resulting in high affinity. Surface plasmon resonance experiments have also confirmed Tinengotinib's tight binding and durable affinity.

Tinengotinib lacks the bulky dimethoxyphenyl moiety shared by infigratinib, pemigatinib and futibatinib. Co-crystal structures with FGFR2 confirmed that it does not extend into the back pocket. Tinengotinib generates three hydrogen bonds with the hinge region of FGFR2 – compared to one or two seen in earlier generation FGFR inhibitors – thus leading to a higher affinity to FGFR. It binds to the active conformation of the receptor. Tinengotinib exhibits quick-on and very slow-off binding kinetics relative to infigratinib and binds to the target almost two times stronger than the earlier generation FGFR inhibitors. Taken together, Tinengotinib would less likely be affected by acquired mutations causing steric hindrance, or increase in ATP affinity, or conformational change to the active form of kinase domain, and retain high affinity against mutated receptors.

Clinical data of Tinengotinib have shown that compared to literature data of chemotherapy, Tinengotinib significantly prolonged the survival of third-line advanced or metastatic CCA patients, demonstrating clear clinical benefits. In a pooled analysis of clinical studies in the U.S., as of March 28, 2024, among 43 CCA patients who had progressed on prior FGFR inhibitors, after being treated with Tinengotinib and had at least one tumor scan, the ORR was 30% (13/43), the DCR was 93% (40/43), and the median PFS was 6.0 months. The promising clinical data was also observed in the clinical trial conducted in the China. In China, two of three (66.7%) CCA patients who had progressed on prior FGFR inhibitors were treated with Tinengotinib and achieved PR. As of March 28, 2024, one patient lasted for more than 8 months, the other patient has lasted for 14 months, who is still on treatment. A Phase III randomized, controlled, global multicenter study is under patient enrollment to further evaluate the efficacy and safety of Tinengotinib versus physician's choice of chemotherapy in patients with FGFR-altered, chemotherapy and FGFR-inhibitor refractory/relapsed CCA. We are also conducting a pivotal trial in China under an accelerated approval protocol for the treatment of chemotherapy and FGFR-inhibitor refractory/relapsed CCA.

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Waterfall plots of CCA patients (N=43)



Abbreviations: ORR=objective response rate; DCR=disease control rate; M=mutation; F=fusion/rearrangement; PR=partial response; SD=stable disease; PD=progression disease; P-=Pemigatinib; R-=RLY-4008; F-=Futibatnib; D-=Derazantinib; I-=Infigratinib; E-=Erdafinitib; O*=other investigational FGFRi. #4 mg BID

Source: Company data

In addition, Tinengotinib’s unique combination of targets effectively plays a role in enhancing efficacy while minimizing toxicity. Clinical data demonstrates good safety and tolerability of Tinengotinib, with a minimal incidence of adverse reactions commonly associated with FGFR inhibitors, such as hyperphosphatemia, ocular toxicity, and nail toxicity. Clinical data from the prior Phase I and Phase II clinical trials for the indication of CCA revealed that the most common TRAEs include hypertension, diarrhea, and oral mucositis. Other types of common adverse reactions are consistent with those seen with small molecule targeted inhibitors, and clinical control measures are well-established. Therefore, Tinengotinib, with its unique molecular binding mode to FGFR, demonstrates a high degree of differentiation in treating FGFR mutation-driven solid tumors. It presents formidable technical barriers and excels in both efficacy and safety.

In view of the superior safety and efficacy, Tinengotinib was granted Breakthrough Therapy Designation by the NMPA and the Fast-Track Designation by the FDA for the treatment of CCA. It was also granted Orphan Drug Designation by the FDA for the treatment of CCA and by the EMA for the treatment of BTC.

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mCRPC

Prostate cancer is an epithelial malignant tumor mostly occurring in the prostate with molecular characteristics that include androgen receptor positivity and expression of luminal molecular markers. Prostate cancer is sensitive to androgen deprivation therapy and NHT. However, following long-term treatment with these approaches, patients may develop resistance to these treatments. According to Frost & Sullivan, the global incidence of mCRPC was 203.9 thousand in 2023, and the incidence of mCRPC in China was 48.4 thousand in 2023, with the five-year survival rate of mCRPC patients being less than 30% globally. Currently, first-line and second-line treatment approaches still primarily involve novel endocrine therapy and chemotherapy. There is a lack of new effective treatment drugs for resistant and progressing patients.

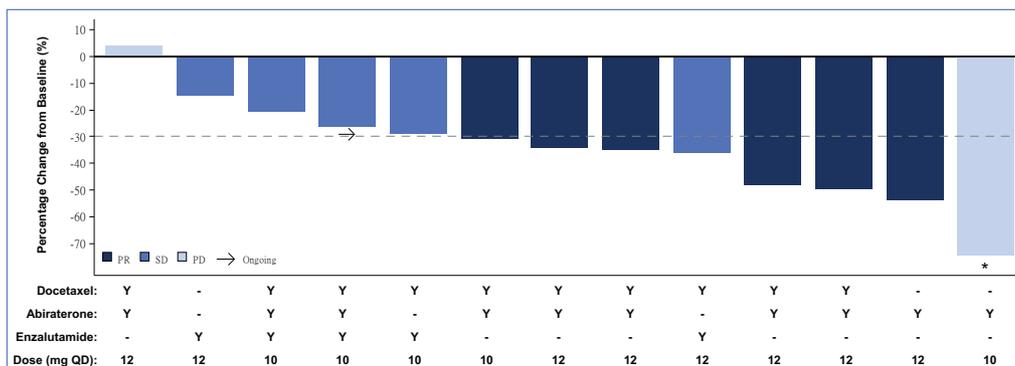
According to the research results from Dr. Charles L. Sawyers, chair of Human Oncology and Pathogenesis Program in MSKCC and lead developer in mCRPC treatments enzalutamide and apalutamide, and his team, published on Science since 2017, hormone-sensitive prostate cancer cells become resistant to hormone therapy due to a gradual loss of androgen receptor expression and luminal molecular marker expression and gain of basal, mesenchymal and stem-like gene expression signatures, ultimately developing into neuroendocrine prostate cancer. This process is known as lineage plasticity, a crucial resistance mechanism for enzalutamide/abiraterone-treated prostate cancer. Blocking lineage plasticity has become a focal point in the treatment of mCRPC. Furthermore, the research result also revealed a strong correlation between the activation and upregulation of the FGFR/JAK pathway and the driving mechanism behind prostate cancer lineage plasticity.

By inhibiting the FGFR/JAK signaling pathway, Tinengotinib can disrupt and reverse the process of lineage plasticity in prostate cancer, restoring the expression of androgen receptors and sensitivity to novel hormonal treatments in mCRPC. This novel and unique mechanism positions Tinengotinib as a highly promising innovative drug for treating mCRPC.

BUSINESS

Preclinical studies in abiraterone-resistant mCRPC PDX mouse model suggested that through simultaneously inhibiting FGFR/JAK pathway, Tinengotinib can reverse the lineage plasticity by recovering the androgen receptors in mCRPC to restore their sensitivity to abiraterone. The promising efficacy has also been verified in our clinical trials. According to our Phase I/II clinical trials of Tinengotinib as monotherapy in 22 efficacy-evaluable heavily pre-treated mCRPC patients who are resistant to hormonal treatments as of August 28, 2023, the preliminary efficacy observed in 13 patients with measurable lesions was promising, showing an ORR of 46% (6/13) and a DCR of 85% (11/13). As delineated in the waterfall plot below, more than 90% of patients had tumor size reduction and over 60% of patients experienced a more than 30% reduction in tumor volume. The encouraging preliminary efficacy warrants further investigation, and further combination study to explore Tinengotinib and novel hormone therapies will be initiated to target mCRPC patients who have developed resistance to prior hormone therapy treatment.

Waterfall plots of mCRPC patients (N=13)



Abbreviations: PR=partial response; SD=stable disease; PD=progression disease.

Notes:

*: non-target lesions worsened, new liver lesions appeared;

Y: the patient was treated with docetaxel/abiraterone/enzalutamide before treated with Tinengotinib;

-: the patient did not receive docetaxel/abiraterone/enzalutamide before treated with Tinengotinib.

Source: Company data

Other Indications

As a unique MTK inhibitor, Tinengotinib can comprehensively regulate cell proliferation, angiogenesis, and the immunological pathways, inhibiting the development of various solid tumors and modulating the tumor microenvironment. As such, it can exert antitumor effects in a wide range of tumors other than CCA and mCRPC.

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- Breast cancer. Breast cancer can be categorized by different gene expression and receptor status – most commonly, estrogen receptor and progesterone receptor, together referred to as HR, and HER2. HR+ means that tumor cells have receptors for the hormones estrogen or progesterone, which can promote the growth of HR+ tumors. HER2+ means that tumor cells make high levels of a protein called HER2/neu, which has been shown to be associated with certain aggressive types of breast cancer. HER2– means the tumor cells make little (IHC scores of 1+ or 2+) to no HER2/neu protein (IHC scores of 0).

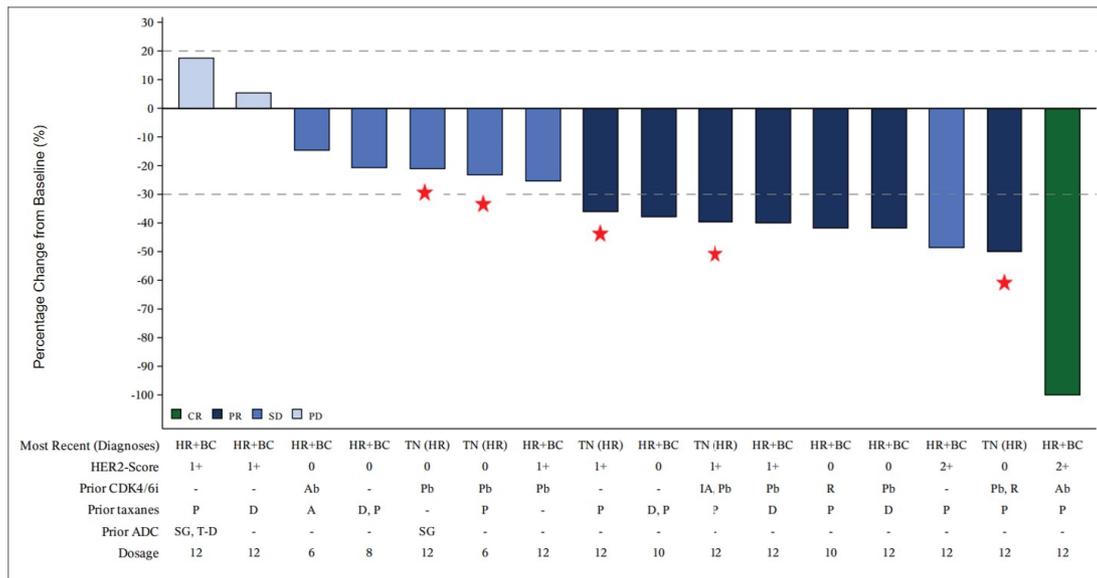
HR+/HER2–, a predominant subtype, accounts for approximately 65% of breast cancer. In current treatment guidelines, the standard first-line treatment for HR+/HER2– breast cancer is endocrine therapy combined with CDK4/6 inhibitors. After disease progression, endocrine therapy combined with other targeted therapy is the standard second-line treatment, but its effectiveness is limited.

TNBC, which lacks estrogen receptor and progesterone receptor and is HER2–, is the most malignant breast cancer subtype, accounting for approximately 15% of breast cancer cases. TNBC can be transformed from HR+/HER2– breast cancer after received prior-line treatment. According to Frost & Sullivan, some HR+/HER2– breast cancer can transform into TNBC. TNBC encompasses multiple subtypes characterized by distinct genetic drivers, including Aurora A and B kinases in the basal-like 1 subtype, and FGFR, PDGFR, and VEGF signaling pathways in the mesenchymal and mesenchymal stem-like subtypes. TNBC is a very aggressive form of breast cancer, which grows and spreads faster, has fewer treatment options, and tends to have a worse prognosis. Currently, chemotherapy is the primary treatment for TNBC, but its effectiveness is limited.

Clinical trial results from the U.S. and China demonstrated excellent clinical efficacy of Tinengotinib alone in HR+/HER2– breast cancer patients who have undergone multiple treatments, such as endocrine therapy, CDK4/6 inhibitor therapy, and chemotherapy. In a pooled analysis of breast cancer patients in the U.S. and China, Tinengotinib monotherapy demonstrated an ORR of 50% (8/16) and a DCR of 88% (14/16) in patients who were originally diagnosed as HR+/HER2– and 24% ORR (4/17) and a DCR of 71% (12/17) in TNBC patients. Notably, among the 16 patients who were originally diagnosed as HR+/HER2–, five transformed TNBC patients reached 60% ORR (3/5) and 100% DCR (5/5). One HR+/HER2– patient has been on the treatment for over 20 months and reached confirmed complete response.

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Waterfall plots of patients originally diagnosed as HR+/HER2- breast cancer (N=16)



★ Originally diagnosed as HR+/HER2- BC, most recent test diagnosed as TNBC

Abbreviations: CR=complete response; PR=partial response; SD=stable disease; PD=progression disease; BC=breast cancer; TN=triple negative.

Notes:

CDK4/6i: Pb=palbociclib; R=ribociclib; Ab=abemaciclib; IA=investigational CDK4 inhibitor.

Taxanes: A=abraxane; D=docetaxel (taxotere); P=taxol (paclitaxel).

ADC=antibody-drug conjugate.

T-D=Fam-trastuzumab deruxtecan-nxki; SG=Sacituzumab govitecan-hziy.

-: patient did not take this drug.

Source: Company data

- Biliary tract cancer.** Due to the novel mechanism of both targeted therapy and TME modulation, Tinengotinib can be used in combination with immune checkpoint inhibitors to potentially generate synergistic antitumor effect. Tinengotinib blocks angiogenesis by inhibiting VEGFR. It also completely abolishes the differentiation of protumorigenic macrophages in a cellular assay. Furthermore, Tinengotinib displays enhanced tumor growth inhibition when combined with anti-PD-1 and anti-PD-L1 antibodies in preclinical tumor models. Taken together, our preclinical studies demonstrated that Tinengotinib possessed strong effects to modulate the TME. Such observation was further verified through our clinical results. From our Phase Ib/II clinical trial, among nine efficacy-evaluable patients treated with Tinengotinib plus atezolizumab, the ORR and the DCR were 33% (3/9) and 78% (7/9), respectively. These encouraging data suggest Tinengotinib’s great potential in combination therapy with immunotherapies.

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- Pan-FGFR solid tumor. FGFR alterations are prevalent in patients with solid tumors, accounting for approximately 7.1% of all solid tumor patients. FGFR alterations include gene amplifications, fusions/rearrangements, and point mutations. Tinengotinib can potentially overcome the acquired resistance to FGFR1/2/3 alterations after FGFR inhibitor treatment. It can exert antitumor activities for patients with key FGFR mutations who are not eligible for erdafitinib treatment. Therefore, in comparison to erdafitinib, Tinengotinib may cover a broader range of FGFR mutation types. In a pooled retrospective analysis of data from four clinical trials, 51 patients with documented or detected FGFR 1/2/3 mutations and measurable target lesions. Partial responses were observed in 17/51 (33.3%) patients across 6 distinct tumor types, including CCA, breast, prostate, urothelium, colon and head and neck cancer. The DCR was 88.2%. The median PFS reached 6.9 months. In addition, clinical data demonstrates good safety and tolerability of Tinengotinib, with a minimal incidence of adverse reactions commonly associated with FGFR inhibitors, such as hyperphosphatemia, ocular toxicity, and nail toxicity.

Highly Differentiated Pipeline Targeting Oncology and Other Diseases

Our focus on oncology diseases is to discover and develop highly innovative drug candidates with differentiated attributes to address challenges faced by patients with hard-to-treat solid tumors and hematological malignancies or those who have acquired or developed resistance to prior standard therapies. In addition to oncology diseases, we are also exploring innovative treatment options for chronic diseases that are challenging to be controlled or cured, such as inflammatory and cardiometabolic diseases.

Our Oncology Pipeline

- TT-00973 is an internally discovered and developed, potential best-in-class, novel AXL/FLT3 inhibitor with significantly high potency against AXL. AXL belongs to the TYRO3-AXL-MER family, which is a homologous type I receptor-tyrosine kinase that has been found to be overexpressed in various cancers including NSCLC, breast cancer, and ovarian cancer, and is of significant importance in clinical prognosis assessment for cancer patients. The AXL signaling pathway mediates epithelial-mesenchymal transition, participates in DNA damage repair, and influences the tumor microenvironment, playing a crucial role in tumor metastasis, chemotherapy and targeted therapy resistance, and immune evasion. Targeting AXL for therapy holds promise as a new strategy for cancer treatment. Currently, multiple AXL-targeted therapies in various modalities are under clinical development, including small molecule inhibitor, monoclonal antibody, antibody-drug conjugate, and AXL “decoy” protein. However, to date, there were no AXL-targeted therapies approved for marketing worldwide.

TT-00973 is a potent kinase inhibitor with high potency to AXL. Preclinical data suggested that TT-00973 effectively inhibited cellular AXL with an $IC_{50} < 1$ nM. TT-00973 also demonstrated excellent efficacy in AXL-overexpressing NSCLC CDX model, and exhibits significant synergistic antitumor effects when used in combination with chemotherapy, indicating great clinical potential for TT-00973. As of the Latest Practicable Date, we are conducting a Phase I dose escalation study of TT-00973 in patients with solid tumors, and we have observed that TT-00973 was well tolerated with good PK profile to support once daily dosing, and achieved partial responses in patients with solid tumors.

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- TT-01488 is an internally developed, potential best-in-class, noncovalent, reversible BTK inhibitor that is used for treating various relapsed or refractory hematologic malignancies. Due to its unique molecular design, it can overcome mutations associated with acquired resistance caused by covalent BTK inhibitors. BTK plays a central role in the pathogenesis of B-cell lymphomas by continuously activating downstream signals of the B-cell receptor. As of the Latest Practicable Date, a total of five covalent irreversible small molecule BTK inhibitors were approved for marketing globally. However, acquired resistance is often observed in patients treated with these therapies. According to Frost & Sullivan, acquired resistance to covalent BTK inhibitors is primarily mediated by mutations at their covalent binding site, such as the BTK C481 point mutation, which significantly impairs binding affinity of covalent BTK inhibitors to their target. In addition, currently available BTK inhibitors have been associated with adverse reactions including bleeding, dermatitis, diarrhea, and atrial fibrillation, partially due to off-target inhibition of EGFR and Tec family proteins. TT-01488 is designed as a noncovalent reversible BTK inhibitor that binds to the BTK kinase domain and is not affected by the C481S mutation, with significantly improved selectivity. As of the Latest Practicable Date, there was no noncovalent reversible BTK inhibitor approved for marketing in China.

In our preclinical studies, TT-01488 has shown great potential to overcome resistance, with improved target selectivity and potent antitumor activity. In an *in vitro* kinase activity assay, TT-01488 exhibited significant kinase selectivity, with an EGFR to BTK ratio of 2304-fold, and a Tec to BTK ratio of 14-fold. *In vivo* studies also demonstrated that TT-01488 exhibited superior antitumor activity in B-cell lymphoma mouse models. These findings suggest a more favorable safety profile for TT-01488. Based on these encouraging preclinical results, we have obtained IND approvals from the NMPA and the FDA and initiated a Phase I clinical trial for hematologic malignancies in China in March 2023. Promising efficacy of complete response and partial response have been observed in patients with acquired resistance to irreversible BTK inhibitors during the Phase I dose escalation study.

Pipeline for Other Diseases

- TT-01688 is a highly selective oral S1P1 modulator currently in clinical stage, with the potential to treat various inflammatory diseases. According to Frost & Sullivan, the prevalence of UC and AD in China was approximately 541.6 thousand and 71.6 million, respectively, in 2023. For patients receiving biologics, over 60% of patients with moderate to severe UC fail to achieve one-year clinical remission, and over 40% of patients with moderate to severe AD fail to achieve a four-point improvement according to the Worst Pruritus Numerical Rating Scale. Although JAK inhibitors have been approved in the U.S. for UC, an IBD that causes inflammation and ulcers (sores) in one’s digestive tract, and AD treatment, they have been plagued by safety concerns and received black box warnings from the FDA regarding increased risks of severe infections, malignancies, and thrombosis, limiting their long-term use.

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S1P1 is a promising target for inflammatory diseases with a favorable safety profile. S1P1 modulators reduce the number of circulating lymphocytes in the blood and prevent reactive lymphocytes from migrating to inflammatory sites. As of the Latest Practicable Date, no selective S1P1 modulator was approved for UC or AD treatment in China with several candidates undergoing clinical development, among which TT-01688 was one of the most clinically advanced selective S1P1 modulators. It has high activity against S1P1 with negligible effect on S1P2 and S1P3 as well as GIRK, which is associated with potential cardiovascular adverse reactions. Its superior safety and PK/PD profiles have been demonstrated in the Phase I clinical trial. Although not a head-to-head study, in the Phase I clinical trial, the biological efficacy of TT-01688 is equal to or better than that of ozanimod and etrasimod, TT-01688 is well-tolerated with all the AEs being mild or moderate in severity in the Phase I clinical trial in healthy adult subjects.

In-licensed from LG Chem, we have the exclusive rights to develop, manufacture and commercialize this product in Greater China. LG Chem has completed Phase I studies of TT-01688 in healthy subjects in South Korea. We have initiated a Phase Ib clinical trial of TT-01688 for the treatment of UC in May 2022 and a Phase II clinical trial of TT-01688 for the treatment of AD in September 2022 in China.

- TT-00920 is an internally discovered and developed, potential first-in-class, highly selective oral PDE9 inhibitor, targeting chronic heart failure. According to Frost & Sullivan, the prevalence of heart failure has been steadily increasing, reaching approximately 32.4 million globally and 12.5 million in China in 2023. Based on left ventricular ejection fraction, heart failure is classified into HFpEF and HFrEF, each with unique pathophysiology. On the one hand, although there has been significant advancement in the research and development of therapies for HFrEF, there is still a need for innovative drugs to further improve clinical efficacy. On the other hand, the pathogenesis of HFpEF remains unclear. Although the FDA approved entresto and sotagliflozin (a SGLT2 inhibitor functions through a different mechanism of action than TT-00920) for HFpEF, there is still an unmet need for HFpEF treatment.

Compared to traditional drugs, which are neurohormonal modulators with few directly targeting myocardial cells to improve cardiac remodeling, TT-00920 as a selective PDE9 inhibitor acts directly on myocardial cells, activating the endogenous protective NP/cGMP signal in the heart. Furthermore, its unique mechanism of action may synergize with existing treatment methods to form an improved treatment regimen for HFpEF and HFrEF with superior efficacy. Preclinical studies have shown that TT-00920 restored cardiac NP/cGMP signaling, significantly enhanced cardiac function, and reversed ventricular remodeling in heart failure. In addition, compared to monotherapy, TT-00920 in combination with valsartan (an angiotensin receptor antagonist) demonstrated superior efficacy, suggesting that TT-00920 may synergize with existing treatments for heart failure.

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The safety of PDE9 inhibitors has been widely validated for treating CNS diseases. Compared to these CNS-penetrant PDE9 inhibitors, TT-00920 exhibited low CNS exposure and high cardiac distribution, favoring the treatment of heart failure and avoiding CNS adverse reactions. In the completed Phase I trials in healthy subjects in China and the U.S., TT-00920 was well tolerated, and demonstrated favorable pharmacokinetic properties and anticipated biomarker changes.

Insightful Drug R&D Life Cycle Driven by “ACE” Approach

Backed by our experienced management team, we have successfully advanced six pipeline products into the clinical stage. Among them, Tinengotinib, as a molecule without any referenceable development path, was rapidly developed into pivotal clinical stage in China and the U.S. within seven years since its conception. These exemplified our innovation acumen, and highly efficient and cost-effective R&D capabilities.

We consistently adopt our proprietary ACE optimization approaches to efficiently optimize the drug research and development process for each asset to maximize their therapeutic potential as well as clinical and commercial value. The following are the characteristics of our “ACE” optimization techniques.

- Adaptive, focusing on clinically meaningful drug differentiation. Through robust biological science-driven discovery capabilities, we carefully select and evaluate potential targets with solid biological mechanisms and strong disease link. Through competitive landscape analysis, we identify key limitations and deficiencies imposed by existing drugs, and establish differentiated molecule to proactively take measures at each stage of preclinical and clinical design to ensure future products are highly competitive in their respective fields. This allows us to identify differentiated compounds with potential competitive advantages rapidly. Using Tinengotinib as an example, during the molecule screening process, our goal was to identify a potent compound targeting key FGFR kinase domain mutations. By developing a set of internally designed biological assays for screening compound scaffolds, we successfully identified a novel scaffold, which ultimately led to the discovery of Tinengotinib.
- Comprehensive, focusing on high quality drug properties. While developing drug candidates with differentiated profile, we also recognize the importance to improve their druggability. We have developed a comprehensive list of drug parameters to select a final drug candidate with a most desirable drug profile. Internally, a number of parameters are used to evaluate drug candidates, including those pertaining to potency, selectivity, bioavailability, safety and PK/PD profiles. These comprehensive evaluations can help us better understand the nature of each drug candidate, boosting the likelihood of clinical development success.

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- Expandable, focusing on indication expansions. We strategically tailor our drug candidates to expand into new indications. Such strategy is accomplished mainly through two routes. First is to leverage our R&D system and our in-depth understanding of mechanisms of action of candidates, their potential targeted patient population, and the unmet medical needs in the relevant treatment field to develop innovative drug candidates with multi-potential to address clinical needs in a number of treatment fields. Second is to further explore our drug candidates’ potential in combination with existing treatment to fully capture their market opportunities.

Our innovative pipeline is nurtured by our full-integrated end-to-end R&D system, which is established through the discovery, accumulation, application and verification of our R&D technology. Our R&D system is capable of performing key R&D steps ranging from early-stage target identification and mechanism of action verification, molecular discovery and optimization, to late-stage clinical development and translational medicine research. Our fully integrated R&D platform integrates all the necessary capabilities to streamline our target-to-market timeline. These capabilities will be housed in four main functional units: drug discovery, clinical development, CMC and regulatory affairs. The platform fostered our core competitiveness of designing highly differentiated molecules *de novo* based on the structure-activity relationship between the drug and its targets, and achieving a two-way research cycle of “Bench to Bed” and “Bed to Bench”.

Strong Global Capabilities Covering R&D, Regulatory Affairs and Business Development

We adopt a global R&D strategy for developing our pipeline products, with many in-house developed pipelines advancing clinical trials in both China and the U.S. We excel in integrating international resources. We have a capable regulatory affairs team, possessing extensive knowledge and experience in communications with the NMPA, the FDA, the EMA and other regulatory authorities. As of the Latest Practicable Date, we have received clearance from the NMPA, the FDA, the MFDS, the MHRA, the EMA and the TFDA to initiate pivotal/registrational clinical trials of Tinengotinib for CCA. We are currently conducting a multi-regional registrational Phase III clinical trial across the U.S., South Korea, United Kingdom, eight countries in the EU and Taiwan. We are also conducting a pivotal Phase II trial in China under an accelerated approval protocol.

As Tinengotinib is an innovative multi-indication product, with innovative and unique mechanisms of action across multiple indications, top international principal investigators reputed in the study of relevant indications have been attracted and served as principal investigators of Tinengotinib. For example, we collaborate with a few world-renowned labs in the U.S. to further investigate the mechanism of actions of Tinengotinib in prostate cancer, and advance clinical research in the relevant realm. Furthermore, the research results related to Tinengotinib have been published or presented orally at major international medical conferences such as the American Society of Clinical Oncology, the European Society for

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Medical Oncology, the San Antonio Breast Cancer Symposium, and American Association for Cancer Research. As of the Latest Practicable Date, we have published over 25 articles, abstract or posters in influential international journals or conferences.

We have built a global network and value-creating strategic partnerships and collaborations. Our experience and capabilities in drug discovery, research and development, and business development enable us to build partnerships and collaborate with multinational corporations and domestic-leading biopharmaceutical companies, including LG Chem, Roche, Teijin, and EA Pharma. Our partnerships cover various business collaboration models, including clinical collaboration, joint research and development, and in-licensing arrangement. All of these collaborations are strategy-driven to maximize the value of the assets.

- Clinical collaboration. In 2021, we entered into a collaboration agreement with Roche to explore and maximize the potential value of the combination of Tinengotinib and atezolizumab for patients with BTC in China. We view such collaboration with a global leading multinational pharmaceutical company as a convincing testament to our strong R&D capabilities.
- Joint research and development. In 2020, we entered into two strategic collaboration agreements with Teijin for joint research and development of innovative drugs in the target fields of oncology and inflammatory diseases. In 2023, we entered a collaboration agreement with EA Pharma for joint research of a novel target for inflammatory and metabolic diseases. We believe our collaborations with Teijin and EA Pharma enable us to gain access to new technology, accelerate the R&D of new programs and extend our reach to the overseas market.
- In-licensing arrangement. We have established an excellent track record of in-licensing deals and patent acquisitions to enrich our focused portfolio. In April 2021, we in-licensed TT-01688 from LG Chem to develop and commercialize the novel S1P1 modulator in Greater China, which brought us a clinical stage, potentially best-in-class asset with potentially multiple indications in our interested areas.

We aim to maximize the value of our company through global partnerships. We gain access to materials generated by our partners outside China to complement our international development efforts. We work closely with our partners in clinical development, and share resource and data to expedite clinical development, the regulatory process and market access for our products globally. We intend to continue growing these collaborations and leveraging the commercialization capabilities and distribution channels our strategic partners offer to bring our products to market effectively and efficiently.

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Management Team with Rich Industry Experience and Strong Execution Capabilities

We have assembled a stable management team with extensive experience in both multinational and Chinese pharmaceutical companies. Our management team has an average of more than 15 years of industry experience and we have a proven track record of drug innovation. Since inception, our management team has been working together, bringing in synergistic and complementary expertise that covers the R&D process, spanning discovery, translational research, clinical development, regulatory affairs and business development. We believe that our diverse experience and collaborative culture are largely responsible for the continued success of our business and innovation.

Dr. Frank Wu, our founder, Chairman and CEO, has over 27 years of science and leadership experience in biopharmaceutical companies. Before founding our Company, Dr. Wu was the general manager of Shandong XuanZhu Pharmaceutical. He has more than ten years of research leadership experience at Boehringer Ingelheim Pharmaceuticals Inc. and Guilford Pharmaceuticals Inc. He was a former member of the prestige American Chemistry Society Division of Medicinal Chemistry long range planning committee.

Mr. Wu Di is our executive director and vice president of strategy and business development. He brings to us a wealth of drug discovery and business development experience in the industry. He has over 16 years of experience in the biopharmaceutical industry across the U.S. and China, with prior experience in Boehringer Ingelheim Pharmaceuticals Inc. He graduated from Stern Business School of New York University.

Dr. Fan Jing is our chief medical officer. She brings to us over 20 years of experience in clinical development of oncology drugs. Previously held positions at internationally renowned multinational pharmaceutical companies such as GlaxoSmithKline, Bristol Myers Squibb Company, Boehringer-Ingelheim, and AstraZeneca.

Ms. Cui Songxi is our vice president of operations. She has over 25 years of rich experience in government, public administration, state-owned asset management and multinational JV companies such as Nanjing Sharp Electronics Co., Ltd and Nanjing Putian Toshiba Communication Co., Ltd.

Dr. Peng Peng is our vice president of project management. He has over 15 years of rich experience in drug discovery and development, toxicology and project management, with a focus on oncology. Prior to joining us, he had extensive experience in innovative drug research and development in biotech companies such as Crown Bioscience Technology (Beijing) Co., Ltd and Shandong XuanZhu Pharmaceutical.

Dr. Sheng Zejuan is our vice president of biology. She has more than 15 years of industry experience in drug research and discovery in the U.S. and China. She has a wealth of drug discovery experience in multiple therapeutic areas, including immunology and neuroscience. She previously worked for Genentech Inc. She obtained her doctor’s degree from University of California, Berkeley.

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Dr. Sun Caixia is our executive director of clinical development. She has over 10 years of experience in clinical development. Dr. Sun used to serve in various senior positions focusing on innovative drug clinical research in pharmaceutical companies. She holds a medical doctorate degree in internal medicine from the medical school of Nanjing University.

Ms. Feng Jie is our secretary of the board. She has over 13 years of experience in investor relations management, financing, and corporate governance. Ms. Feng formerly served as a joint company secretary of Simcere Pharmaceutical.

OUR STRATEGIES

Advance Clinical Trials of Our Drug Candidates

We will continue to execute our global clinical development strategy, leveraging the advantage of efficient regulatory approval pathways and large patient populations in the relevant countries and regions to maximize trial efficiency and fully exploit the global potential of our drug candidates.

Advance Registrational Trial of Tinengotinib for Commercialization

We have implemented and will continue implementing a comprehensive clinical development strategy for our Core Product Tinengotinib, to fully explore its potentials.

- We are conducting a multi-centered, controlled, open-label, global Phase III registrational trial in CCA across the U.S., South Korea, United Kingdom, eight countries in the EU and Taiwan. We plan to complete patient enrollment of the Phase III registrational trial in the second half of 2026. In addition to the global registrational clinical trial, we are conducting an open-label, single-arm pivotal Phase II trial in China in CCA. We plan to complete this trial in the second half of 2025, and then submit the NDA to the NMPA for conditional marketing approval.
- In addition to multiple clinical trials we have initiated to evaluate the safety and efficacy of Tinengotinib monotherapy in solid tumors, with mCRPC being one of the recruited indications, an investigator-initiated Phase Ib/II trial is expected to be initiated at MSKCC in the U.S. to explore the combination therapy of Tinengotinib with NHT for mCRPC. The trial is expected to be initiated in the second half of 2024. In addition, with the IND approval obtained from the NMPA in February 2024, we expect to initiate a Phase II trial of Tinengotinib in combination with NHT in China in the first half of 2025.
- We are also conducting a Phase Ib/II trial in China to explore the combination therapy of Tinengotinib and atezolizumab for BTC and Tinengotinib monotherapy for solid tumors. We plan to complete the trial in the fourth quarter of 2024. In addition, we plan to conduct a Phase II/III clinical trial of Tinengotinib in combination with immunotherapy for BTC in China. We anticipate to initiate the Phase II/III clinical trial in 2025.

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- Furthermore, we are conducting a Phase Ib/II trial of Tinengotinib monotherapy for solid tumors in the U.S. We anticipate to complete the trial in the fourth quarter of 2024.

To expedite the development and potential future commercialization of our Core Product and solidify its market position, we have adopted an international clinical development strategy to focus on both domestic and overseas clinical trials. Leveraging the advantages and strengths of developing in different regions, we can optimize our clinical trial plans to expedite the regulatory approval process globally. We plan to leverage resources from the U.S., the EU, China and other regions to ensure effective patient enrollment. Our plan involves maintaining collaborations with key clinical institutions, clinical departments and lead principal investigators and accessing their abundant clinical trial resources in the U.S. and EU, while also capitalizing on the larger patient pool available in China.

Advance Clinical Development of Other Drug Candidates

In addition to our Core Product, we intend to further advance selected drug candidates. Specifically, we will continue our exploration in the antitumor treatment realm by developing TT-00973 and TT-01488. Additionally, we remain committed to the research and development of drugs for the treatment of inflammatory and cardiometabolic diseases, an area that we have also been focusing on since our inception.

- TT-00973. As of the Latest Practicable date, we were conducting a Phase I trial of TT-00973 in solid tumors in the China. We expect to complete the Phase I trial in the first half of 2026, and initiate a Phase II trial for selected indications in the second half of 2026 in China.
- TT-01488. As of the Latest Practicable Date, we were conducting a Phase I trial of TT-01488 in patients with B-Cell malignancies in the China. Upon the expected to obtain results of the primary endpoint of the Phase I trial in the second half of 2025, we plan to initiate a Phase II trial in the first half of 2026.
- TT-01688. As of the Latest Practicable Date, LG Chem has completed the Phase I clinical trial in healthy subjects in South Korea, which showed that TT-01688 was well tolerated in all doses tested. We are currently conducting a Phase Ib study for UC and a Phase II study for AD in China, which we expect to complete in the second half of 2024.

Establish a Commercial Network for Promoting Tinengotinib Globally

As Tinengotinib indicated for CCA has progressed into the pivotal clinical stage, we have strategically developed distinct commercialization plans for both domestic and international markets to ensure a seamless transition to commercialization upon receiving marketing approval.

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Our domestic strategy will focus on establishing and leveraging our internal marketing team, which will spearhead commercialization efforts. We plan to start with commercialization of Tinengotinib for CCA treatment in China. Patients suffered from this disease often seek medical attention in a handful of hospitals reputed for treatment of CCA. With pemigatinib approved for treating CCA and several potential FGFR inhibitors entering the China market, patients progressed from these existing products will be naturally identified. Considering the targeted patient population of Tinengotinib is readily reachable, we are currently poised to establish an in-house commercial team. We believe that an experienced marketing leader will be critical to success in commercialization. We will soon start the hiring process for a potential marketing director hoping to join us before 2026, who will lead the marketing strategy and future commercialization plan. With profound understanding of mechanisms of action of Tinengotinib, its indications including CCA and mCRPC, and its clinical benefit for the treatment of the disease, we believe that this team will not only bring the drug to patients in urgent need of medication, but also increase the brand awareness of both Tinengotinib and our company.

Our international commercialization approach centered around international collaboration. Specifically, we look forward to collaborating with world-leading pharmaceutical companies with abundant marketing resources and deep root in local region to maximize the value of Tinengotinib overseas. We expect that upon receiving the marketing approvals, the collaborators will assume responsibility for promoting the product in overseas markets and will also continue to assist Tinengotinib in developing subsequent indications, including, mCRPC, breast cancer, and BTC.

Continue to Execute Our Global Strategy via Broad and Diversified Collaboration

In furtherance of our global strategy, we may seek collaboration opportunities from time to time. Over the past years, we have collaborated with global and regional pharmaceutical or biotech companies to complement and consolidate our research and development capabilities. We believe collaboration and partnerships have been and will continue to be critical sources of drug innovation and effective strategies for exploiting the global market. Therefore, we intend to further enrich our pipeline through a combination of internal discovery and external business development efforts.

We plan to continue to seek potential out-licensing opportunities and collaborate with global and domestic partners to develop drug candidates to maximize the commercial value of our products. In addition, we may further collaborate with world-leading pharmaceutical companies or license-in promising drug candidates. Furthermore, we intend to maximize our global market potentials by leveraging our network and promoting our connections with renowned domestic and overseas academic institutions. Based on our existing relationship established in the U.S., China, the EU, Japan and South Korea, we will further explore business opportunities in global major markets. We are exploring new modes of research and business collaboration and plan to integrate ourselves more deeply into the global market based on our profound market insight.

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Continuously Attract, Retain and Incentivize Talent of High Quality and Diversity

We place a high priority on R&D talent recruitment. We aim to build a highly talented R&D team with an interdisciplinary background and strong expertise. To fully support our continued growth, we will continue to invest in attracting and retaining top talent in various aspects of our operations worldwide, including drug discovery, clinical development, regulatory affairs, CMC, and sales and marketing.

With the commercialization of our products and expansion to the global market, we will further develop a team with a global vision, diverse background, and varied expertise to meet our different operational requirements and execute different regional development strategies. We will also pursue strategies to retain talent globally by implementing an incentive plan to align their long-term interests with ours.

OUR PRODUCT PIPELINE

Since our inception, we have adopted and executed our strategic business model of a combination of internal development and global cooperation on innovative and differentiated biopharmaceutical products. Leveraging our strong drug discovery and development capabilities, we have strategically discovered and developed a pipeline of three drug candidates focused on oncology diseases and another four drug candidates focused on inflammatory and cardiovascular diseases, with a total of six assets at the clinical stage. We aspire to become a global leader in developing, manufacturing and commercializing innovative, next-generation and differentiated small molecule therapeutic drug candidates, addressing critical medical needs for patients globally.

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The following chart illustrates our pipeline and summarizes the development status of our selected clinical-stage and preclinical stage drug candidates as of the Latest Practicable Date:

Drug Candidate	Target/Mechanism	Indication	Mono/Combo	Clinical Stage					Expected Upcoming Milestone	Rights Region
				Preclinical	IND Enabling	Phase I	Phase II	Pivotal Phase II/Phase III		
Timegotinib (TT-00420) ★ Unique MTK (FGFR/VEGFR/ JAK/Aurora)	CCA ¹		Mono	China					Complete the trial in 2H 2025	Global
				MRCT ³					Complete patient enrollment in 2H 2026	
	mCRPC		Mono	U.S. ² , China ³					Complete the trial in Q4 2024	Global
				U.S. ⁴ , China					Initiate the trial in 2H 2024 (US)/ 1H 2025 (China)	
	HER2– breast cancer		Mono	U.S. ² , China ³					Complete the trial in Q4 2024	Global
				U.S. ² , China ³					Clinical timeline TBD	
	BTC		Combo (PD-L1)	China ³					Complete the trial in Q4 2024	Global
				U.S. ² , China ³					Complete the trial in Q4 2024	
	Pan-FGFR solid tumor		Mono	U.S. ² , China ³					Complete the trial in Q4 2024	Global
				China					Complete the trial in 1H 2026	
TT-00973	AXL/FLT3	Solid tumor	Mono	U.S., China					Obtain results from primary endpoint in 2H 2025	Global
TT-01488	Reversible BTK	CLL/MCL/WM	Mono	U.S., China					Complete the trial in 2H 2024	Global
TT-01688	SIP1	UC	Mono	China					Complete the trial in 2H 2024	Greater China ⁶
TT-00920	PDE9	AD	Mono	U.S., China					Complete the trial in 2H 2024	Global
TT-01025	VAP-1	NASH	Mono	U.S., China					Clinical timeline TBD	Global
TT-02332	NLRP3	Metabolic/Inflammation	Mono	U.S., China					Clinical timeline TBD	Global
				IND submission in the first half of 2025					Global	

★ Core Product

Abbreviations: CCA=cholangiocarcinoma; mCRPC=metastatic castration-resistant prostate cancer; HER2– breast cancer=human epidermal growth factor receptor 2 negative breast cancer; BTC=biliary tract carcinoma; CLL=chronic lymphocytic leukemia; NHT=chronic lymphocytic leukemia; NHT=chronic lymphocytic leukemia; NHT=chronic lymphocytic leukemia; WM=mantle-cell lymphoma; MCL=mantle-cell lymphoma; WM=waldenström’s macroglobulinemia; HF=heart failure, UC=ulcerative colitis; AD=atopic dermatitis; NASH=nonalcoholic steatohepatitis; MRCT=multi-regional clinical trial; TBD=to be determined; Q4=fourth quarter; 1H=first half; 2H=second half.

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Notes:

1. We received Breakthrough Therapy Designation for CCA from the NMPPA in July 2023, and received Fast-Track Designation for CCA from the FDA in August 2021.
2. We are exploring these indications under the same trial protocol of one clinical trial (NCT04742959) conducted in the U.S.
3. We are exploring these indications under the same trial protocol of one clinical trial (CTR20212760) conducted in China.
4. This trial is an investigator-initiated trial.
5. We are currently conducting a Phase III multi-regional clinical trial (NCT05948475) of Tinengotinib monotherapy for the treatment of CCA across the U.S., South Korea, United Kingdom, eight countries in the EU and Taiwan.
6. We in-licensed exclusive rights from LG Chem to use, develop, manufacture, commercialize and otherwise exploit TT-01688 in Greater China. For more information, see “– Collaboration and License Agreements – License-in Agreement with LG Chem.”

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CORE PRODUCT: TINENGOTINIB – POTENTIAL FIRST-IN-CLASS, UNIQUE MTK INHIBITOR

Overview

Tinengotinib, our Core Product, is a registrational clinical-stage, internally discovered and developed, potential first-in-class, unique MTK inhibitor targeting drug-resistant, relapsed or refractory cancers. In clinical trials, Tinengotinib monotherapy study has demonstrated favorable tolerability and promising response in patients with advanced solid tumors who have no available standard therapeutic treatment options. It was granted Breakthrough Therapy Designation by the NMPA and Fast-Track Designation by the FDA for the treatment of CCA. It was also granted Orphan Drug Designation by both the FDA for the treatment of CCA and by EMA for the treatment of BTC. In September 2018 and February 2019, we received IND approvals for conducting clinical trials of Tinengotinib capsule in solid tumors from the FDA and the NMPA, respectively. In November 2020 and May 2021, we received IND approvals for conducting clinical trials of Tinengotinib tablet in solid tumors from the FDA and the NMPA, respectively. As of the Latest Practicable Date, we had started several advanced clinical studies globally, including a multi-regional registrational Phase III clinical trial for CCA following FDA, MFDS, MHRA, EMA and TFDA’s regulatory clearance, and a pivotal Phase II clinical trial for CCA following the NMPA’s regulatory clearance. Specifically, we enrolled the first patient in the Phase III study and the pivotal Phase II study for the treatment of CCA in December 2023 in the U.S. and November 2023 in China, and these trials are under active patient enrollment.

Mechanism of Action

Tinengotinib is a unique MTK inhibitor that targets three key pathways including FGFR/VEGFR, JAK and Aurora kinases. It can be used as a precision therapy for FGFR-driven cancers, such as FGFR altered CCA, pan-FGFR solid tumor, and as a novel therapy for a broad range of cancer types, including prostate cancer, HER2– breast cancer and BTC.

FGFR altered CCA and solid tumors

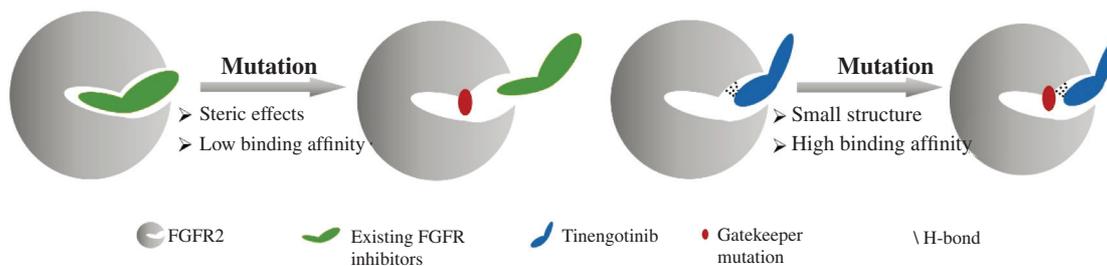
The oncogenesis and development of CCA involves multiple molecular pathways altered through for example genetic mutations, chromosomal changes, aberrant epigenetic landscapes, microRNA dysregulation. FGFR fusions resulting from chromosomal rearrangements are among the most common events considered to contribute to the development of CCA. For patients with unresectable advanced or metastatic CCA that has relapsed after prior systemic chemotherapy, several FGFR inhibitors, including pemigatinib from Incyte Corporation and futibatinib from Taiho Pharmaceutical, have been approved by the FDA for the treatment of CCA in 2020 and 2022, respectively, and pemigatinib also has been approved by the NMPA for the treatment of CCA in 2022.

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Although responding to FGFR inhibitors initially, CCA patients with FGFR2 fusions will eventually develop drug resistance, and there is a global lack of effective therapies. In CCA patients who experienced disease progression after FGFR inhibitors treatment, most of them gain drug resistance due to polyclonal mutations of FGFR. Therefore, the next-generation FGFR inhibitors ideally possess the ability to inhibit all these mutations in order to overcome the resistance. Nevertheless, due to the complexity of drug development, several U.S. biotechnology companies withdrew from clinical trials or altered the course of their clinical development efforts, underscoring the urgency for innovative treatments in this challenging clinical landscape.

Tinengotinib, distinguished by its innovative mechanism and robust clinical evidence, is poised to address this market gap and stands as a global frontrunner in the treatment of advanced or metastatic CCA. Through high resolution x-ray diffraction of co-crystallization, we observed a very unique binding mode of Tinengotinib to FGFR2 protein with two distinct features: (a) Due to its small size, Tinengotinib does not reach the hydrophobic pocket like other FGFR inhibitors. It is positioned away from the pocket so that there is no steric hindrance from acquired gatekeeper mutation residues in the kinase domain; and (b) Tinengotinib forms three hydrogen bonds with the backbone residues in the hinge region, leading to high affinity and long-lasting binding.

Binding mechanism of Tinengotinib vs. existing FGFR inhibitors



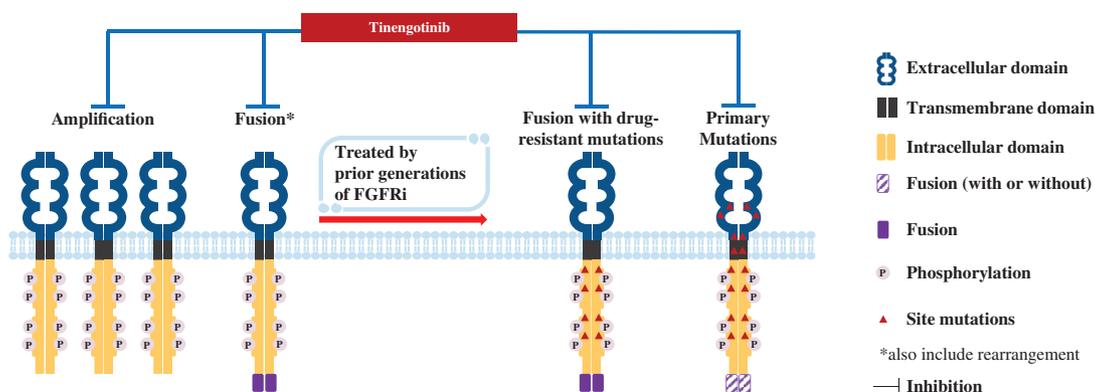
Source: Company data

Therefore, Tinengotinib binds to FGFR 1/2/3 kinase domain through a unique binding mode other than existing FGFR inhibitors due to its novel chemical scaffold. It does not interact with the hydrophobic pocket deeper within the FGFR2 kinase domain, making its binding to the FGFR kinase domain less likely to be affected by mutations of amino acids prone to contribute to acquired resistance. This enables Tinengotinib to overcome the acquired resistance in CCA patients who progressed on prior FGFR inhibitors, addressing a significant unmet medical need due to the lack of effective treatment options.

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The unique binding mode enables Tinengotinib to strongly inhibit more than 10 clinically identified FGFR2 acquired mutations as demonstrated *in vitro* kinase assays, including gatekeeper mutations, molecular brake mutations and others. The molecular docking results show that Tinengotinib have similar binding mode to FGFR1 and FGFR3, resulting in excellent potency to FGFR1/3 mutations as demonstrated *in vitro* kinase assays. Tinengotinib is the world's first and the only investigational drug that has entered registrational stage to treat FGFR inhibitor relapsed or refractory CCA patients.

Tinengotinib targets various FGFR alterations



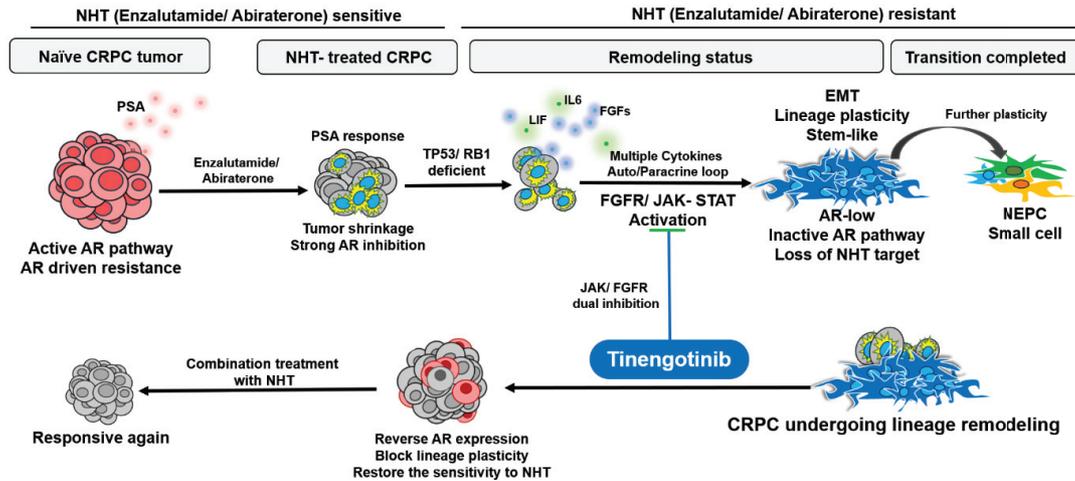
Source: Company data

mCRPC

According to the research from Dr. Charles L. Sawyers, chair of Human Oncology and Pathogenesis Program in MSKCC and lead developer in mCRPC treatments enzalutamide and apalutamide, and his team, published on Science in 2017, hormone-sensitive prostate cancer cells become resistant to hormone therapy due to a gradual loss of androgen receptor expression and luminal molecular marker expression and gain of basal, mesenchymal and stem-like gene expression signatures, ultimately developing into neuroendocrine prostate cancer. This process is known as lineage plasticity, a crucial resistance mechanism for enzalutamide/abiraterone-treated prostate cancer. Blocking lineage plasticity has become a focal point in the treatment of mCRPC. A following study from Dr. Charles L. Sawyers' lab also revealed a strong correlation between the activation and upregulation of the FGFR/JAK pathway and the driving mechanism behind prostate cancer lineage plasticity. Simultaneous inhibition of FGFR and JAK pathways could potentially reverse lineage plasticity and restore AR expression. And these results were published on Science in 2022.

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MoA of Tinengotinib for the Treatment of mCRPC



→ Stimulation/Induction/Activation; —| Inhibition

Abbreviations: NHT= novel hormone therapy; CRPC= castration-resistant prostate cancer; PSA= prostate specific antigen; AR= androgen receptor; EMT= epithelial–mesenchymal transition.

Source: Company data

Tinengotinib is the world’s first and the only investigational drug capable of simultaneously and effectively inhibiting the FGFR/JAK pathway with clinical evidence in the treatment of mCRPC. By inhibiting the FGFR/JAK signaling pathway, Tinengotinib can disrupt and reverse the process of lineage plasticity in prostate cancer, restoring the expression of androgen receptors and sensitivity to novel hormonal treatments in mCRPC. This novel and unique mechanism positions Tinengotinib as a highly promising innovative drug for treating mCRPC.

HER2– Breast Cancer

A number of putative mechanisms that confer resistance to endocrine therapy and CDK4/6 inhibition have been identified for HER2– breast cancer, including loss of hormone receptor expression and conversion to TNBC, retinoblastoma gene RB1 loss, and FGFR1/2 and MYC amplification.

Loss of RB1 is common in treatment-refractory HER2– breast cancer. It leads to a hyperactivated or “primed” spindle-assembly checkpoint, which highly depend on Aurora A for mitotic exit and survival, and a synthetic lethal interaction between the loss of RB1 and Aurora A inhibition has been identified in preclinical cancer models. Alisertib, a selective Aurora A kinase inhibitor, has demonstrated antitumor efficacy in HR+/HER2– metastatic breast cancer patients. Furthermore, the underlying mechanism of MYC-induced resistance to CDK4/6 inhibitors was recently discovered by researchers. It was found that MYC binds to the promoter of E3 ubiquitin ligase KLHL42 and promotes its transcription, which results in RB1 ubiquitination and degradation. In addition, Aurora A and MYC transcriptionally upregulate

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each other through a positive feedback loop, and amplification of both genes often co-exist in the same cancer cell. In our preclinical studies, Tinengotinib suppressed the expression of MYC in breast cancer cell lines, presumably through the inhibition of Aurora A.

Activating FGFR pathway has emerged as a prominent player of acquired resistance to HR+ directed therapy and CDK4/6 inhibitors in breast cancer. In one study, the researchers found that FGFR pathway was altered via genomic alterations in FGFR1, FGFR2, or FGF3 amplifications, or FGFR2 mutations in 40% of post-resistance biopsies from 60 patients with HR+ metastatic breast cancer, and the resistance could be overcome by FGFR inhibition. Currently there is an on-going trial of futibatinib in HER2- advanced breast cancer patients with FGFR alterations.

Taken together, as a potent aurora kinase and FGFR inhibitor that potentially achieves synergistic antitumor effect, Tinengotinib holds great potential to treat HR+/HER2- metastatic breast cancer and transformed TNBC patients.

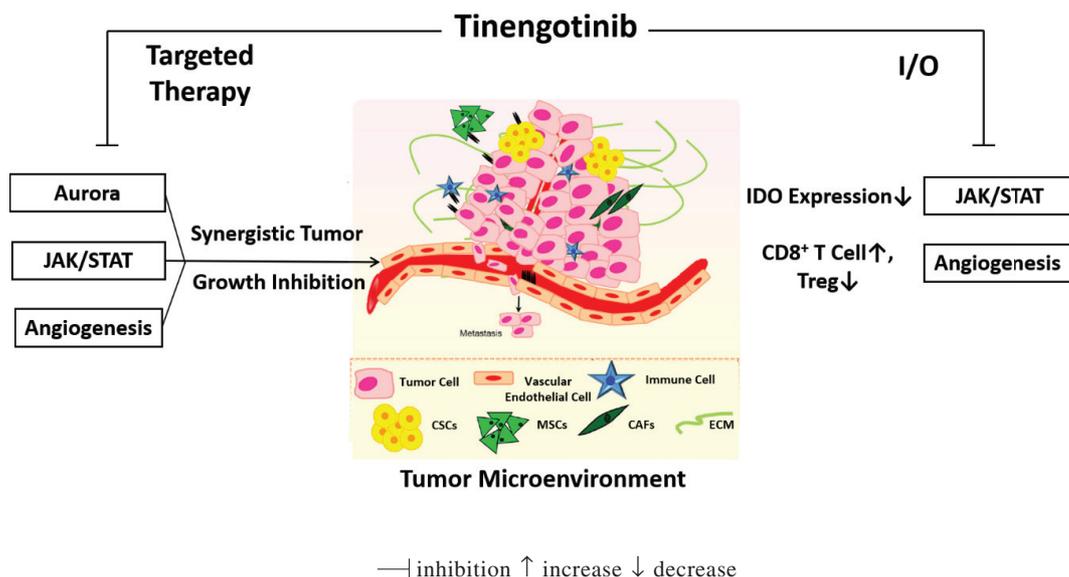
Tinengotinib in Combination with Immune Checkpoint Blockade as a TME Modulator

A recent paradigm shift has repositioned small-molecule kinase inhibitors as both targeted and immune modulators. Tinengotinib is a selective MTK inhibitor. In addition to FGFR1/2/3, it also inhibits VEGFR, JAK and Aurora, and thus could function as a TME modulator, which makes it a promising candidate for the treatment of heterogeneous tumors such as BTC with no clear genomic gene alterations.

Tinengotinib produces significant inhibition of angiogenesis in preclinical models, and reduces expression of CD34, a known vascular endothelial cell biomarker, in tumors in animal models. In the TME, TAMs play an important role in promoting immune suppression and accelerating tumor cell growth, survival, and metastasis. In our preclinical studies, the differentiation of human peripheral blood mononuclear cells to protumorigenic macrophages is completely abolished by Tinengotinib. It has been reported that inhibition of Aurora kinase activates the expression of TH1-type chemokines in TNBC cells. Treatment of TNBC cells with Tinengotinib clearly increases the expression of both TH1 chemokines CXCL10 and CXCL11 in a dose-dependent manner. Finally, Tinengotinib displays enhanced tumor growth inhibition when combined with anti-PD-1 and PD-L1 blockade in preclinical studies, which makes it potentially a promising candidate for combination therapy with immune checkpoint blockade. Therefore, we believe the unique combination of Tinengotinib's target profile represents a novel mechanism of action to improve the efficacy of immune checkpoint blockade in solid tumors.

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The novel mechanisms of Tinengotinib



Abbreviations: I/O=immunotherapy; IDO=Indoleamine 2,3-dioxygenase; Treg=Regulatory T cells; CSCs=cancer stem cells; MDSCs=myeloid-derived suppressor cells; CAFs=cancer-associated fibroblasts; ECM=extracellular matrix.

Source: Company data

Market Opportunity and Competition

Market Opportunity in CCA with FGFR Drug Resistance

According to Frost & Sullivan, CCA has become a serious global public health issue. The number of CCA patients globally increased from approximately 234.9 thousand in 2018 to 280.0 thousand in 2023. CCA is an aggressive type of tumor that can progress rapidly and become fatal due to invasion across all body areas if treatment is not administered at an early stage. Currently, CCA is considered incurable unless fully resected in the early-stage through surgery. CCA is frequently diagnosed at an advanced, unresectable stage because of the late presentation of obvious clinical symptoms of the disease and the lack of effective screening modalities. Surgery including liver transplantation is the primary treatment for eligible patients in all kinds of CCA, facilitated by neo-adjuvant therapy or other pre-operative therapies to obtain surgical eligibility. However, there was a high recurrence rate, perioperative complications and poor patient survival rate among CCA patients treated with surgery and liver transplantation. To be specific, the actual five-year survival rate after the transplantation is approximately 30%. For late-stage CCA with progressed and/or metastatic disease, chemotherapy combination of gemcitabine and cisplatin is presently the first-line treatment. Targeted therapy is viable if the patients are qualified for genetic markers including, but not limited to, FGFR2, NTRK, MSI-H/dMMR and IDH1, which allows for more precise treatment. For more details of CCA treatment and limitations, see “Industry Overview – Small Molecule Oncology Targeted Therapy – Major Indications for Oncology Targeted Therapy — CCA.”

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FGFR alterations (including fusion and rearrangement, point mutation and gene amplification) are observed in 25.2% of CCA patients, and FGFR fusions and rearrangements are observed in 7.4% of CCA patients. As of the Latest Practicable Date, the FDA had approved three FGFR inhibitors for the treatment of CCA, i.e. futibatinib, infigratinib and pemigatinib, and one FGFR inhibitor for the treatment of urothelial cancer, i.e. erdafitinib. In China, only pemigatinib was approved by the NMPA for the treatment of CCA. Nonetheless, the approved FGFR inhibitors are not able to address drug resistance to prior FGFR inhibitors.

On a global scale, as of the Latest Practicable Date, Tinengotinib stood out as the only drug candidate in registrational stage for treating CCA that has progressed on the prior FGFR inhibitor treatment. For details, see “Industry Overview – Small Molecule Oncology Targeted Therapy – Major Indications of MTK Inhibitors – CCA – FGFR Inhibitor – Competitive Landscape.”

Early studies already demonstrated that almost all patients develop acquired drug resistance after receiving treatment of FGFR inhibitors. With the potential efficacy in CCA patients who progressed on prior FGFR inhibitors, we believe that Tinengotinib is able to address the unmet medical need. Currently, all FGFR inhibitors available on the market for CCA do not directly compete with Tinengotinib regarding resistance to FGFR inhibitors. Furthermore, FGFR inhibitors in the developmental stage lack clinical data demonstrating their efficacy in addressing FGFR inhibitor resistance. Consequently, they are also unable to establish a direct competitive relationship with Tinengotinib in terms of FGFR inhibitor drug resistance.

Currently, we have initiated two pivotal/registrational clinical trials to evaluate the potential of Tinengotinib. Specifically, we are performing clinical trials of Tinengotinib as a third-line treatment in CCA patients who have progressed on prior chemotherapy and one FGFR inhibitor. Once the trials are successful, we will be seeking market approval for the treatment of FGFR-altered, chemotherapy- and FGFR inhibitor-refractory/relapsed CCA.

Market Opportunity in mCRPC

CRPC is characterized by disease progression despite ADT or the emergence of new metastases. In CRPC, tumors progress rapidly, have a high likelihood of metastasis, and the median survival time is relatively short, with limited treatment options available. Currently, there is no proven cure for CRPC, and treatments aim only to prolong survival. Endocrine therapy combinations can temporarily slow prostate cancer progression, but typically, patients develop castration resistance within one and half to two years. CRPC is associated with a poor prognosis and diminished quality of life. Historically, the mean survival of CRPC patients was estimated to be 12-18 months, depending on the extent of metastatic disease and the presence of symptoms.

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According to Frost & Sullivan, the number of new cases of mCRPC around the world increased from 176.4 thousand in 2018 to 203.9 thousand in 2023. It is expected to grow to 220.2 thousand in 2026 and further to 238.0 thousand in 2030. In China, the risks of having prostate cancer are increasing. Also, approximately 60% of prostate cancer cases in China are diagnosed in the late stage or occur metastasis at the first diagnosis, severely affecting prognosis. The incidence of mCRPC in China increased from 42.8 thousand in 2018 to 50.5 thousand in 2023. The number is expected to grow to 57.3 thousand in 2026 and further reach 67.1 thousand in 2030.

Enzalutamide and abiraterone, are an important group of first-line treatment for prostate cancer, as known as NHT, and they are also the backbone treatment of current therapies. However, prostate cancer patients will become resistant to these treatments. Currently, there is a lack of an effective small molecular targeted therapy that universally addresses mCRPC patients in the second-line setting. Therefore, innovative therapy for mCRPC is still in urgent need.

Market Opportunity in HER2– Breast Cancer

According to Frost & Sullivan, breast cancer is the most common cancer for women. It can be categorized by different gene expression and receptor status – most commonly, estrogen receptor and progesterone receptor, together referred to as HR, as well as HER2. HR+ means that tumor cells have receptors for the hormones estrogen or progesterone, which can promote the growth of HR+ tumors. HER2+ means that tumor cells make high levels of a protein called HER2/neu, which has been shown to be associated with certain aggressive types of breast cancer. HER2– means the tumor cells make little (IHC scores of 1+ or 2+) to no HER2/neu protein (IHC scores of 0).

According to Frost & Sullivan, the global incidence of HER2– breast cancer increased from 1,671.1 thousand to 1,926.4 thousand between 2018 and 2023. This number is projected to reach 2,099.5 thousand in 2026 and is expected to rise to 2,396.3 thousand in 2030. The incidence of HER2– breast cancer in China rose from 256.9 thousand to 292.1 thousand between 2018 and 2023. It is projected to further increase to 312.2 thousand in 2026 and is anticipated to reach 337.5 thousand in 2030. In current treatment guidelines, the standard first-line treatment for HR+/HER2– breast cancer is endocrine therapy combined with CDK4/6 inhibitors. After disease progression, endocrine therapy combined with other targeted therapy is the standard second-line treatment, but its effectiveness is limited.

As of the Latest Practicable Date, there were five innovative products approved by the FDA for the treatment of HR+/HER2– breast cancer. In China, there were seven innovative products approved by the NMPA for the treatment of HR+/HER2– breast cancer. None of these products were MTK inhibitors. On the global scale, three products under clinical development for the treatment of HR+/HER2– breast cancer, including Tinengotinib, were MTK inhibitors.

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As of the Latest Practicable Date, there was no small molecule targeted drug approved by the FDA or the NMPA for the treatment of TNBC. Globally, eight product candidates under clinical development for the treatment of TNBC, including Tinengotinib, were MTK inhibitors. In China, three product candidates under clinical development for the treatment of TNBC, including Tinengotinib, were MTK inhibitors.

Competitive Advantages

Overview of Tinengotinib’s Potential Indications

Tinengotinib targets three key pathways including FGFR/VEGFR, JAK and Aurora. The unique binding mode with FGFR enables Tinengotinib to overcome polyclonal mutations, rendering it target FGFR-driven cancers, including FGFR altered CCA and pan-FGFR solid tumor, and the distinct combination of the key pathways makes it capable of being efficacious in a broad range of cancer types, including prostate cancer, breast cancer and BTC. For more information regarding the ongoing and planned clinical trials of Tinengotinib, see “Core Product: Tinengotinib – Potential First-in-class, Unique MTK Inhibitor – Summary of Clinical Trials – Overview of Clinical Studies of Tinengotinib.”

FGFR Inhibitor Refractory/Relapsed CCA – Encouraging Efficacy

According to Frost & Sullivan, studies demonstrated that nearly all patients treated with existing FGFR inhibitors ultimately experienced disease progression due to acquired resistance to FGFR inhibitors. Since 2020, several FGFR inhibitors, including pemigatinib from Incyte Corporation, infigratinib from QED (has withdrawn due to strategy consideration) and futibatinib from Taiho Pharmaceutical, have been approved by the FDA for the treatment of CCA, and pemigatinib also received NDA approval from the NMPA for the treatment of CCA in 2022. Most acquired resistance to FGFR inhibitors can be attributed to polyclonal mutations in the FGFR2 kinase domain, such as the gate keeper mutation V564F, the molecular brake mutation N549K, the irreversible inhibitor specific mutation C491S, and a various of other mutations.

The capability of Tinengotinib to inhibit FGFR2, as indicated by IC_{50} values, was tested in *in vitro* kinase assays, composed of wild type FGFR2 and eleven mutated FGFR2 with acquired resistance mutations. According to Frost & Sullivan, *in vitro* potency benchmark standards are typically IC_{50} less than 10 nM in enzyme and cell-based assays. As shown in the table below, all IC_{50} value is less than 2 nM, which indicates Tinengotinib retained high potencies in eleven clinically identified mutations associated with acquired drug resistance to FGFR2 inhibitors. Notably, most of the activities were in the picomolar range.

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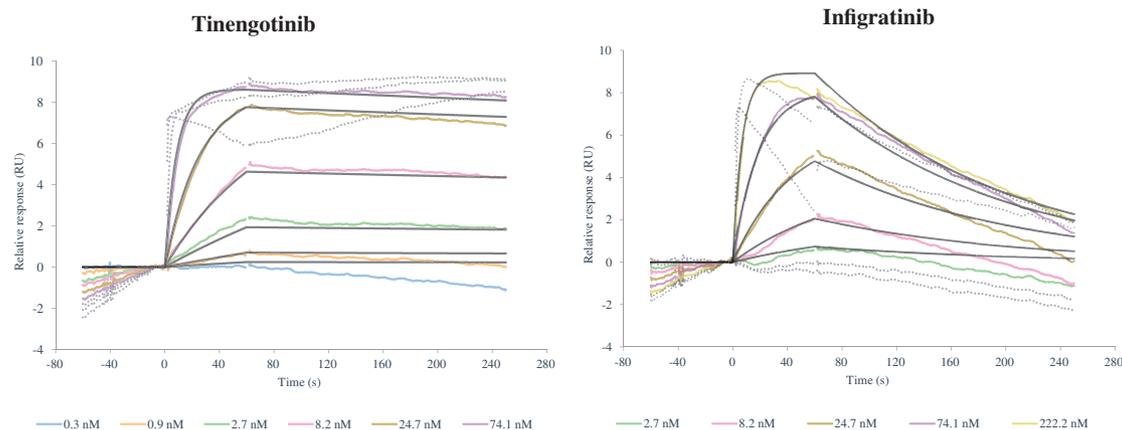
The inhibitory activities of Tinengotinib against main clinically identified acquired resistant mutations in FGFR2

IC ₅₀ , nM	FGFR2	Gate Keeper		Molecular Brake				Others				
	WT	V564F	V564I	N549K	E565A	N549H	K641R	L617V	K659M	K714R	C491F	C491S
Tinengotinib	1.52	0.16	1.43	0.42	1.34	0.04	0.33	0.48	0.35	0.48	0.59	0.7

Source: Company data

Our SPR study demonstrated high binding avidity between Tinengotinib and FGFR2. The binding avidity of two molecules is a measure of the cumulative strength of their binding interactions, which is typically measured and reported as the equilibrium dissociation constant. A smaller dissociation constant, i.e. K_D indicates a greater affinity for binding. In the SPR study, Tinengotinib exhibited a K_D almost two orders of magnitude stronger than infigratinib, the approved selective FGFR1/2/3 inhibitor. Tinengotinib also demonstrated the feature of slow-dissociation from the protein.

SPR analyses of the association and dissociation phase of Tinengotinib and infigratinib with the kinase domain of FGFR2



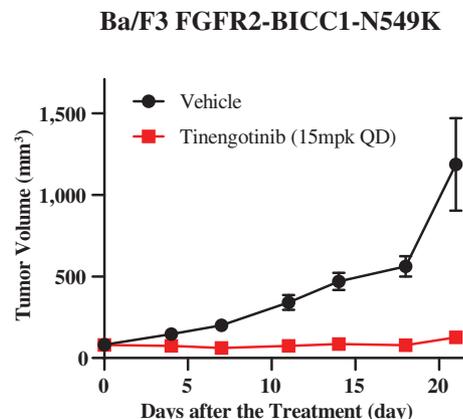
Source: Company data

In addition, Tinengotinib's inhibitory activity against FGFR2 mutations was confirmed in a panel of engineered Ba/F3 cells, in which seven out of 11 clinically identified resistance mutations were introduced into FGFR2-BICC1 to promote IL-3-independent cell proliferation. As shown in the table below, Tinengotinib inhibited all mutations tested. To further assess Tinengotinib's activity against FGFR2 resistance mutations, it was tested *in vivo* in the Ba/F3-FGFR2-BICC1 N549K xenograft models and demonstrated significant antitumor efficacy.

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The growth inhibitory activities of Tinengotinib against a panel of engineered Ba/F3 cells expressing acquired resistant mutations in FGFR2 *in vivo* and *in vitro*

Cell line	Tinengotinib (IC, nM)
Ba/F3-FGFR2-BICC1-N549K	29.2
Ba/F3-FGFR2-BICC1-N549H	18.0
Ba/F3-FGFR2-BICC1-K659N	20.7
Ba/F3-FGFR2-BICC1-E565A	47.5
Ba/F3-FGFR2-BICC1-E565G	88.6
Ba/F3-FGFR2-BICC1-L617M	21.4
Ba/F3-FGFR2-BICC1-V564F	13.9
Ba/F3-FGFR2-BICC1	9.3

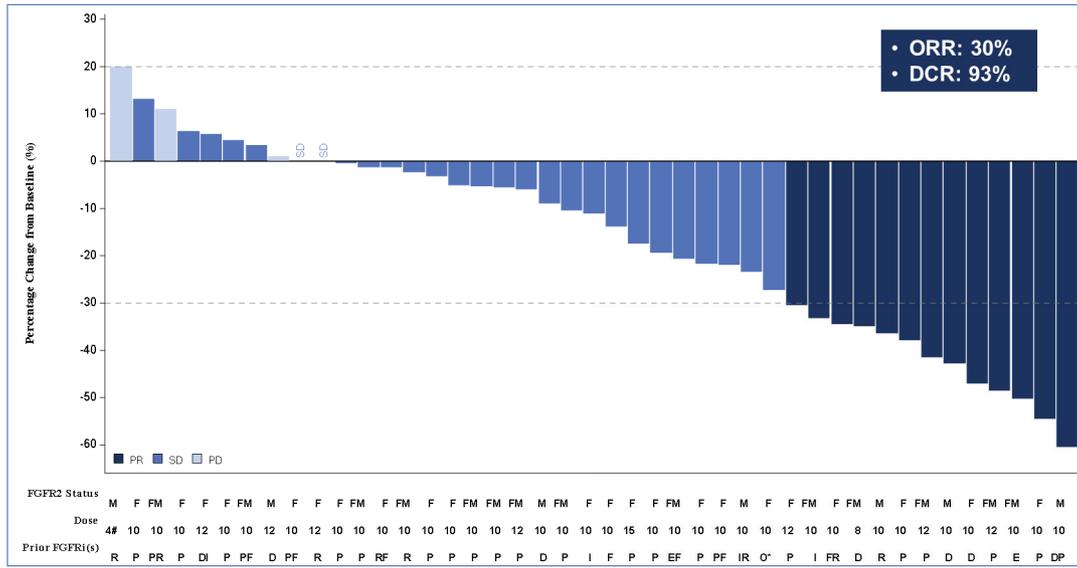


Source: Company data

In a pooled analysis of clinical studies (NCT04919642, NCT04742959 and NCT03654547) in the U.S., as of March 28, 2024, among 43 CCA patients who had progressed on prior FGFR inhibitors, after being treated with Tinengotinib and at least one tumor scan, the results showed that the ORR was 30% and the DCR was 93%. The promising clinical data were also observed in the clinical trial conducted in the China. In China, two of three (66.7%) CCA patients who had progressed on prior FGFR inhibitors were treated with Tinengotinib and achieved PR. As of March 28, 2024, one patient lasted for more than 8 months, the other patient has lasted for 14 months, who is still on treatment. Compared to literature data of chemotherapy, Tinengotinib significantly prolonged the survival of third-line advanced or metastatic CCA patients, demonstrating clear clinical benefits. A Phase III randomized, controlled, global multicenter study (FIRST-308) is now under patient enrollment to further evaluate the efficacy and safety of Tinengotinib versus physician’s choice of chemotherapy in patients with FGFR-altered, chemotherapy and FGFR-inhibitor refractory/relapsed CCA. We are also conducting a pivotal trial in China under an accelerated approval protocol for the treatment of chemotherapy and FGFR-inhibitor refractory/relapsed CCA.

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Waterfall plots of CCA patients (N=43)

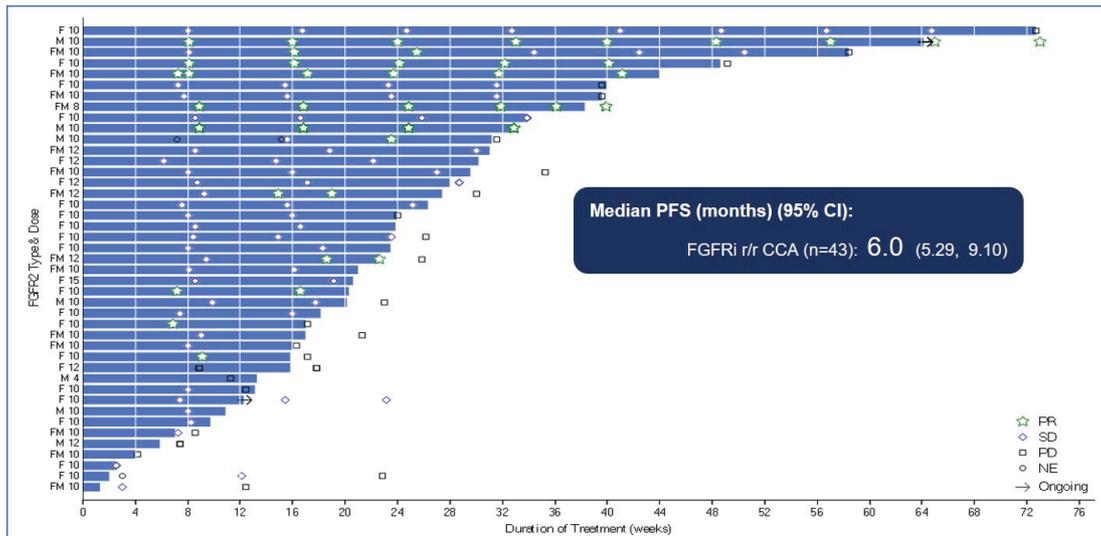


Abbreviations: ORR=objective response rate; DCR=disease control rate; M=mutation; F=fusion/rearrangement; PR=partial response; SD=stable disease; PD=progression disease; P=Pemigatinib; R=RLY-4008; F=Futibatnib; D=Derazantinib; I=Infigratinib; E=Erdafitinib; O*=other investigational FGFRi. #4 mg BID

Source: Company data

Among the 43 evaluable patients, the median PFS was 6.0 months, with the longest observed benefit extending beyond 72 weeks.

Swimmer plots for duration of treatment (FGFR inhibitor relapsed/refractory, N=43)



Abbreviations: M=mutation; F=fusion/rearrangement; PR=partial response; SD=stable disease; PD=progression disease; NE=not evaluable.

Source: Company data

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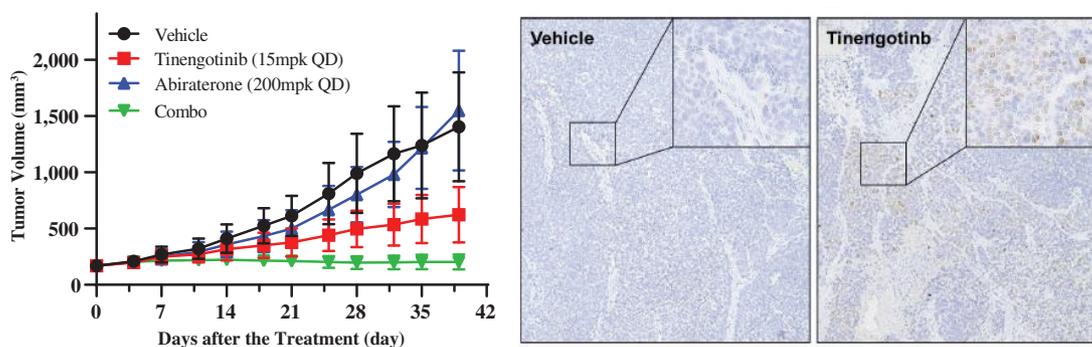
The molecular binding mode of Tinengotinib in FGFR2 kinase domain is in a very different spatial conformation from the prior FGFR inhibitors. The binding mode of Tinengotinib positions it away from acquired mutations residues in the kinase domain. Tinengotinib forms three hydrogen bonds with the backbone residues in the hinge region, leading to high affinity and long-lasting binding. Therefore, Tinengotinib has the potential to be a next-generation FGFR inhibitor to overcome these clinically detected acquired mutations.

mCRPC – Promising Antitumor Efficacy

In addition to CCA, Tinengotinib also demonstrated efficacy in mCRPC treatment. The potential mechanism of action was published by Dr. Charles L. Sawyer and his team at MSKCC. Charles Sawyer Laboratory revealed that neuroendocrine trans-differentiation, also known as lineage plasticity, of hormone-sensitive prostate cancer cells is a pivotal resistance mechanism to enzalutamide/abiraterone. This trans-differentiation is closely linked to the upregulation of the FGFR/JAK pathway. Concomitant inhibition of the FGFR and JAK pathways has the potential to revert neuroendocrine cells to their original hormone-sensitive state. According to Frost & Sullivan, as of the Latest Practicable Date, Tinengotinib stands as the sole drug worldwide capable of concurrently inhibiting the FGFR/JAK pathway with clinical evidence in mCRPC patients.

In our preclinical study in abiraterone-resistant androgen receptor-loss mCRPC PDX model, treatment with Tinengotinib restored the sensitivity to abiraterone by lineage plasticity remodeling. In the study, we investigated Tinengotinib monotherapy (15mg/kg QD) and its combination with abiraterone (15mg/kg Tinengotinib+200mg/kg abiraterone QD) in comparison with vehicle and abiraterone monotherapy (200mg/kg QD). As anticipated, the results showed comparable tumor growth in mice treated with vehicle and abiraterone monotherapy, indicating the tumor is abiraterone resistant. Tinengotinib monotherapy showed significant antitumor effect, while its combination with abiraterone showed a synergistic antitumor effect. Autopsy results further verified the mechanism of action. As shown in the below right figure, intratumoral AR expression was detected by immunohistochemistry, which was dyed in brown. The immunohistochemistry analysis revealed that the vehicle group showed no AR expression and dominance of neuroendocrine biomarkers, while after Tinengotinib monotherapy treatment, tumor regained AR expression.

The *in vivo* growth inhibitory activities of Tinengotinib against heavily-treated mCRPC with intratumoral AR recovery

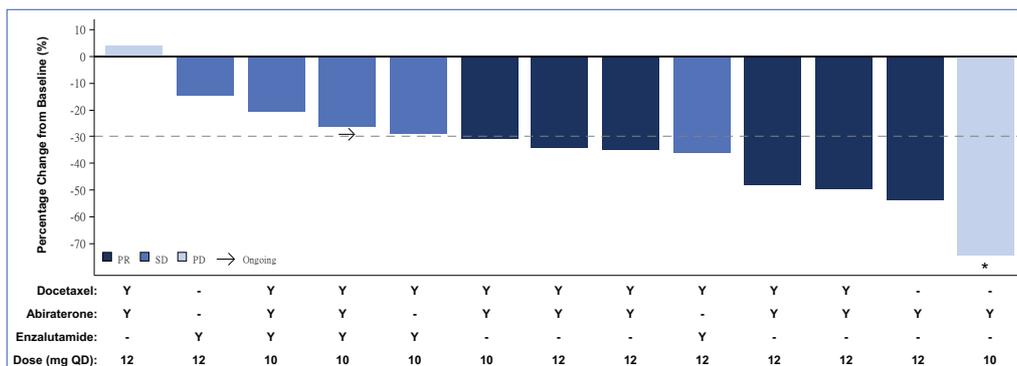


Source: Company data

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Furthermore, the promising efficacy has been verified in our clinical trials. In a pooled analysis of patients in the U.S. and China as of August 28, 2023, Tinengotinib monotherapy has shown encouraging antitumor efficacy in heavily pre-treated mCRPC patients. According to our Phase I/II clinical trials of Tinengotinib as monotherapy in 22 efficacy-evaluable heavily pre-treated mCRPC patients who had been pre-treated with hormonal treatments, the preliminary efficacy observed in 13 patients with measurable lesions was promising, showing an ORR of 46% and a DCR of 85%. As delineated in the waterfall plot below, six achieved PR, five achieved SD, and more than 90% of patients had tumor size reduction and over 60% of patients experienced a more than 30% reduction in tumor volume. The encouraging preliminary efficacy warranted further investigation, and the Phase Ib/II IIT clinical trial of Tinengotinib in combination with novel hormonal treatments is set to commence in collaboration with MSKCC in the U.S. In addition, we also received the IND approval from NMPA to conduct a Phase II clinical trial of Tinengotinib in combination with NHT in February 2024.

Waterfall plots of mCRPC patients (N=13)



Abbreviations: PR=partial response; SD=stable disease; PD=progression disease.

Notes:

*: non-target lesions worsened; new liver lesions appeared.

Y: the patient was treated with docetaxel/abiraterone/enzalutamide before being treated with tinengotinib.

-: the patient did not receive docetaxel/abiraterone/enzalutamide before being treated with tinengotinib.

Source: Company data

Heterogeneous tumors – high potential as monotherapy or as a backbone of combination

As a unique MTK inhibitor, Tinengotinib inhibits FGFR/VEGFR, JAK and Aurora kinases, which are involved in tumor cell proliferation, survival, migration, angiogenesis and immuno-oncology. The unique combination of Tinengotinib’s target profile and mechanism of action allows it to effectively treat patients with highly heterogeneous tumors, such as HER2–breast cancer and in combination with PD-1/PD-L1 inhibitor(s) to treat BTC.

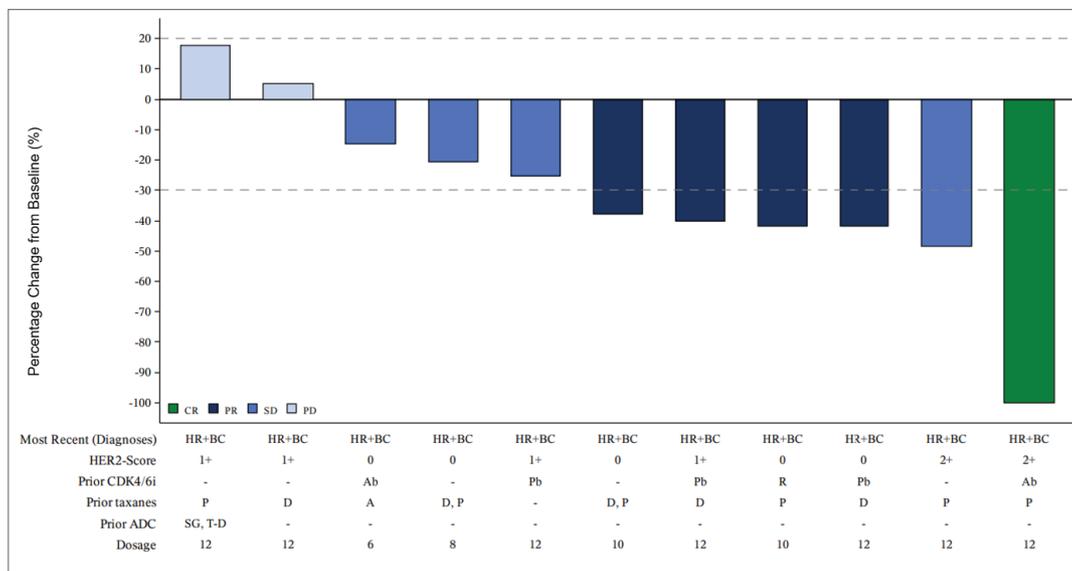
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HR+/HER2-, a predominant subtype of breast cancer, accounts for around 65% cases. In current treatment guidelines, the standard first-line treatment for HR+/HER2- breast cancer is endocrine therapy combined with CDK4/6 inhibitors. After disease progression, endocrine therapy combined with other targeted therapy is the standard second-line treatment, but its effectiveness is limited. We will consider continuing to invest resources in this disease area to address significant unmet clinical needs.

TNBC, which lacks estrogen receptor and progesterone receptor and is HER2-, is the most malignant breast cancer subtype, accounting for approximately 15% of breast cancer cases. It encompasses multiple subtypes characterized by distinct genetic drivers, including Aurora kinases in the basal-like 1 subtype, and FGFR, and VEGF signaling pathways in the mesenchymal and mesenchymal stem-like subtypes. TNBC is a very aggressive form of breast cancer, which grows and spreads faster, has fewer treatment options, and tends to have a worse prognosis. Currently, chemotherapy is the primary treatment for TNBC, but its effectiveness is limited.

Clinical trial results from China and the U.S. demonstrated excellent clinical efficacy of Tinegotinib alone in HER2- breast cancer patients, including both HR+/HER2- breast cancer and TNBC who have undergone multiple treatments. In the Phase I and Phase Ib/II clinical trials, total 36 patients with metastatic breast cancer were enrolled and received treatment. Among them, 11 patients were with efficacy evaluable HR+/HER2- disease. As of March 30, 2024, after receiving Tinegotinib monotherapy, the ORR was 45% (5/11), the clinical benefit rate (CBR, CR+PR+SD≥24 weeks) was 64% (7/11) and the DCR was 82% (9/11).

Waterfall plots of HR+/HER2- breast cancer patients (N=11)



Abbreviations: CR=complete response; PR=partial response; SD=stable disease; PD=progression disease; BC: breast cancer.

Notes:

CDK4/6i: Pb=palbociclib; R=ribociclib; Ab=abemaciclib; IA: Investigational CDK4 inhibitor.

Taxanes: A=abraxane; D=docetaxel (taxotere); P=taxol (paclitaxel).

ADC: antibody-drug conjugate.

T-D: Fam-trastuzumab deruxtecan-nxki;

SG: Sacituzumab govitecan-hziy.

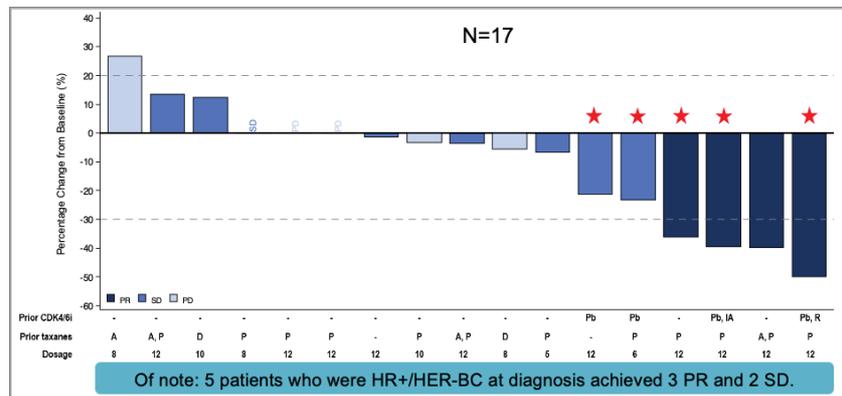
-: patient did not take this drug.

Source: Company data

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As of October 1, 2023, 17 patients were efficacy evaluable TNBC patients. Among them, five TNBC patients were originally diagnosed with HR+/HER2– breast cancer patients. Most of them had received endocrine therapies, CDK 4/6 inhibitors, and chemotherapies before evolving to TNBC. After Tinengotinib treatment, three achieved PR and two achieved SD, which indicated 60% ORR and 100% DCR.

Waterfall plots of TNBC patients (N=17)



★ Originally diagnosed as HR+/HER2–BC, most recent test diagnosed as TNBC

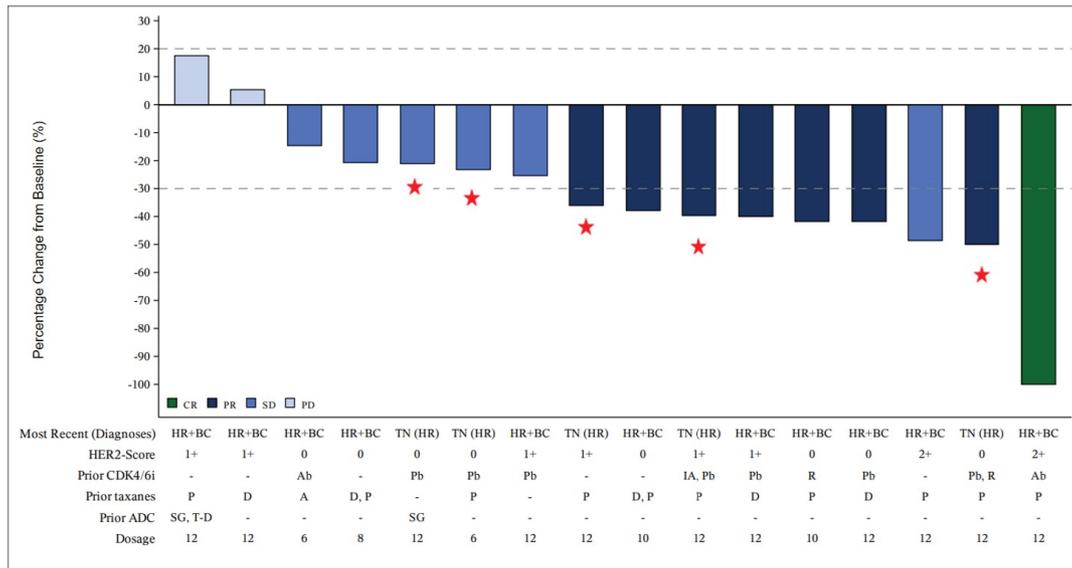
Abbreviations: Pb=palbociclib; R=ribociclib; IA=investigational CDK4 inhibitor; A=abraxane; P=taxol (paclitaxel); D=docetaxel (taxotere); CDK4/6i=CDK4/6 inhibitor.

Source: Company data

If we combine the clinical data of all 16 breast cancer patients who were originally diagnosed as HR+/HER2–, regardless of the hormone receptor score before enrollment to Tinengotinib treatment, as of March 30, 2024, we observed an ORR of 50% (8/16) and a DCR of 88% (14/16). This promising data warranted our further investigation of Tinengotinib either alone or combination with other agents to treat patients originally diagnosed with HR+/HER2– breast cancer and then progressed on standard of treatment.

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Waterfall plots of patients originally diagnosed as HR+/HER2- breast cancer (N=16)



★ Originally diagnosed as HR+/HER2- BC, most recent test diagnosed as TNBC

Abbreviations: CR=complete response; PR=partial response; SD=stable disease; PD=progression disease; BC=breast cancer; TN=triple negative.

Notes:

CDK4/6i: Pb=palbociclib; R=ribociclib; Ab=abemaciclib; IA=investigational CDK4 inhibitor.

Taxanes: A=abraxane; D=docetaxel (taxotere); P=taxol (paclitaxel).

ADC: antibody-drug conjugate.

T-D: Fam-trastuzumab deruxtecán-nxki; SG=Sacituzumab govitecan-hziy.

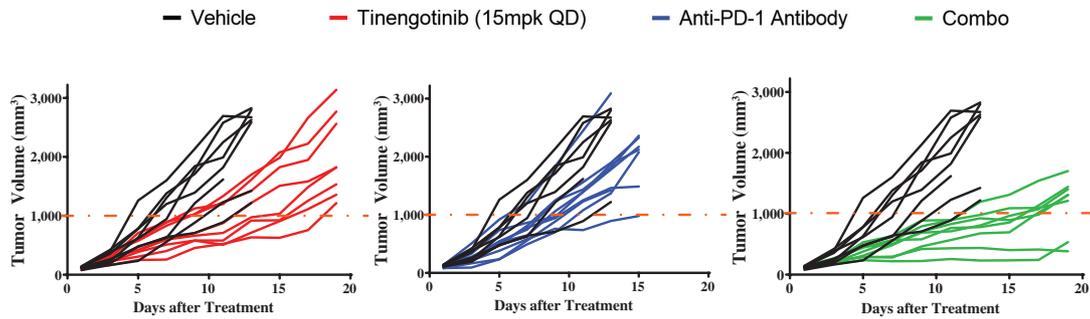
-: patient did not take this drug.

Source: Company data

Due to the novel mechanism of both targeted therapy and TME modulation, Tinengotinib demonstrated synergistic effect in combination with a mouse anti-PD-1 antibody in preclinical syngeneic tumor model. As such, we have initiated the combination therapy of Tinengotinib and Roche’s PD-L1 antibody (atezolizumab) in China for the treatment of BTC.

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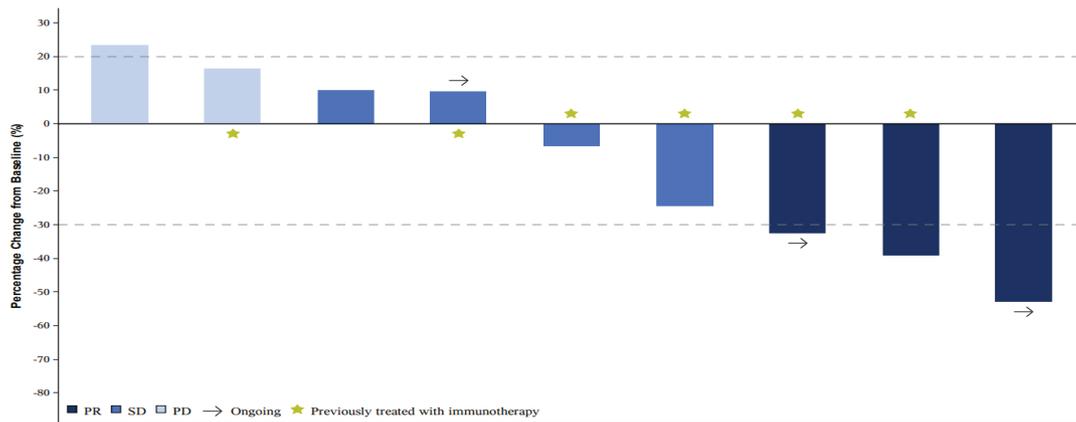
The tumor growth inhibitory activities of Tinengotinib, anti-PD-1 antibody, and the combination in syngeneic CT26 model



Source: Company data

The potential synergistic antitumor effect was also verified through our clinical studies. As of December 14, 2023, from our Phase Ib/II clinical trial, among nine enrolled BTC patients (all efficacy-evaluable) treated with Tinengotinib plus atezolizumab, the ORR and the DCR were 33% (3/9) and 78% (7/9), respectively.

Waterfall plots of BTC patients treated with Tinengotinib plus atezolizumab (N=9)



Abbreviations: PR=partial response; SD=stable disease; PD=progression disease

Source: Company data

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Clear Clinical Evidence in Solid Tumors with FGFR1/2/3 Alterations

Given the sequence homology between the kinase domains of FGFR1/3 and FGFR2, Tinengotinib is believed to have a similar binding mode to FGFR1/3 as it does to FGFR2, implying a high potential to overcome FGFR1/3 mutations.

In our preclinical studies, Tinengotinib demonstrated high potency against gate keeper mutations of FGFR1 and FGFR3, with IC₅₀ values equal to or less than 5 nM in addition to its high potency against wild type. These findings supported that Tinengotinib be suitable for wide range of solid tumors with FGFR1/2/3 alterations, such as prostate cancer, bladder cancer, endometrial cancer, non-small cell lung cancer, and colon cancer.

The inhibitory activities of Tinengotinib against acquired resistant mutations in FGFR1 and FGFR3

Target	FGFR1 WT	FGFR1 V561M	FGFR3 WT	FGFR3 K650E	FGFR3 V555M
Tinengotinib (IC ₅₀ , nM)	2	1.3	5	1.34	3.47

Source: Company data

In a pooled retrospective analysis of data from four clinical trials as of February 27, 2024, a total of 51 patients were documented or detected FGFR 1/2/3 mutations, including CCA (N=29), colon cancer (N=6), TNBC (N=3), prostate cancer (N=2), head and neck cancer (N=3), urothelial cancer (N=3), cervical cancer (N=1), endometrial cancer (N=1), pancreatic cancer (N=1), gastric cancer (N=1) and leiomyosarcoma (N=1). Interim analysis showed that partial responses were observed in 17/51 (33.3%) patients across six distinct tumor types, including CCA, breast, prostate, urothelium, colon and head and neck cancer. The DCR was 88% (45/51). The median PFS reached 6.9 months.

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Summary of Clinical Trials

Overview of Clinical Studies of Tinengotinib

An overview of the clinical studies of Tinengotinib is summarized below:

<u>NCT/CTR No.</u>	<u>Phase</u>	<u>Site</u>	<u>Study Design</u>	<u>Status</u>	<u>Competent Authority</u>	<u>Patient Cohorts</u>	<u>Key Inclusion Criteria</u>
NCT05948475	III (registrational)	U.S.; EU; United Kingdom; South Korea; Taiwan	Randomized, controlled, global multicenter study to evaluate the efficacy and safety of oral Tinengotinib vs. physician’s choice in subjects with FGFR-altered, chemotherapy- and FGFR Inhibitor-refractory/relapsed CCA	Active, recruiting	FDA, EMA, MHRA, MFDS, TFDA	Part A: Tinengotinib (8mg, 10 mg) and physician’s choice Part B: Tinengotinib selected dose (8 mg or 10 mg) and physician’s choice	<ul style="list-style-type: none"> • Adult CCA patients • Histologically or cytologically confirmed CCA/adenocarcinoma of biliary origin with radiological evidence of unresectable or metastatic disease • Documentation of FGFR2 fusion/rearrangement gene status • Subjects must have received at least one line of prior chemotherapy and exactly one FGFR inhibitor (pemigatinib, infigratinib or futibatinib)

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NCT/CTR No.	Phase	Site	Study Design	Status	Competent		Key Inclusion Criteria
					Authority	Patient Cohorts	
CTR20232860	II (pivotal)	China	Open-label, multicenter study to evaluate the efficacy and safety of oral Tinengotinib tablets in subjects with CCA who failed or relapsed to prior treatment of chemotherapy and FGFR inhibitor	Active, recruiting	NMPA	N/A	<ul style="list-style-type: none"> • Adult CCA patients • Histologically or cytologically confirmed CCA/adenocarcinoma of biliary origin with radiological evidence of unresectable or metastatic disease • Subjects must have received one or two lines of prior systemic chemotherapy • Documentation of FGFR2 gene alteration and must have failed to prior treatment of exactly one FGFR inhibitor
NCT04919642	II	U.S.	Open-label, multicenter study to evaluate the efficacy and safety of Tinengotinib tablet in adult patients with CCA	Patient enrollment completed	FDA	<p>Cohort A1: FGFR2 fusions who have failed at least one previous treatment with an FGFR inhibitor</p> <p>Cohort A2: FGFR2 fusions who have responded on at least one previous treatment with an FGFR inhibitor and discontinued due to progressive disease</p> <p>Cohort B: other FGFR alterations, including FGFR2 mutations and FGFR1/3 alternations</p> <p>Cohort C: no FGFR alternations</p>	<ul style="list-style-type: none"> • Adult CCA patients • Advanced/metastatic or surgically unresectable CCA after at least one line of systemic chemotherapy • Documented FGFR alteration

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NCT/CTR No.	Phase	Site	Study Design	Status	Competent	Patient Cohorts	Key Inclusion Criteria
					Authority		
NCT04742959	Ib/II	U.S.	Multicenter, open-label study of Tinengotinib tablet, as monotherapy or in combination regimens, in patients with advanced solid tumors	Patient enrollment completed	FDA	Cohort A: advanced solid tumors ⁽¹⁾ Cohort B: HER2– breast cancer ⁽²⁾ Cohort C: advanced solid tumors ⁽³⁾	<ul style="list-style-type: none"> • Adult cancer patients • Locally advanced or metastatic solid tumors without standard therapy
CTR20212760	Ib/II	China	Multicenter, open-label study of Tinengotinib tablet, as monotherapy or in combination regimens, in patients with advanced solid tumors or combination regimens in biliary tract carcinoma and HER2– breast cancer including TNBC	Active, recruiting	NMPA	Cohort A: advanced solid tumors Cohort B: BTC Cohort C: TNBC	<ul style="list-style-type: none"> • Adult cancer patients • Locally or metastatic advanced solid tumors • BTC/TNBC without standard therapy
NCT03654547/ CTR20190522	I	U.S. and China	First-in-human, multicenter, open-label study in adult patients with advanced solid tumors and triple negative breast cancers	Completed	FDA and NMPA	Dose Escalation Cohort: advanced solid tumors Dose Expansion Cohort: TNBC and selected advanced tumors	<ul style="list-style-type: none"> • Adult cancer patients • Locally advanced or metastatic solid tumors without standard therapy
NCT04705922	I	U.S.	Single-center, open-label, 3-way crossover, randomized food effect and relative bioavailability study in healthy volunteers	Completed	FDA	N/A	<ul style="list-style-type: none"> • Adult healthy subjects aged between 18 and 64 • BMI: 18-32 kg/m², weight at least 50 kg • Healthy condition as determined by the investigator

Notes:

- (1) to assess the safety and tolerability of Tinengotinib tablet in patients with advanced solid tumors;
- (2) to assess the safety and tolerability of Tinengotinib tablet in combination with nab-paclitaxel in patients with metastatic HER2– breast cancer, including TNBC;
- (3) to characterize the clinical PK profile of Tinengotinib tablet administered as different dosage frequency in patients with advanced solid tumors.

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A Registrational Phase III Study of Tinengotinib in Adult Patients with CCA (NCT05948475)

Trial Design. This is a randomized, controlled, global multicenter, Phase III study to evaluate the efficacy and safety of oral Tinengotinib versus physician's choice in subjects with FGFR-altered, chemotherapy- and FGFR inhibitor refractory/relapsed CCA. This trial will be conducted in the U.S., South Korea, United Kingdom, eight countries in the EU and Taiwan in two parts: Part A and Part B. Approximately 200 subjects will be enrolled. Eligible subjects will be randomized in a 2:2:1 ratio to receive Tinengotinib 8 mg QD, Tinengotinib 10 mg QD or physician's choice in Part A; and eligible subjects will be randomized in a 2:1 ratio to receive the recommended Part B dose or physician's choice in Part B.

The primary outcome measures of Part A are incidence, duration and severity of AEs. The secondary outcome measures include ORR and DOR. The primary outcome measure of Part B is PFS by BICR. The secondary outcome measures include OS, ORR, DOR and PFS based on RECIST version 1.1.

Trial Status. We received regulatory clearance from the FDA for conducting this study in July 2023 and enrolled the first patient in December 2023. Currently, this trial is on-going.

A Pivotal Phase II Study of Tinengotinib in Adult Patients with CCA (CTR20232860)

Trial Design. This is a pivotal, open-label, single-arm, multicenter Phase II study to evaluate the efficacy and safety of oral Tinengotinib tablets in subjects with CCA who failed or relapsed to prior treatment of chemotherapy and FGFR inhibitor. This study will be conducted in China in more than 30 clinical sites. Approximately 50 subjects will be enrolled. Eligible subjects will receive Tinengotinib 10 mg QD orally as the initial dose level in 21-day cycles until confirmed disease progression, intolerable toxicity, death, or withdrawal of consent.

The primary outcome measure is ORR by BICR. The secondary outcome measures include PFS, OS, ORR by investigator, DCR, DOR and incidence, duration, and severity of AEs.

Trial Status. We received regulatory clearance from the NMPA for conducting this study in July 2023 and enrolled the first patient in November 2023. Currently, this trial is on-going.

A Phase II Study of Tinengotinib in Adult Patients with CCA (NCT04919642)

Trial Design. This is an open-label, multicenter Phase II study to evaluate the efficacy and safety of Tinengotinib tablet in adult patients with CCA. This trial was conducted in the U.S. The primary objectives of the study are to evaluate the efficacy of Tinengotinib as a single agent in patients with advanced/metastatic or surgically unresectable CCA with: (i) FGFR2 fusions who failed prior FGFR inhibitor treatment; (ii) FGFR2 fusions who responded on prior FGFR inhibitor treatment and discontinued due to disease progression; (iii) other FGFR alterations; and (iv) tumors that do not contain a detectable FGFR alteration.

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The primary endpoints are the ORR of CCA patients. Foundation Medicine has been engaged for FGFR alteration analysis. Retrospective analysis of FGFR alterations of patients enrolled and treated was conducted.

Trial Status. The last patient was enrolled in October 2023.

Study results. As of the cut-off date December 12, 2023, 55 patients with CCA were enrolled, 18 in Cohort A1, 11 in Cohort A2, 13 in Cohort B, and 13 in Cohort C. 58.2% of the enrolled patients had at least three lines of prior therapy. ECOG PS was 0 in 50.9% patients. Among 42 patients with FGFR alterations, 78.6% had at least one prior FGFR inhibitor therapy.

Safety Profile. Among 55 treated patients, the most common Grade 3 TRAEs were hypertension (29%), palmar-plantar erythrodysesthesia syndrome (9%), stomatitis (7%), diarrhea (7%) and fatigue (7%). No Grade 4-5 TRAE was observed.

Efficacy Profile. Interim results showed that 26% ORR, 95% DCR, and 47% CBR were observed in CCA patients harboring FGFR alterations (Cohort A1+A2+B); 40% ORR, 90% DCR, and 47% CBR were observed in CCA patients with acquired resistance to prior-FGFRi (s) (Cohort A2); 31% ORR, 92% DCR, 62% CBR, and 8.05 months of mPFS were observed in CCA patients with other FGFR-alteration (Cohort B); and 75% DCR, 8% CBR, and 3.84 months of mPFS were observed in CCA patients FGFR wide-type patients (Cohort C).

Conclusions. Tinengotinib showed promising clinical benefits for FGFR2 fusion CCA and for non-fusion FGFR alterations CCA after prior FGFR inhibitor therapy. Tinengotinib-related toxicities were manageable.

A Phase Ib/II Study of Tinengotinib in Patients with Advanced Solid Tumors (NCT04742959)

Trial Design. This is a Phase Ib/II, multicenter, open-label study of Tinengotinib tablet, as monotherapy or in combination regimens, in patients with advanced solid tumors. This trial is conducted in the U.S. The study consists of three arms: Arm A is a study of Tinengotinib tablet monotherapy, Arm B is a study of Tinengotinib tablet in combination with nab-paclitaxel, and Arm C is a study to assess the safety and tolerability, PK and preliminary efficacy of Tinengotinib tablet monotherapy administered as QD or BID with the total daily dose ranges from 5 mg to 12 mg in subjects with advanced solid tumors.

Patients enrolled in Arm A had indications including metastatic CCA, HER2– breast cancer including TNBC, bladder cancer, SCLC, prostate cancer, thyroid cancer, sarcoma, gastric cancer, gallbladder cancer and other advanced solid tumors. Based on preliminary efficacy results from Phase Ib, Phase II will enroll additional patients in select indications to evaluate the efficacy of Tinengotinib monotherapy.

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Patients enrolled in Arm B may have invasive HER2– breast cancers, including TNBC. Phase Ib will be a dose escalation study of Tinengotinib in combination with nab-paclitaxel, guided by “3+3” design, to determine a RP2D. Phase II will enroll additional patients with metastatic HER2– breast cancers to further evaluate the efficacy of the combination regimen.

The primary objectives are: (1) Arm A Phase Ib: To assess the safety and tolerability of Tinengotinib tablet 12 mg QD in subjects with advanced solid tumors; (2) Arm B Phase Ib: To assess the safety and tolerability of Tinengotinib tablet in combination with nab-paclitaxel in subjects with metastatic HER2– breast cancer including TNBC; (3) Arm C: To assess the safety and tolerability of Tinengotinib tablet administered QD or BID with the total daily dose ranges from 5 mg to 12 mg in subjects with advanced solid tumors; (4) Arm C: To characterize the clinical PK profile of Tinengotinib tablet administered as QD or BID with the total daily dose ranges from 5 mg to 12 mg in subjects with advanced solid tumors. The secondary objectives are: (1) Arm A Phase II: To assess the preliminary efficacy of Tinengotinib in subjects with advanced solid tumors; (2) Arm B Phase II: To assess the preliminary efficacy of Tinengotinib in combination with nab-paclitaxel in subjects with metastatic HER2– breast cancer including TNBC; (3) Arm C: To assess the preliminary efficacy of Tinengotinib tablet administered as QD or BID with the total daily dose ranges from 5 mg to 12 mg in subjects with advanced solid tumors; (4) To characterize the clinical PK profile of Tinengotinib tablets.

The primary safety endpoints will be assessed through the following parameters: adverse events, clinical laboratory tests, physical examination, vital signs, weight and 12-lead electrocardiogram. Dose escalation cohort’s primary safety endpoint is DLT. The secondary efficacy endpoints are ORR, DCR, DOR, PFS and OS. The secondary PK endpoints are $AUC_{0-\infty}$, AUC_{0-t} , C_{max} , $t_{1/2}$, t_{max} , V_{ss} , V_{ss}/F , CL or CL/F, C_{min} , C_{ave} and fluctuation percentage.

Trial Status. We have initiated this study in August 2021, and expect to complete the trial in the fourth quarter of 2024. As of April 3, 2023, 177 patients with solid tumors were enrolled and treated, including 172 in monotherapy cohorts. These enrolled patients had FGFR-altered CCA, mCRPC, HER2– breast cancer or pan-FGFR-altered solid tumor. Based on the preliminary efficacy observed in the subjects with mCRPC and HER2– breast cancer, more patients were enrolled to further evaluate the efficacy of Tinengotinib monotherapy. As of October 1, 2023, six patients were enrolled in combination cohort.

Safety Profile. Tinengotinib TRAEs in monotherapy arms were reported in 127/172 (73.8%) patients. Sixty-three (36.6%) were Grade 1-2, 62/172 (36.0%) were Grade 3, 2/172 (1.2%) were Grade 4 (large intestine perforation, glutamic pyruvic transaminase/glutamic oxaloacetic transaminase increased), no Grade 5 TRAE reported. Common TRAEs ($\geq 10\%$) were hypertension (32.0%), stomatitis (22.1%), diarrhea (16.3%), palmar-plantar erythrodysesthesia syndrome (14.0%), nausea (12.8%) and fatigue (10.5%). All six (100%) patients receiving tinengotinib in combination with nab-paclitaxel experienced TRAEs. Among them, 16.7% were Grade 1, 66.7% were Grade 3, no patient had Grade 4 TRAEs, and one

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patient had Grade 5 (pulmonary hemorrhage). Common TRAEs ($\geq 20\%$) of Tinengotinib in combination with nab-paclitaxel were neutrophil count decreased/neutropenia (50.0%), stomatitis (50.0%), hypertension (33.3%), hyponatremia (33.3%), hypokalemia (33.3%) and nausea (33.3%).

Efficacy Profile. In 124 efficacy-evaluable patients of Tinengotinib monotherapy arms, the ORR and DCR were 15% (18/124) and 65% (80/124), respectively. All tumor responses were partial response. Clinical benefit (CR + PR + SD ≥ 6 months) were observed in 25% (31/124) patients, including CCA, prostate cancer, HR+/HER2- breast cancer, TNBC, ovarian cancer, squamous oropharyngeal carcinoma, fallopian tube cancer, urothelial carcinoma, cervical cancer, bladder cancer, endometrial cancer, leiomyosarcoma, cancer of duodenum, melanoma, colon cancer and lung cancer. The ORR was 18% (3/17) in CCA, and among them, the ORR reached 40% (2/5) in FGFR-altered CCA patients. Of the FGFR-altered CCA patients, 80% (4/5) had received prior FGFR targeted therapy. The ORR in prostate cancer, HR+/HER2- breast cancer and TNBC was 50% (5/10), 33% (2/6), 38% (3/8), respectively. Among six breast cancer patients received the combination therapy of Tinengotinib and nab-paclitaxel, 100% had tumor size reduction with one patient achieving PR and three patients achieving SD.

Conclusions. Tinengotinib monotherapy was well-tolerated and had no new safety signals when compared to the first-in-human study. Preliminary PK analysis showed a linear increase on exposure in terms of geometric mean $C_{max, ss}$ and $AUC_{0-24h, ss}$ from 5 mg QD to 12 mg QD. No significant difference in exposure was observed in QD vs BID. Encouraging antitumor activity of Tinengotinib monotherapy was observed in patients with heavily pre-treated solid tumors, including but not limited to prostate cancer, HR+/HER2- breast cancer, TNBC and CCA including FGFR2-altered CCA pre-treated with prior FGFR targeted therapy.

A Phase Ib/II Study of Tinengotinib in advanced solid tumors, including BTC and HER2- Breast Cancer (CTR20212760)

Trial Design. This is a multicenter, open-label study of Tinengotinib tablet, as monotherapy or in combination regimens, in patients with advanced solid tumors or combination regimens in BTC and HER2- breast cancer including TNBC. This trial was conducted in China.

The study consists of three arms: (i) Arm A is a study of Tinengotinib tablet monotherapy. About 12 to 18 patients with advanced solid tumor, including advanced CCA, SCLC, HER2- breast cancer including TNBC, bladder cancer, prostate cancer, thyroid cancer, gastric cancer, gallbladder cancer and other advanced solid tumors, will be enrolled to receive Tinengotinib tablet once a day to evaluate the safety and preliminary efficacy; (ii) Arm B is a study of Tinengotinib tablet in combination with atezolizumab injection Tecentriq[®]. Approximately 12 to 18 patients with BTC will be enrolled to receive Tinengotinib tablets in combination with atezolizumab injection intravenously in a 21-day cycle to assess safety and initial efficacy; (iii) Arm C is a study of Tinengotinib tablet in combination with nab-paclitaxel. About 12 to 18 patients with advanced TNBC will be enrolled to receive Tinengotinib tablet in combination with nab-paclitaxel to evaluate the safety and preliminary efficacy.

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Based on the preliminary efficacy results from Phase Ib and previous clinical trials, additional patients in each arm will be enrolled in Phase II part of study to evaluate the efficacy of Tinengotinib tablet monotherapy or combination therapy.

The primary objectives are: (1) Arm A Phase Ib: To assess the safety and tolerability of Tinengotinib tablet in subjects with advanced solid tumors, and to explore the MTD and/or RP2D; (2) Arm B Phase Ib: To assess the safety and tolerability of Tinengotinib tablet in combination with atezolizumab injection Tecentriq[®], and to explore the MTD and/or RP2D; (3) Arm C Phase Ib: To assess the safety and tolerability of Tinengotinib tablet in combination with nab-paclitaxel in subjects with metastatic HER2– breast cancer including TNBC, and to explore the MTD and/or RP2D. The second objectives in Arm A, Arm B and Arm C are to evaluate the preliminary efficacy, respectively.

The primary safety endpoints will be assessed through the following parameters: adverse events, clinical laboratory tests, physical examination, vital signs, weight, and 12-lead electrocardiogram. Dose escalation cohort’s primary safety endpoint is DLT. The secondary efficacy endpoints are ORR, DCR, DOR, PFS and OS. The secondary PK endpoints are $AUC_{0-\infty}$, AUC_{0-t} , C_{max} , $t_{1/2}$, t_{max} , V_{ss} , V_{ss}/F , CL or CL/F , C_{min} , C_{ave} and fluctuation percentage.

Trial Status. We have initiated the trial in April 2022, and expect to complete the trial in the fourth quarter of 2024. As of September 8, 2023, 50 patients with solid tumors were enrolled and treated with monotherapy (Arm A). Based on the preliminary efficacy observed in the subjects with FGFR-altered CCA, mCRPC, pan-FGFR-altered advanced solid tumors in Arm A Phase Ib and several studies globally, the Phase II cohorts for FGFR-altered CCA, mCRPC, pan-FGFR-altered advanced solid tumors have been opened for enrollment in Arm A. As of December 14, 2023, nine patients (eight CCA and one gallbladder carcinoma) were enrolled in dose escalation (Phase Ib) of Arm B and treated with Tinengotinib plus atezolizumab. Based on the promising efficacy data, a Phase II clinical trial of Tinengotinib plus atezolizumab for the treatment of BTC is ongoing. No patients were enrolled in Arm C.

Safety Profile.

- Arm A: Tinengotinib-related AEs in monotherapy arms were reported in 49/50 (98.0%) patients. 20/50 (40.0%) were Grade 1-2, 28/50 (56.0%) were Grade 3, 1/50 (2.0%) was Grade 4, and no Grade 5 TRAE was reported. Common \geq Grade 3 TRAEs ($\geq 5\%$) were hypertension, white blood cell count decreased, anaemia, neutrophil count decreased, platelet count decreased, proteinuria and palmar-plantar erythrodysesthesia syndrome.
- Arm B: No DLT was observed in the dose escalation phase. TRAEs were reported in nine (100%) patients, including four patients experienced Grade 1-2 TRAEs, and five experienced Grade 3 TRAEs. No Grade 4-5 TRAEs were observed. All three

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patients in higher dosage regimen (12 mg QD) experienced Grade 3 TRAEs. Common \geq Grade 3 TRAEs ($\geq 10\%$) included hypertension, palmar-plantar erythrodysesthesia syndrome, diarrhea, fatigue, neutrophil count decreased and platelet count decreased.

Efficacy Profile.

- Arm A: Among 39 efficacy-evaluable patients treated with Tinengotinib monotherapy, the median PFS have reached 5.7 months. For 31 efficacy-evaluable patients with measurable target lesions, the ORR and the DCR were 19% (6/31) and 84% (26/31), respectively. PRs were observed in six patients with CCA, prostate cancer and urothelial carcinoma. Among all CCA patients (eight patients with FGFR alteration, four patients with no FGFR alterations), the ORR was 33% (4/12) and the DCR was 83% (10/12). For four CCA patients who harbored FGFR2 fusion, the ORR was 75% and the DCR was 100%. Two responders with prior FGFR inhibitor treatments achieved tumor reductions of 44% and 32%. Another responder with no prior FGFR inhibitor treatment achieved 81% tumor reduction.
- Arm B: Among nine enrolled patients (all efficacy-evaluable) treated with Tinengotinib plus atezolizumab, the median PFS has reached 3.2 months, with three patients still on study at the time of the cut-off date. The ORR and the DCR were 33% (3/9) and 78% (7/9), respectively. Three patients achieved PR. One prior immunotherapy-naïve patient achieved tumor reduction of 52.9%, lasting for more than nine months after receiving Tinengotinib 8 mg QD plus atezolizumab. One patient with prior immunotherapy (sintilimab), target therapy (donafenib) and chemotherapy achieved tumor reduction of 39% after receiving Tinengotinib 10 mg QD plus atezolizumab. Another patient with prior immunotherapy (durvalumab) and chemotherapy had tumor reduction of 33% after receiving Tinengotinib 12 mg QD plus atezolizumab. Among four patients who achieved SD, three patients had received immunotherapy previously.

Conclusions. Tinengotinib monotherapy was well-tolerated in Chinese patients and 10 mg QD was selected as the RP2D. Encouraging efficacy of Tinengotinib monotherapy was observed in patients with heavily pre-treated solid tumors, especially in CCA patients harboring FGFR2 alteration with prior treatment of FGFR inhibitor therapy. Furthermore, Tinengotinib in combination with atezolizumab was well-tolerated with a manageable safety profile in Chinese BTC patients. Preliminary encouraging efficacy of Tinengotinib in combination with atezolizumab was observed in patients with heavily pre-treated BTC, including patients treated with immunotherapy previously.

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A Phase I, First-In-Human Study of Tinengotinib in Patients with Advanced Solid Tumors (NCT03654547/CTR20190522)

Trial Design. This was an open-label, first-in-human Phase I study enrolling adult patients with advanced TNBC and other advanced solid tumors in the U.S. and China. The study consisted of two phases: dose escalation and dose expansion. A total of 40 patients with advanced solid tumors were enrolled into dose groups of Tinengotinib at 1mg, 3mg, 5mg, 8mg, 10mg, 12mg and 15mg in the dose-escalation phase. A total of eight subjects were enrolled into 12mg dosage group in the dose-expansion phase. As of the data cut-off date March 15, 2022, 48 patients have been enrolled and treated in this study.

The primary objectives of this study were to determine the MTD, dose recommended for dose expansion, optimal biological dose, and/or dose-limiting toxicity of Tinengotinib as a single agent when administered orally to adult patients with advanced solid tumors. The secondary objectives of this study were to assess the safety and tolerability, characterize the clinical PK profile of Tinengotinib, and assess the preliminary efficacy of Tinengotinib in patients with advanced solid tumors.

Trial Status. We received IND approvals from the FDA in September 2018 and from the NMPA in February 2019. The first patient of the trial was enrolled in January 2019 in the U.S. This trial was completely concluded in November 2023.

Safety Profile. Overall, Tinengotinib was well tolerated. Most toxicities were Grade 1 and 2. No drug related Grade 4-5 toxicities were reported.

Among the total 48 subjects who received Tinengotinib and were evaluable for safety in both dose escalation and dose expansion, 41 subjects (85.4%) had a study drug related TEAEs. The most common study drug related TEAEs ($\geq 20\%$) were hypertension (50%), diarrhea (33.3%), palmar-plantar erythrodysesthesia syndrome (29.2%), stomatitis (29.2%), nausea (22.9%), and vomiting (20.8%). 21 subjects (43.8%) had drug-related Grade 3 TEAEs, including hypertension (27.1%), stomatitis (4.2%), diarrhea (2.1%), palmar-plantar erythrodysesthesia syndrome (2.1%) and nausea (2.1%). No drug-related Grade 4 or Grade 5 TEAEs were reported. The most common study drug related TEAE (i.e. hypertension), was in line with the anti-angiogenesis effect of Tinengotinib. Other common study drug related TEAEs had been widely reported in the class of pan-FGFR inhibitors. However, certain common TEAEs reported from other pan-FGFR inhibitors, such as hyperphosphatemia, eye toxicity or nail toxicity, were rarely reported from the patients who received Tinengotinib treatments.

Efficacy Profile. Tumor response was evaluable in 43 of 48 subjects who received at least one dose of Tinengotinib and had at least one post-baseline scan (dose escalation, n=36; dose expansion, n=7). Seven subjects (16.3%) achieved a PR, including three subjects with CCA (8 mg, 10 mg, and 12 mg doses), two subjects with HR+/HER2- breast cancer (10 mg and 12 mg doses), one subject with TNBC (12 mg dose), and one subject with CRPC (12 mg dose). 23 subjects (53.3%) had stable disease (SD), including six subjects (14.0%) with SD lasting ≥ 24 weeks.

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Conclusion. In summary, the preliminary safety and efficacy data from the Phase I clinical trial supported the continuous clinical investigation of Tinengotinib in humans. The preliminary efficacy data indicated the potential clinical benefit of Tinengotinib in patients with CCA, TNBC, prostate cancer and other indication(s).

A Phase I Study of Tinengotinib Tablet in Healthy Volunteers (NCT04705922)

Trial Design. This was a single-center, open-label, three-way crossover, randomized single dose Phase I study conducted to evaluate the food effect on the pharmacokinetics of Tinengotinib tablet and to determine the relative bioavailability of Tinengotinib tablet and Tinengotinib capsule in adult healthy volunteers.

A total of 24 eligible subjects were enrolled in the study. Eight subjects in each dose group were randomly assigned. In each dose group, subjects will undergo a baseline/screening period, three treatment periods. In each treatment period, subjects will be admitted to the clinical unit on Day -1, stay in-house for 11 nights/12 days, and be discharged on Day 11. Subjects will be administered a single dose of Tinengotinib orally on Day 1 of either Tinengotinib tablet under fed condition, Tinengotinib tablet under fasting condition, or Tinengotinib capsule under fasting condition and crossed over after at least a 14-day washout period. Blood samples for Tinengotinib plasma concentration-time profiles were collected on all subjects of the study.

The primary objectives of this study were to assess the food effect on the pharmacokinetics of Tinengotinib tablet following a single oral administration in adult healthy volunteers and to determine the relative bioavailability of Tinengotinib tablet versus Tinengotinib capsule under fasted condition in adult healthy volunteers. The secondary objectives of this study were to investigate the safety and tolerability of single oral doses of Tinengotinib tablet and capsule in adult healthy volunteers and additional pharmacokinetic parameters as applicable.

Trial Status. The trial was initiated in December 2020 and completed in March 2021.

Safety Profile. Tinengotinib tablet and/or capsule were administered as single dose in each treatment period. All healthy subjects tolerated the assigned treatment well. No SAE or \geq Grade 3 CTCAE AEs were reported. No study drug related clinically significant laboratory abnormalities occurred. The most common study drug related AE reported was low grade hypertension. The occurrence of hypertension was in line with the anti-angiogenesis effect of Tinengotinib. The common AEs reported in the healthy subjects were consistent with the common AEs reported in the adult patients with solid tumors treated in TT420X2101 (NCT03654547/CTR20190522) study.

Conclusion. The PK results showed Tinengotinib capsule and Tinengotinib tablet formulations were comparable with no food effect. Tinengotinib tablet or capsule was well tolerated in healthy volunteers.

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Clinical Development Plan

We are executing a comprehensive global clinical trial development plan targeting an array of cancer indications for Tinengotinib. We plan to bring Tinengotinib to market rapidly as a monotherapy. We are focusing on third-line patients with CCA who do not have standard treatment options. In parallel, we will expand the application of Tinengotinib to other indications, such as mCRPC, HER2– breast cancer including TNBC, and those patients with FGFR1/2/3 alterations. We also plan to explore the combination therapy of Tinengotinib with certain standard of treatment or anti-PD-L1 antibody to treat different solid tumors.

As of the Latest Practicable Date, the FDA approved three FGFR inhibitors and the NMPA approved one FGFR inhibitor for the treatment of CCA. Nonetheless, the approved FGFR inhibitors are not able to address drug resistance. For details, see “Industry Overview – Small Molecule Oncology Targeted Therapy – Major Indications of MTK Inhibitors – CCA – FGFR Inhibitors – Competitive Landscape.” As Tinengotinib can potentially overcome the relevant limitations, we intend to expedite clinical trials of Tinengotinib and rapidly capture the market in CCA and then expand the market share to other indications within three to five years. Below sets forth our clinical development plan.

Indication	Mono/Combo	Clinical Trial		
		Stage	Location	Upcoming Milestone
CCA	Mono	Pivotal Phase II (CTR20232860)	China	Complete the trial in the second half of 2025, and then submit an NDA
		Registrational Phase III (NCT05948475)	U.S, EU, South Korea, the United Kingdom and Taiwan	Complete patient enrollment in the second half of 2026
mCRPC	Combo (+NHT)	Phase Ib/II (IIT) (NCT06457919)	U.S.	Initiate the trial in second half of 2024
	Combo (+NHT)	Phase II (N/A)	China	Initiate the trial in the first half of 2025
HER2– Breast Cancer	Combo	Phase I (NCT04742959, and CTR20212760)	U.S. & China	Clinical timeline to be determined
BTC ⁽¹⁾	Combo (+ anti-PD-L1 antibody)	Phase Ib/II (CTR20212760)	China	Complete the trial in the fourth quarter of 2024

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<u>Indication</u>	<u>Mono/Combo</u>	<u>Clinical Trial Stage</u>	<u>Location</u>	<u>Upcoming Milestone</u>
Solid Tumors ⁽¹⁾	Mono	Phase Ib/II (NCT04742959 and CTR20212760)	U.S. & China	Complete the trials in the fourth quarter of 2024

Abbreviations: IIT=investigator initiated trial; NHT=novel hormone therapies; N/A=not available as of Latest Practicable Date.

Note:

- (1) We are exploring mCRPC, HER2– breast cancer, and pan-FGFR solid tumor under the same trial protocol of one clinical trial (NCT04742959) conducted in the U.S. In addition, we are exploring mCRPC, HER2– breast cancer, BTC and pan-FGFR solid tumor under the same trial protocol in one clinical trial (CTR20212760) conducted in the China.

License, Rights and Obligations

As Tinengotinib is internally discovered and developed by us, we maintain the global rights to develop and commercialize Tinengotinib.

Material Communications

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

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

OTHER ONCOLOGY PIPELINE PRODUCTS

TT-00973: AXL/FLT3 Inhibitor

Overview

TT-00973 is an internally discovered and developed, highly potent AXL/FLT3 inhibitor with significantly high potency against AXL. AXL kinase is a key player in survival, metastasis, and drug resistance in cancer, aberrant activation of AXL signaling is associated with poor prognosis in many types of cancers. AXL represents a promising therapeutic target in cancer treatment, both as single agent and in combination with other therapies. TT-00973 is potent in abrogating AXL activation in tumor cells, and demonstrates effective antitumor activity in murine xenograft models with AXL overexpression. We have received the IND approval from the NMPA in August 2022. We are conducting a Phase I dose escalation study in patients with solid tumors in China with the first patient enrolled in April 2023.

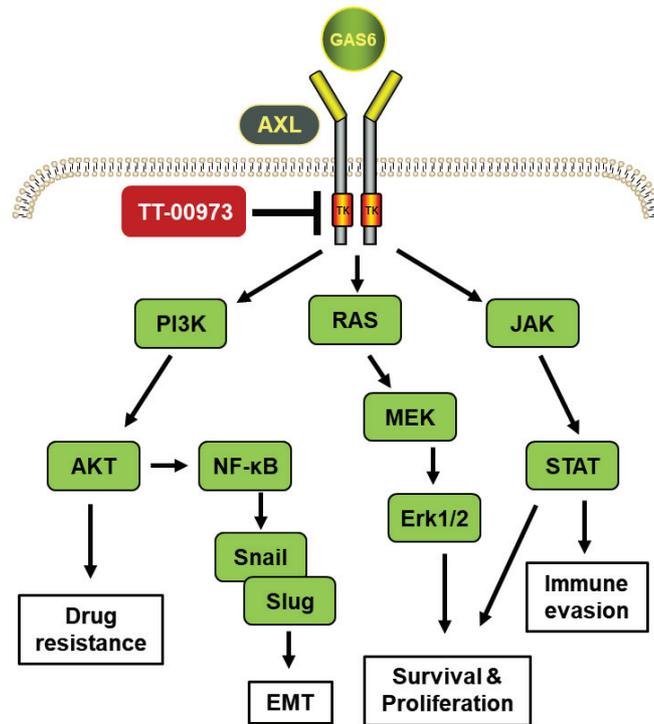
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Mechanism of Action

AXL is a member of the TAM (TYRO3, AXL, and MER) family activated by the high-affinity ligand Gas6. High level expression of AXL has been associated with poor prognosis in various cancers, including ovarian, urothelial, lung cancer and acute myeloid leukemia. Overactivation AXL signaling is associated with drug resistance, tumor cell growth, metastasis, invasion, epithelial-mesenchymal transition, angiogenesis, immune regulation, and stem cell maintenance, implicating AXL as a promising drug target in cancer treatment.

TT-00973 is a highly potent AXL inhibitor. It strongly inhibits AXL both in biochemical assay and in cancer cells. In mouse xenograft CDX models with AXL overexpression, TT-00973 showed promising antitumor efficacy as a single agent. The diagram below illustrates the mechanism of action of TT-00973 targeting AXL pathway.

TT-00973 is capable of inhibiting AXL in a variety of cancer cells



→ Stimulation/Induction/Activation; —| Inhibition

Abbreviations: GAS6=Growth arrest-specific 6; PI3K=phosphoinositide 3-kinase; JAK=Janus kinase; MEK=MAPKK, mitogen-activated protein kinase kinase; NF-κB=nuclear factor kappa-light-chain-enhancer of activated B cells; STAT=signal transducer and activator of transcription; Erk1/2=extracellular signal-regulated kinases 1 and 2; MAPK=mitogen-activated protein kinase.

Source: Company data

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Competitive Advantages

Potent AXL Inhibitor

Biochemical and cellular phosphorylation assays have shown that TT-00973 was a potent AXL inhibitor. As summarized in the table below, TT-00973 effectively inhibited cellular AXL with an IC₅₀<1 nM.

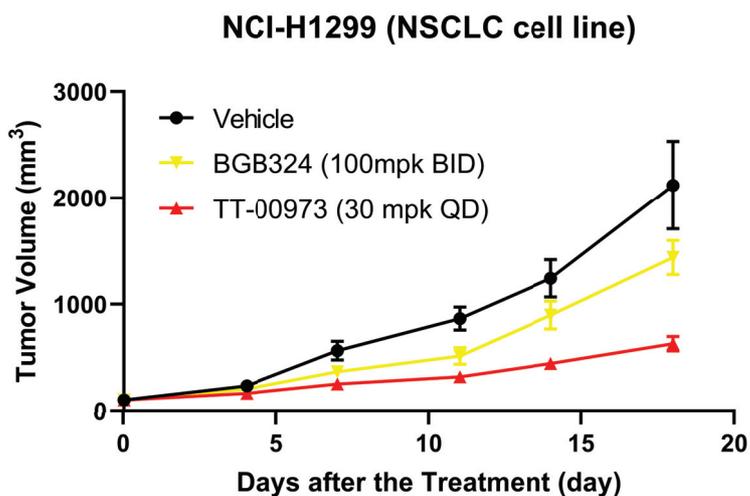
The inhibitory activity of TT-00973 against AXL

Inhibitory activities against AXL	IC ₅₀ (nM)
TT-00973	0.41
BGB324	30

Source: Company data

High Potential in Solid Tumors with AXL-Overexpression

The therapeutic efficacy of TT-00973 on AXL-overexpression solid tumor was evaluated in the treatment of subcutaneous human NSCLC model NCI-H1299 in female BALB/c nude mice. As shown in the figure below, monotherapy of TT-00973 or BGB324 were administered to the NCI-H1299 tumor-bearing mice. TT-00973 monotherapy at 30mg/kg demonstrated a significant antitumor efficacy with a tumor growth inhibition of 69.5%.



Source: Company data

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Currently, we are conducting a Phase I study of TT-00973 in patients with solid tumors, and we have observed partial responses in patients with certain types of solid tumors. The encouraging data warranted further clinical investigation on TT-00973 for the treatment of selected solid tumors.

Summary of Clinical Trial

Phase I clinical trial in the China in solid tumor conducted

Trial Design. This is a Phase I study conducted in the China, which is designed to assess the safety, tolerability, pharmacokinetics profile, and preliminary efficacy of TT-00973 in adult patients with solid tumor. The primary objectives of the study are to explore the safety and tolerability, MTD and RP2D of TT-00973. The secondary objectives are to characterize the PK profiles and preliminarily efficacy profiles of TT-00973, and determine the preliminary efficacy in patients with advanced solid tumor, if feasible.

This study is planned to include two parts: Part 1 is a dose escalation study based on an accelerated titration method combined with “3+3” design; Part 2 is a dose expansion cohort to evaluate TT-00973 in selected tumor types. The RP2D will be determined based on the totality of safety, pharmacokinetics, and efficacy data from the dose escalation cohorts and dose expansion cohorts.

Trial Status. This trial is currently on-going.

Clinical Development Plan

We have received IND approval of TT-00973 in solid tumors from the NMPA in August 2022. As of the Latest Practicable Date, patient enrollment of a Phase I clinical trial was on-going in China. We plan to complete the Phase I clinical trial in China in the first half of 2026, and initiate a Phase II trial in the second half of 2026 in China.

Licenses, Rights and Obligations

As TT-00973 is internally discovered and developed by us, we maintain the global rights to develop and commercialize TT-00973.

Material Communications

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

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TT-00973 SUCCESSFULLY.

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TT-01488: Non-covalent, Reversible BTK Inhibitor

Overview

TT-01488 is an internally developed, non-covalent, reversible BTK inhibitor to overcome acquired resistance developed from marketed covalent BTK inhibitors in various types of relapsed or refractory hematological malignancies. In a head-to-head kinase panel evaluation, in addition to its higher potency, TT-01488 demonstrated strong kinase selectivity on EGFR and Tec, indicating its potential to have fewer off-target side effects and thus a better safety profile. In the lymphocytic xenograft models, TT-01488 showed encouraging antitumor effect. We received the IND approval from the FDA and the NMPA in January 2022 and April 2022, respectively. Currently, we are conducting a Phase I dose-escalation clinical study of TT-01488 for B-cell lymphoma in China with the first patient enrolled in March 2023.

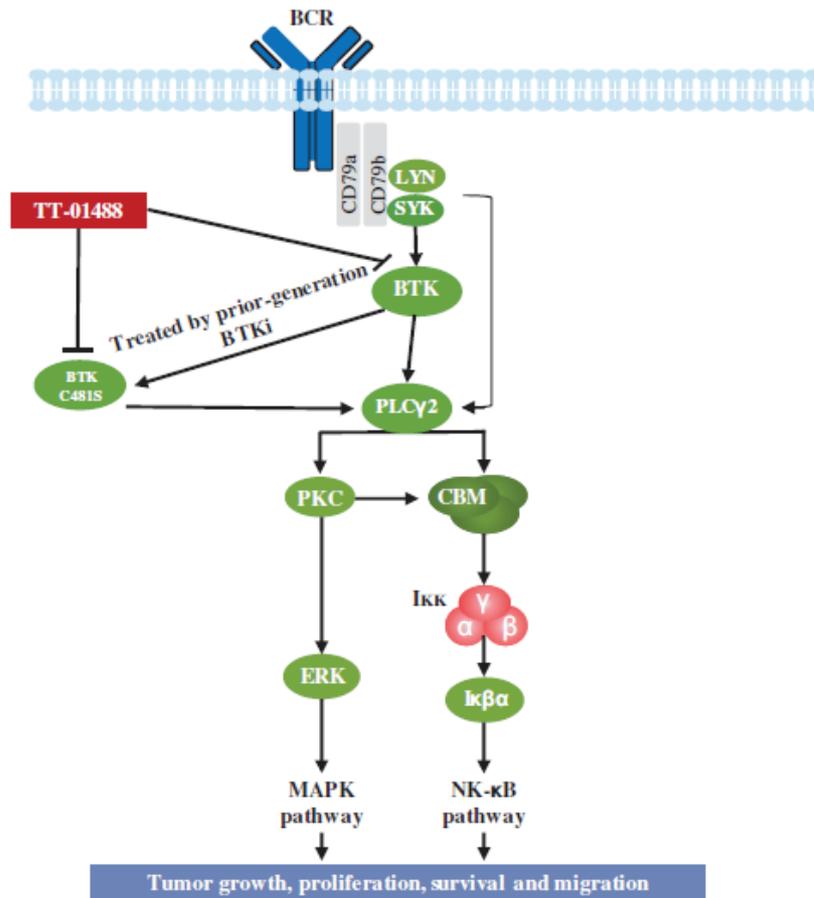
Mechanism of Action

BTK is one of the Tec-family non-receptor tyrosine kinases, a key component of BCR signaling pathway, functioning as an important regulator of cell proliferation and cell survival in various B cell malignancies. BCR activation triggers the formation of a signalosome, which includes protein tyrosine kinases LYN, SYK and BTK, as well as PLC γ 2 and phosphoinositide 3-kinase. Within the signalosome, BTK is phosphorylated by LYN and SYK. SYK and BTK subsequently phosphorylate PLC γ 2, leading to calcium mobilization, activation of ERK, AKT and nuclear factor- κ B, which subsequently results in cell survival, proliferation, differentiation and antibody production.

Covalent irreversible small-molecule inhibitors of BTK have shown excellent antitumor activity in preclinical and clinical studies and have transformed the management of B-cell malignancies. Despite its initial clinical benefit for most patients, resistance to the first generation of irreversible BTK inhibitors continues to emerge as more patients are treated and follow-up time extends. Covalent BTK inhibitors can form a covalent bond with the C481 site of BTK, however when C481S mutation occurs, they will not be able to maintain the covalent bond, which eventually leads to drug resistance. TT-01488 is a non-covalent, reversible BTK inhibitor that binds to and inhibits BTK regardless of C481S mutation. The diagram below illustrates the mechanism of action of TT-01488.

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TT-01488 is capable of inhibiting BTK as well as BTK harboring C481S resistant mutation in B-cell malignancies



→ Stimulation/Induction/Activation; —| Inhibition

Abbreviations: BCR=B cell receptor; BTK=Bruton's tyrosine kinase; PLCγ2=phospholipase C gamma 2; PKC=protein kinase C; CBM=CARMA1-BCL10-MALT1 complex; ERK=extracellular signal-regulated kinase; IκBα=inhibitors of κB kinase alpha.

Source: Company data

Competitive Advantages

Overcome Drug Resistance

Covalent BTK inhibitors have transformed the management of B-cell malignancies, including chronic lymphocytic leukemia, mantle cell lymphoma, Waldenström macroglobulinemia, and marginal zone lymphoma. Despite their efficacy, treatment failure often occurs through the development of resistance or intolerance, with long-term follow-up showing cumulative discontinuation rates as high as 36%. Emerging evidence suggests that acquired resistance is mediated predominantly by BTK C481S point mutations at the binding site of covalent BTK inhibitors. New treatment approaches are needed to address this acquired resistance and maintain comparable or better safety profile at the same time.

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By design, TT-01488 is capable of inhibiting both wild type BTK as well as BTK with C481S mutation. As shown below, TT-01488 potently inhibited both forms of BTK in kinase as well as HEK-293 cellular assay with comparable activities. Ibrutinib, a first-generation covalent irreversible BTK inhibitor and ARQ-531, a leading reversible BTK inhibitor in Phase II/III study, was evaluated head-to-head in the same assays. TT-01488 demonstrated strong potency in BTK wild type and BTK C481S-overexpressing HEK-293 cells. Consistently, TT-01488 was effective against B-cell lymphoma cell lines *in vitro*. As expected, ibrutinib, the first generation of covalent irreversible BTK inhibitor, lost a significant amount of activity to BTK C481S.

The inhibitory activities of TT-01488 against wild type BTK, BTK with C481S mutation and B-cell lymphoma cell lines expressing wild type BTK

Inhibitor	Kinase Assay ⁽¹⁾		Transfected in HEK-293 Cells		TMD-8 cell	OCI-LY10 cell	HBL-1 cell
	BTK WT IC ₅₀ (nM)	BTK C481S IC ₅₀ (nM)	BTK WT pBTK IC ₅₀ (nM)	BTK C481S pBTK IC ₅₀ (nM)			
TT-01488	0.60	0.42	22.0	15.8	1.1	7.38	15.5
ARQ-531	1.30	1.06	246.5	222.4	20.7	205.7	230.0

Note:

(1) The kinase results are from the ADP-Glo kinase assay.

Source: Company Data

Improved Target Selectivity

During the treatment of the prior BTK inhibitors, it has been reported that adverse effects such as bleeding, rash, diarrhea and atrial fibrillation, which are classified as safety issues of BTK-targeted therapies, are partly due to off-target inhibition on EGFR and Tec family proteins other than BTK. In a head-to-head kinase panel evaluation, TT-01488 showed great kinase selectivity for EGFR and Tec, indicating a potentially favorable safety profile in patients.

The inhibitory activities of TT-01488 against wild type BTK, BTK with C481S mutation, EGFR, and Tec

Kinase ⁽¹⁾	TT-01488		ARQ-531	
	IC ₅₀ (nM)	Selectivity (fold)	IC ₅₀ (nM)	Selectivity (fold)
BTK	0.23	/	1.57	/
EGFR	530	2,304	83.3	53
Tec	3.21	14	1.83	1.2

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Note:

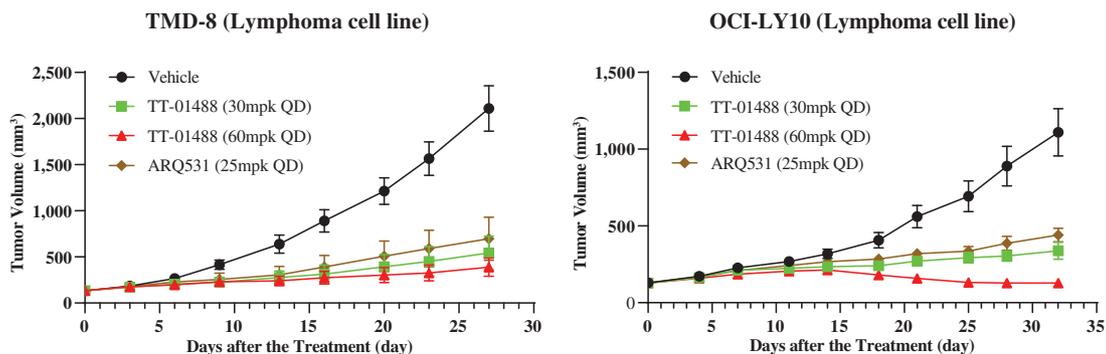
(1) The kinase results are from the HotSpot Kinase profiling assay.

Source: Company Data

Antitumor Efficacy and Favorable Safety

The antitumor activity of TT-01488 was evaluated in two human lymphocytic xenograft models TMD-8 and OCI-LY10. In the treatment of TMD-8 model, TT-01488 at 30 mg/kg and 60mg/kg showed significant antitumor activity with a tumor growth inhibition of 75.9% and 83.7%, respectively. In the treatment of DLBCL OCI-LY10 model, the tumor growth inhibition of TT-01488 at 30mg/kg and 60mg/kg were 69.4% and 88.3%, respectively.

The tumor growth inhibitory activities of TT-01488 in TMD-8 and OCI-LY10 lymphoma cell lines derived *in vivo* xenograft models



Source: Company data

Promising efficacy of complete response and partial response have been observed in patients with acquired resistance to irreversible BTK inhibitors during the Phase I dose escalation study.

Summary of Clinical Trial

Phase I clinical trial in patients with B-cell malignancies

Trial Design. This is a Phase I study to evaluate TT-01488 monotherapy in patients with B-Cell malignancies. The primary objectives of the study are to evaluate DLT and identify MTD, if feasible, or establish DRDE. Preliminary efficacy and PK profile will be evaluated as well.

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This study is planned to include two parts: Part 1 is a dose escalation study based on a modified 3+3 design; Part 2 will be a dose expansion cohort to evaluate TT-01488 at the DRDE or MTD in patients. DRDE and RP2D may be determined based on the totality of safety, PK, and efficacy data from the dose escalation cohorts and dose expansion cohorts.

Trial Status. As of the Latest Practicable Date, the study was on-going.

Clinical Development Plan

We received IND approval from the FDA and the NMPA in January 2022 and April 2022, respectively. As of the Latest Practicable Date, patient enrollment was on-going in China. We expect to obtain the results of the primary endpoint of the Phase I trial in the second half of 2025 and then initiate a Phase II trial in the first half of 2026.

Licenses, Rights and Obligations

As TT-01488 is internally developed by us, we maintain the global rights to develop and commercialize TT-01488.

Material Communications

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

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TT-01488 SUCCESSFULLY.

NON-ONCOLOGY PIPELINE PRODUCTS

TT-01688: Highly Selective, Oral S1P1 Modulator

Overview

TT-01688 is an in-licensed, highly selective, oral S1P1 modulator targeting multiple inflammatory diseases. We obtained the exclusive rights to develop and commercialize TT-01688 in Greater China from LG Chem. TT-01688 is a clinically advanced, highly selective S1P1 modulator with potential low cardiovascular side effects. S1P1 is a promising autoimmune disease target with a favorable target safety profile. It shows promise for the treatment of UC, which has been clinically validated by a S1P1 modulator ozanimod. Accumulating clinical evidence shows that S1P1 modulators can potentially be used for treating a variety of other immunological disorders, including AD. TT-01688 has proven its high selectivity for the S1P1 target and excellent mechanistic PK/PD profiles in preclinical and Phase I clinical studies. As of the Latest Practicable Date, TT-01688 had completed the Phase I study in South Korea by our partner LG Chem. We received IND approval of TT-01688 from the NMPA to conduct Phase Ib clinical trials for the treatment of UC in China in November

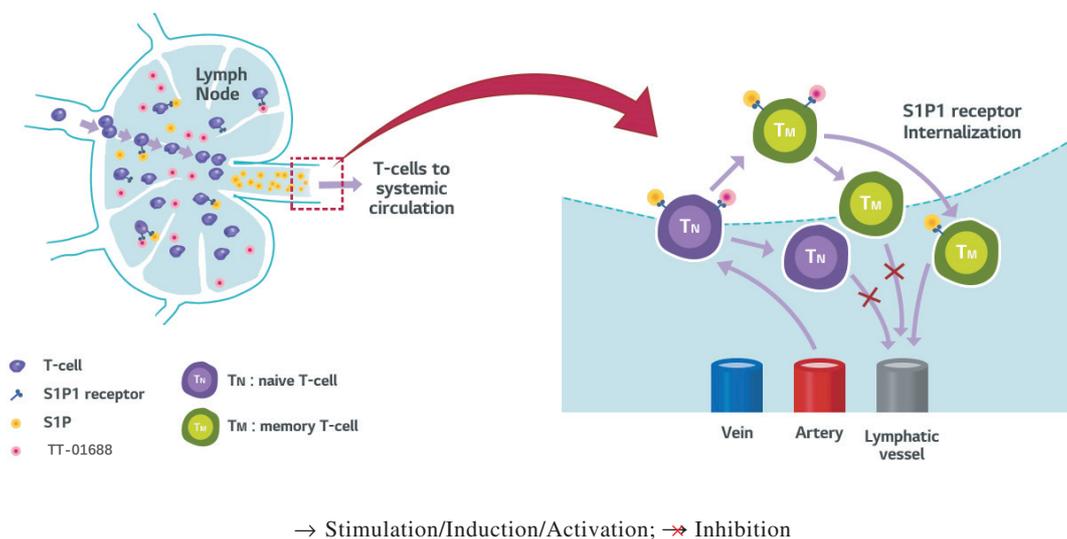
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2021, and initiated a Phase Ib clinical trial in May 2022. In addition, we received IND approval for conducting Phase II clinical trials for the treatment of AD from the NMPA in April 2022, and initiated a Phase II trial in September 2022.

Mechanism of Action

The S1P1 expresses on lymphocytes and plays a crucial role in the trafficking of lymphocytes from lymphoid organs. The S1P1 modulator can induce internalization and degradation of the S1P1, rendering B and T lymphocytes incapable of migrating from secondary lymphoid organs, which leads to a reduction in circulating lymphocytes in the blood. Non-selective binding to other S1P subtypes, particularly S1P2 and S1P3, may lead to AEs, including vasoconstriction and blood pressure increase. TT-01688 is a novel oral S1P1 modulator with high selectivity against S1P2, S1P3 and S1P4 and potential for lower cardiovascular risk. The diagram below illustrates the mechanism of action for TT-01688.

TT-01688, a S1P1 modulator, reduces circulating lymphocytes by inducing S1P1 receptor internalization



Source: LG Chem Data

Market Opportunity and Competition

TT-01688 is a selective S1P1 modulator which triggers anti-inflammatory effect through modulating lymphocyte mobilization, suggesting potential in a broad set of immunologic disorders. It is intended primarily for UC and AD, which are historically underdiagnosed and undertreated globally and in China.

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UC

UC is a chronic immune-mediated inflammatory condition of the large intestine that is frequently associated with inflammation of the rectum but often extends proximally to involve additional areas of the colon. In China, the prevalence of UC reached 541.6 thousand in 2023. According to Frost & Sullivan, approximately 70% of Chinese UC patients experience a moderate to severe disease course.

According to the Frost & Sullivan, aminosalicylates are the standard of care for the first-line treatment of adult UC and these agents are largely effective for mild to moderate disease. Moderate to severe UC can be provided with biologic therapies. However, for those patients who do receive biologics, approximately 30%-35% of moderate and severe UC patients fail to response to anti-TNF- α agents, and approximately 30%-40% of moderate and severe UC patients using anti-TNF- α agents are able to achieve one-year clinical remission. Furthermore, patients who respond to biologic drugs can lose response over time due to the development of anti-drug antibodies. In addition, the association of current conventional immunosuppressants and anti-TNF α agents with malignancy and opportunistic infections is not ideal. Finally, the subcutaneous or intravenous route of delivery is not convenient. Together, these circumstances suggest there is an opportunity for an effective and well-tolerated oral, small molecule drug to become established as the standard of care in China for UC.

AD

According to Frost & Sullivan, AD is a chronic, inflammatory skin disorder characterized by dry skin, intense itches and relapsing lesions. Atopic dermatitis has a severe impact on quality of life, including potential occupational, social, and psychological impairments. AD pathology is driven by a combination of impaired skin epithelial barriers, altered microbiota, and aberrant inflammation driven by activated immune cells, including skin-infiltrating T cells and dendritic cells.

According to Frost & Sullivan, the prevalence of AD in China reached 71.6 million in 2023, of which a sizable proportion are pediatric patients. According to Frost & Sullivan, approximately 25-30% of AD patients experience a moderate or severe disease course in the China. Several treatment options are available in China, including basic therapies to protect the skin barrier (e.g. moisturizers), topical therapy, systemic therapy, traditional Chinese medicine and phototherapy. Topical therapy includes corticosteroids, calcineurin inhibitors (Tacrolimus and Pimecrolimus), and antimicrobial agents. Systemic therapy includes antihistamines (loratadine and cetirizine), immunosuppressive drugs (cyclosporine and methotrexate), glucocorticoid and IL-4R α Inhibitor (dupilumab). Safety concerns limit the long-term use of the current treatment options, particularly for children, due to the increased body surface area to mass ratio in children, which results in increased absorption and systemic exposure. In addition, the current treatment options have been reported to be associated with side effects, including burning and tingling sensations at the application site. In the U.S., although JAK inhibitors have been approved for the treatment of AD, these drugs have been plagued by safety concerns and three of them, namely tofacitinib from Pfizer, upadacitinib from Abbvie, and

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baricitinib from Eli Lilly, received FDA boxed warnings of risks of serious heart-related events, cancer, blood clots and death, which limit the long-term use of current treatment regimens, especially in children. Therefore, there is a significant medical need for safer and more effective treatments for patients with moderate to severe AD.

Competitive Landscape

As of the Latest Practicable Date, there were three S1P receptor modulators approved by the NMPA, all of which were indicated for multiple sclerosis. There were six S1P receptor modulators in clinical development in China, three of which were indicated for UC or AD. For more details, see “Industry Overview – Small Molecule Non-Oncology Targeted Therapy – S1P1 – Competitive Landscape.”

Competitive Advantages

Highly selective S1P1 modulator with potential low cardiovascular adverse effect

As of the Latest Practicable Date, three S1P receptor modulators obtained approval from the NMPA, none of which were indicated for UC or AD. There were several selective S1P1 modulators currently in clinical trials in China, including etrasimod and TT-01688 (previously named as LC51-0255). Non-selective S1P receptor modulator, such as fingolimod, lacks of selectivity on other S1P receptor subtypes. Its non-selective modulation of S1P3, S1P4 and S1P5 may lead to unwanted cardiovascular AEs. In comparison, TT-01688 is highly selective for S1P1 and has a negligible effect on S1P2 and S1P3. Additionally, as illustrated in the chart below, TT-01688 had the least effect on GIRK *in vitro* when compared to other selective S1P1 modulators, ozanimod and etrasimod, suggesting a low cardiovascular risk. TT-01688 may also have a lower risk of clinical drug interactions than ozanimod, due to the fact that it has no effect on MAO-B *in vitro* and no detectable circulating metabolite in preclinical animal studies.

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Potency and selectivity of different clinical S1P1 modulators

Compounds	<i>in vitro</i> Assay (EC ₅₀ , nM)				
	S1P1 ⁽¹⁾	S1P2 ⁽¹⁾	S1P3 ⁽¹⁾	S1P4 ⁽¹⁾	GIRK ⁽²⁾
TT-01688	0.468	>1,000	>1,000	260	261
fingolimod	8.527	421	6.437	2.10	2.5
ozanimod	1.855	>1,000	>1,000	396.6	4.1
etrasimod	1.354	>1,000	>1,000	>1,000	42

Notes:

- (1) beta-Arrestin assay results.
- (2) G protein-coupled Inwardly Rectifying K⁺ channel in isolated rat atrial myocytes.

Source: LG Chem Data

The MAO-B inhibition of TT-01688 and the major metabolites of ozanimod

Compounds	<i>In vitro</i> MAO B Activity (IC ₅₀ , nM)
TT-01688⁽¹⁾	>10,000
CC112273⁽²⁾	5.7
CC1084037⁽²⁾	58

Notes:

- (1) No major circulating metabolite (>5%) of TT-01688 was found in preclinical metabolite analysis in rats.
- (2) The major metabolites of ozanimod found in human. Data refer to ozanimod NDA package NDA#209-899.

Source: LG Chem Data

Promising clinical pharmacodynamic efficacy

S1P1 modulators sequester lymphocytes in lymphoid tissues, resulting in decreased ALC levels in the peripheral circulation, which serves as a robust mechanical pharmacodynamic marker for clinical trials. While no head-to-head clinical trials have been conducted and caution should be exercised when making cross-trial comparisons, as demonstrated in the results from the Phase I clinical trial outlined in charts below, TT-01688’s pharmacodynamic efficacy was comparable to or superior to that of its competitors ozanimod and etrasimod. TT-01688 at a dose of 0.5mg administered over a 21-day period had a similar effect on lymphocyte subtypes reduction as ozanimod at a dose of 1.5mg administered over a 28-day period and etrasimod at a dose of 2mg administered over a 21-day period.

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Phase I pharmacodynamic efficacy (ALC reduction)⁽⁴⁾

	Lymphocyte subtype	Phenotype	TT-01688 ⁽¹⁾			
			0.25 mg (n=8)	0.5 mg (n=8)	1 mg (n=8)	1.5 mg (n=8)
			Day 21	Day 21	Day 21	Day 21
Helper	Naïve T cells	CD4 ⁺ CCR7 ⁺ CD45RA ⁺	-69	-90	-98	-98
	Central memory	CD4 ⁺ CCR7 ⁺ CD45RO ⁺	-55	-86	-95	-95
	TEMRA	CD4 ⁺ CCR7 ⁻ CD45RA ⁺	-67	-73	-96	-90
	Effector memory	CD4 ⁺ CCR7 ⁻ CD45RO ⁺	-47	-74	-87	-80
Cytotoxic	Naïve T cells	CD8 ⁺ CCR7 ⁺ CD45RA ⁺	-69	-90	-95	-93
	Central memory	CD8 ⁺ CCR7 ⁺ CD45RO ⁺	-9	-73	-50	-59
	TEMRA	CD8 ⁺ CCR7 ⁻ CD45RA ⁺	-20	-37	-40	-25
	Effector memory	CD8 ⁺ CCR7 ⁻ CD45RO ⁺	-30	-43	-26	-57
	Total T cells	CD3 ⁺ CD20 ⁻	-50	-71	-76	-74
	B cells	CD3 ⁻ CD20 ⁺	-63	-83	-90	-88

	Lymphocyte subtype	Phenotype	ozanimod ⁽²⁾
			1.5 mg (n=4)
			Day 28
Helper	Naïve T cells	CD4 ⁺ CCR7 ⁺ CD45RA ⁺	-86
	Central memory	CD4 ⁺ CCR7 ⁺ CD45RO ⁺	-88
	TEMRA	CD4 ⁺ CCR7 ⁻ CD45RA ⁺	-3
	Effector memory	CD4 ⁺ CCR7 ⁻ CD45RO ⁺	-69
Cytotoxic	Naïve T cells	CD8 ⁺ CCR7 ⁺ CD45RA ⁺	-85
	Central memory	CD8 ⁺ CCR7 ⁺ CD45RO ⁺	-83
	TEMRA	CD8 ⁺ CCR7 ⁻ CD45RA ⁺	+7
	Effector memory	CD8 ⁺ CCR7 ⁻ CD45RO ⁺	-39
	Total T cells	CD3 ⁺ CD20 ⁻	-68
	B cells	CD3 ⁻ CD20 ⁺	-77

	Lymphocyte subtype	Phenotype	TT-01688 ⁽¹⁾			
			0.25 mg (n=8)	0.5 mg (n=8)	1 mg (n=8)	1.5 mg (n=8)
			Day 21	Day 21	Day 21	Day 21
	T-helper	CD3 ⁺ CD4 ⁺	-58	-83	-94	-90
	T-cytotoxic	CD3 ⁺ CD8 ⁺	-43	-63	-56	-64
	T-naïve	CD3 ⁺ CCR7 ⁺ CD45RA ⁺	-69	-90	-97	-96
	T-effector memory	CD3 ⁺ CCR7 ⁻ CD45RA ⁻	-40	-59	-67	-61
	T-central memory	CD3 ⁺ CCR7 ⁺ CD45RA ⁻	-47	-84	-90	-91
	B cell	CD19 ⁺	-63	-83	-90	-88

	Lymphocyte subtype	Phenotype	etrasimod ⁽³⁾
			2 mg (n=10)
			Day 21
	T-helper	CD3 ⁺ CD4 ⁺	-81
	T-cytotoxic	CD3 ⁺ CD8 ⁺	-43
	T-naïve	CD3 ⁺ CCR7 ⁺ CD45RA ⁺	-80
	T-effector memory	CD3 ⁺ CCR7 ⁻ CD45RA ⁻	-13
	T-central memory	CD3 ⁺ CCR7 ⁺ CD45RA ⁻	-62
	B cell	CD19 ⁺	-73

Notes:

(1) Source: LG Chem data

(2) Source: Jonathan Q, Tran, et al. The Journal of Clinical Pharmacology, 2017

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- (3) Source: Laurent Peyrin-Biroulet, abstracts of the 13th Congress of ECCO
- (4) The comparison not from a head-to-head study involves risks and may not be representative of all the relevant clinical trial data. You are cautioned to not place undue reliance on the above trial results.

Clinical Tolerability

Tolerability profile of TT-01688 was assessed in Phase I clinical trials in healthy adult subjects. TT-01688 is well-tolerated with all the AEs being mild or moderate in severity. One subject in 1mg MAD group was diagnosed with colonic diverticulitis on the last dosing day. After administration of intravenous antibiotics (metronidazole and cefotaxime), the AE resolved without sequelae. This event was assessed as moderate. No case of study discontinuation due to AEs has occurred. The most common TEAE was bradycardia and all bradycardia events were resolved without any action.

Summary of Clinical Trials

Phase I clinical trial in healthy subjects by LG Chem

Trial Design. This Phase I clinical trial was sponsored by LG Chem. The primary objective of this study was to evaluate the safety, tolerability and PK/PD characteristics of single and multiple ascending doses of TT-01688 as a potential treatment of inflammatory diseases such as UC. It was a randomized, double-blind, placebo-controlled study. There were five single-dose cohorts (0.25mg, 0.5mg, 1mg, 2mg and 4mg) and another five multiple-dose cohorts (0.25mg, 0.5mg, 1mg, 1.5mg and 2mg) in this study.

Trial Status. LG Chem has completed this Phase I clinical trial in healthy subjects in South Korea.

Trial Results. TT-01688 was well tolerated at all doses tested in this study. All AEs were mild or moderate in severity. The most common TEAE was bradycardia and all bradycardia events were resolved without any action. The table below summarizes drug-related TEAEs in the MAD study.

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	Placebo (n=10)	0.25 mg (n=8)	0.5 mg (n=8)	1 mg (n=8)	1.5 mg (n=8)	2 mg (n=8)
TEAEs	5(50%)	6(75%)	5(62.5%)	6(75%)	6(75%)	6(75%)
Severity						
Mild	5(50%)	6(75%)	5(62.5%)	6(75%)	6(75%)	6(75%)
Moderate	0(0)	0(0)	0(0)	1(12.5%)	0(0)	0(0)
Severe	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
Drug-Related TEAEs	4(40%)	2(25%)	4(50%)	4(50%)	6(75%)	6(75%)
Serious TEAEs	0(0)	0(0)	0(0)	1(12.5%)	0(0)	0(0)

Note: Event data is presented as the number of subjects (percentage of subjects).

Source: LG Chem Data

S1P1 modulators sequester lymphocytes in the lymphoid tissues, resulting in reductions in ALC in peripheral circulation, which provides a robust mechanical PD marker for a clinical study. Dose dependent reductions in ALC were observed at all doses of TT-01688 in Phase I MAD study. After 21 days of treatment, the mean maximum decrease in ALC from baseline ranged from 62% to 88%. ALC recovered to baseline within 14 days of discontinuation.

Conclusion. In Phase I clinical trial, TT-01688 was well tolerated in healthy subjects when administered once daily for 21 days at dose levels ranging from 0.25 mg to 2 mg. Systemic exposure was dose-proportional, and the PK profile showed that it may be amenable for a once-daily regimen. PD biomarker ALC displayed a dose-dependent reduction. These results support further evaluation of TT-01688 in late stage clinical trials in UC and other inflammatory indications.

Phase Ib clinical trial in healthy subjects and UC patients

Trial Design. This is a randomized, double-blind, parallel Phase Ib study to evaluate the safety, pharmacokinetics, and pharmacodynamics of TT-01688 in healthy subjects and patients with moderate-to-severe active UC. This study is being conducted in China. The study consists of two parts. In Part A, the healthy subjects will receive either 1.5mg fixed dose or 1.5mg titration dose (QD) of TT-01688 for 21 consecutive days. In Part B, UC patients will receive 0.5 mg, 1.0mg, or 1.5mg (QD) of TT-01688, or placebo (QD) for 21 consecutive days.

The primary endpoint is safety. The secondary endpoints include PK and PD.

Trial Status. We initiated this trial in May 2022. As of the Latest Practicable date, the trial was on-going.

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Phase II clinical trial in AD patients

Trial Design. This is a randomized, double-blind, placebo-controlled, parallel-group, Phase II study to evaluate the clinical efficacy and safety of TT-01688 in subjects with moderate-to-severe atopic dermatitis. This study is being conducted in China. The patients will receive 0.5mg, 1mg, or 1.5mg (QD) of TT-01688, or placebo (QD) for 16 consecutive weeks.

The primary endpoint is the change of EASI score compared to the base line. The secondary endpoints include efficacy (including evaluation under EASI, EASI-75, EASI-90, Investigator’s Global Assessment, Body Surface Area, Peak Pruritus Numerical Rating Scale, Dermatology Life Quality Index, Patient-Oriented Eczema Measure), safety, tolerability, and PK.

Trial Status. We initiated this trial in September 2022. As of the Latest Practicable date, the trial was on-going.

Clinical Development Plan

We are currently conducting a Phase Ib study for UC and a Phase II study for AD in China, which we expect to complete in the second half of 2024.

Licenses, Rights and Obligations

We in-licensed TT-01688 from LG Chem in April 2021 for development in Greater China as described under “– Collaboration and License Agreements – License-in Agreement with LG Chem” below. We were granted an exclusive license right to use, research, develop, manufacture, commercialize and otherwise exploit TT-01688 in Greater China.

Material Communications

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

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TT-01688 SUCCESSFULLY.

TT-00920: Oral PDE9 Inhibitor

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Overview

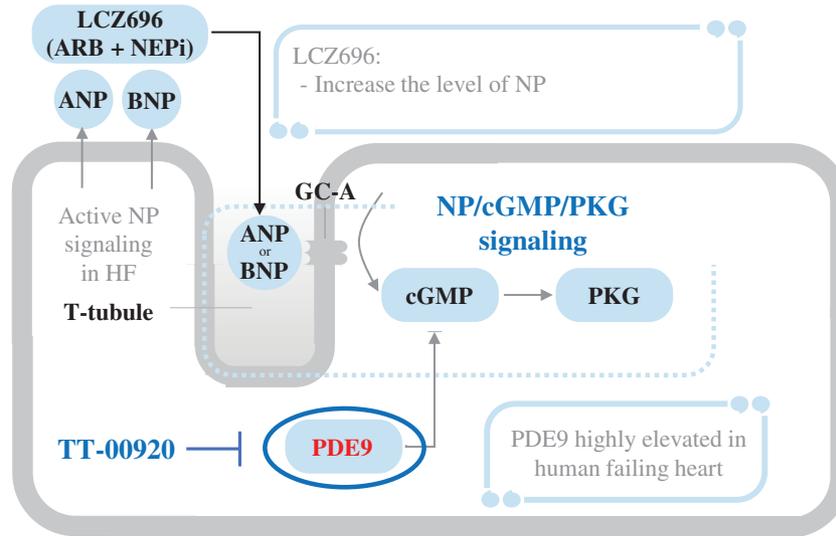
TT-00920 is an internally discovered and developed, highly selective, oral PDE9 inhibitor targeting chronic heart failure with a novel biological mechanism and strong disease rationale. PDE9 expresses in cardiomyocytes, the protein level of which is markedly elevated in heart failure patients, associated with ventricular dysfunction. PDE9 negatively modulates the intrinsic cardioprotective coupled cGMP signaling pathway. TT-00920 activates cardioprotective NP/cGMP pathway by inhibiting PDE9, its unique mechanism of action shows that it has the potential to act synergistically with current therapeutic approaches to form an improved treatment regimen for HFpEF and HFrEF. In preclinical studies, TT-00920 restored cardiac NP/cGMP signaling and remarkably enhanced cardiac function and reversed ventricular remodeling in heart failure. TT-00920 is highly selective for PDE9, and its target safety has been validated by other investigational PDE9 inhibitors targeting CNS diseases. Compared to CNS targeted PDE9 inhibitors such as BI-409306 and PF-04447943, TT-00920 exhibits low CNS exposure and high heart distribution, which facilitates the treatment of heart failure and potentially lowers CNS adverse effects. We have completed two Phase I studies in the U.S. and one Phase I study in China in healthy subjects in 2022 and 2023, respectively.

Mechanism of Action

NP/cGMP signaling regulates cardiomyocyte growth, survival, and stress response, and its activation is cardioprotective. PDE9 catalyzes the hydrolysis of cGMP and negatively modulates cardiac NP/cGMP signaling. In human heart failure, particularly in HFpEF, PDE9 expression and activity are strongly enhanced in cardiomyocytes, blunting NP/cGMP signaling and making the heart more susceptible to failure, suggesting that PDE9 may play a critical role in NP/cGMP signaling in failing hearts. In addition, PDE9 levels are associated with left ventricular filling pressure, left ventricle size as a marker of diastolic burden and right ventricular function in heart failure. Genetic or pharmacological inhibition of PDE9 increases NP/cGMP signaling and reverses pre-established heart disease in a number of heart failure animal models. Close disease link, promising pathway validation and compelling preclinical results strongly support inhibition of PDE9 as an attractive therapeutic strategy for the treatment of chronic heart failure, including HFrEF and HFpEF. By inhibiting PDE9, TT-00920 is expected to synergize mechanistically with current therapies, including Entresto (LCZ696) and angiotensin receptor blockers to form an improved treatment option, especially for HFpEF. The diagram below shows the mechanism of action of PDE9 inhibitors for chronic heart failure.

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TT-00920, a PDE9 inhibitor, activates cardioprotective NP/cGMP/PKG signaling



→ Stimulation/Induction/Activation; —| Inhibition

Abbreviations: ARB=angiotensin II receptor blocker; NEP=neutral endopeptidase; ANP=atrial natriuretic peptide; BNP=brain natriuretic peptide; GC-A=guanylate cyclase-A; cGMP=cyclic guanosine monophosphate; PKG=protein kinase G; PDE9=phosphodiesterase 9; PDE9i=PDE9 inhibitor.

Source: Company data

Market Opportunity and Competition

TT-00920 is intended primarily for the treatment of chronic heart failure. Chronic heart failure is a complex set of clinical syndromes caused by myocardial structure and function changes leading to impaired ventricular ejection or filling function. It is a common terminal stage of a variety of cardiac disorders and also a disease associated with high morbidity and mortality.

Globally, the frequency and incidence of chronic heart failure have been continuously increasing. The global prevalence of heart failure increased from 29.1 million in 2018 to 32.4 million in 2023. Patients with heart failure are classified into two groups according to their left ventricular ejection fraction: HFrEF and HFpEF. Each has its own distinct pathophysiology. The prognosis for heart failure can only be improved when myocardial remodeling is controlled. However, most of the drugs currently approved for heart failure are neurohormonal modulators, and few directly target cardiomyocytes to improve primary cardiac pathology.

Currently, the treatment options for HFpEF remain limited, and most approved drugs for HFrEF are ineffective for HFpEF. A number of clinical trials addressing the effects of drugs on HFpEF are underway, which may provide medical evidence for the future treatment of HFpEF.

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As of the Latest Practicable Date, there was no PDE9 inhibitor approved for commercialization globally or in China. As of the Latest Practicable Date, there were five PDE9 inhibitors in clinical trial globally, but only two of them, including our TT-00920, were indicated for heart failure. In China, TT-00920 is the only PDE9 inhibitor under clinical development for the treatment of chronic heart failure, which acted directly on cardiomyocytes to mechanistically synergize with current therapeutic approaches to form an improved treatment regimen for both HFrEF and HFpEF. For more details, see “Industry Overview – Small Molecule Non-oncology Targeted Therapy – PDE9 Inhibitor – Competitive Landscape.” Although the FDA approved entresto and sotagliflozin (a SGLT2 inhibitor functions through a different mechanism of action than TT-00920) for HFpEF, there is still an unmet need for more effective HFpEF treatment with different mechanisms of action.

Competitive Advantages

Compelling efficacy in heart failure

TT-00920 is a potent PDE9 inhibitor with an IC₅₀ of 6.5 nM from *in vitro* biochemical studies and is highly selective (>100-fold) over other PDE subtypes. In *in vitro* cellular assays, TT-00920 enhanced NP-coupled cGMP. TT-00920 significantly improved cardiac function and protected against cardiac remodeling and fibrosis in a dose-dependent manner in a preclinical myocardial infarction heart failure model in rats, as shown in the figure, with comparable efficacy to the recently FDA-approved drug for chronic heart failure, LCZ696 which is a combination of angiotensin receptor blocker valsartan and neprilysin inhibitor sacubitril. Additionally, although not statistically significant, compared to TT-00920 monotherapy, the combination of TT-00920 and valsartan (an angiotensin receptor blocker) demonstrated a trend of improved efficacy, indicating that TT-00920 may have an additive or synergistic effect with current treatment options in heart failure, including RAAS and Entresto (LCZ696). TT-00920 appears to be a promising oral therapy for chronic heart failure based on current pharmacological findings.

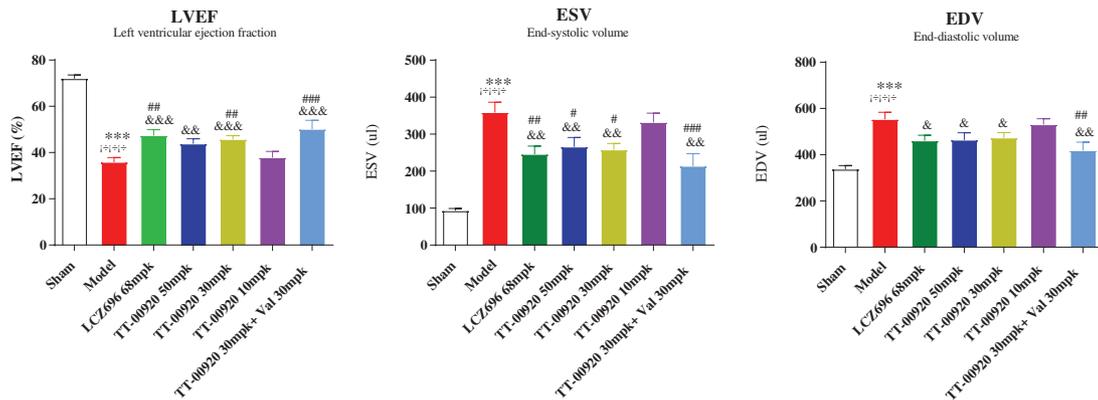
TT-00920 is a potent highly selective PDE9 inhibitor

Human PDE subtype IC ₅₀ (nM)	9A2	1A1	2A	3A	4A1A	4B1	4D3	5A1	6C	7A	8A	10A1	11A
TT-00920	6.5	871	>3000	>3000	>3000	>3000	>3000	>3000	2172	>3000	>3000	>3000	>3000

Source: Company data

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TT-00920 demonstrated dose-dependent efficacy in heart failure rat model



***P<0.001 vs Sham, #P<0.05, ##P<0.01, ###P<0.001 vs Model, by one-way ANOVA Dunnett's test; †††††P<0.001 vs Sham, &P<0.05, &&P<0.01, &&&P<0.001 vs Model, by T-test.

Abbreviation: val=valsartan

Source: Company Data

Potential promising safety profile

As of the Latest Practicable Date, there were no PDE9 inhibitors approved by the FDA. There were a few PDE9 inhibitors in clinical studies for CNS diseases, including BI-409306 from Boehringer Ingelheim, PF-04447943 from Pfizer and E2027 from Eisai. Boehringer Ingelheim, Pfizer and Eisai developed their investigational PDE9 inhibitors for schizophrenia, Alzheimer and Lewy body dementia. Clinical data showed that these PDE9 inhibitors were generally tolerated in patients, validating the clinical safety of the PDE9 inhibitors. The primary adverse effects reported by these PDE9 inhibitors, including headache, somnolence and dizziness, which may likely be CNS related and mainly attributed to the high brain penetration of these compounds. The table below sets forth the multiple PDE9 inhibitors in early clinical studies for CNS diseases, which shows their high brain penetration rate.

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Multiple PDE9 inhibitors in Early Clinical Studies for CNS Diseases⁽⁷⁾

Compound	Company	Indication	Status	Brain penetration (reported)
BI-409306	Boehringer Ingelheim	Alzheimer	Phase II ⁽¹⁾	28% (human) ⁽³⁾
		Schizophrenia	Phase II ⁽²⁾	
PF-04447943	Pfizer	Alzheimer	Phase II ⁽⁴⁾	32% (rat) ⁽⁵⁾
E2027	Eisai	Dementia with Lewy Bodies	Phase II ⁽⁶⁾	Not reported

Notes:

- (1) This Phase II study (NCT02240693 and NCT02337907) is an evaluation of the efficacy, safety and tolerability of orally administered BI-409306, a novel phosphodiesterase type 9 inhibitor, in two randomized controlled studies in patients with prodromal and mild AD. Overall, the clinical data did not demonstrate efficacy of BI-409306 in improving cognition in patients with prodromal and mild AD but BI-409306 is well tolerated.
- (2) This is an Phase II (NCT02281773) randomized, double-blinded, placebo-controlled study to evaluate the efficacy, safety, and tolerability of four orally administered doses of BI-409306 during a 12-week treatment period in patients with schizophrenia on stable antipsychotic treatment. The primary endpoint of cognitive function improvement was not met. BI-409306 was well-tolerated, with an acceptable safety profile.
- (3) Data represents the ratio of C_{max} in CSF (cerebrospinal fluid) compared with that of plasma in human given an oral dose of 200mg.
- (4) This is a Phase II (NCT00930059) multicenter, double-blind, placebo-controlled, parallel group study of PF-04447943 in subjects with mild to moderate AD. Although generally safe and well-tolerated, 12 weeks PF-04447943 treatment did not improve cognition and behavior compared with placebo.
- (5) Data represents the ratio of the CNS permeability in rats (free brain/free plasma).
- (6) This is Phase II (NCT03467152) a placebo-controlled, double-blind, parallel-group, randomized, study to evaluate the efficacy, safety and tolerability of E2027 in subjects with Lewy body dementia. The results were not reported.
- (7) Clinical data is not based on head-to-head studies, clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.

Source:

1. Katja Boland, et al. *Hum Psychopharmacol*. 2017.
2. Michelle M. Claffey et al. *J. Med. Chem*. 2012.
3. Linda A. Hershey, et al. *Drugs Aging*. 2019.
4. clinicaltrial.gov
5. Frölich L, Wunderlich G, et al. *Alzheimers Res Ther*. 2019
6. Brown, David, et al. *Schizophrenia Bulletin*. 2018
7. Elias M S, et al. *Curr Alzheimer Res*. 2014

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In contrast, TT-00920 is designed to be a low CNS exposure compound, and has demonstrated significant lower brain penetration in animal study, suggesting minimal CNS-related AE. Compared to other investigational PDE9 inhibitors for CNS indications such as PF-04447943, TT-00920 exhibited a potential minimal CNS exposure and high cardiac distribution, which facilitates the treatment of heart failure and potentially lowers CNS adverse effects.

The brain/heart/plasma distribution of TT-00920 and PF-04447943 in rats

Compound	Tissue Distribution	
	Brain/Plasma	Heart/Plasma
PF-04447943	45%	69%
TT-00920	6%	226%

Notes:

- (1) Data represents the brain/plasma and heart/plasma ratio at T_{max} in rats given an oral dose of 10 mg/kg.
- (2) Data for brain/heart/plasma distribution of TT-00920 and PF-04447943 was derived from head-to head studies in rats.

Source: Company Data

Summary of Clinical Trials

Phase I clinical trial in the U.S. and China in healthy subjects

SAD study conducted in the U.S.

Trial Design. This is a first-in-human, randomized, double-blind, placebo-controlled SAD study in healthy subjects, which was conducted in the U.S. The primary objectives of the study were to investigate the safety and tolerability and determine the PK profiles. The secondary objectives of the study were to assess the effect of food on the PK of TT-00920 following an oral dose. 34 subjects were enrolled in this study to assess the safety, tolerability, and PK profile and eight subjects for food effect ("FE") evaluation.

Trial Status. We have completed the study in April 2022.

Safety Profile. There were no deaths, SAEs, or TEAEs leading to discontinuation reported during the study in both SAD and FE cohorts. In SAD cohorts, all TEAEs were mild in severity. In FE cohorts, all TEAEs were mild or moderate in severity.

Conclusions. The results showed that oral administration of a single dose of TT-00920 tablets (20-2000 mg) was safe and well tolerated in healthy subjects. All AEs were mild to moderate, and no SAEs were reported. Clinical PK results showed that over the dose range of 100 mg to 1500 mg, peak TT-00920 plasma concentrations appeared to increase in a slightly

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greater than dose-proportional manner. In the presence of food, the TT-00920 primary PK parameters, C_{max} , AUC_{0-t} and $AUC_{0-\infty}$ increased by approximately 60%, 70% and 66%, respectively. Though not formally tested, the presence of food did not appear to change T_{max} .

MAD study conducted in the U.S.

Trial Design. The study is a MAD study, which comprised of two cohorts with 10 subjects per cohort. Subjects received either TT-00920 or placebo for fourteen consecutive days (three times daily) to explore the primary objective of the safety and tolerability of multiple ascending oral doses of TT-00920 in healthy subjects.

Trial Status. We have completed the study in November 2021.

Safety Profile. There were no deaths, SAEs, or TEAEs leading to discontinuation reported during the study.

Conclusions. The observed clinical manifestations, including orthostatic hypotension, tachycardia, and palpitations, were indicative of the association of the study drug with cardiovascular effect. Clinical PK results showed that over the dose range of 500 mg to 1000 mg, TT-00920 exposure appeared to increase in a slightly greater dose-proportional manner.

SAD and MAD study conducted in China

Trial Design. This is a randomized, double-blind, placebo-controlled study in healthy subjects, which was conducted in China. The study was a SAD and MAD study. Subjects in this study received a single dose of TT-00920 tablets during a single dose period, followed by a three to ten-day washout period, and then entered a seven-day multiple dose period, in which subjects received study drug three times daily. There were three cohorts with ten subjects per cohort. The primary objectives of the study were to investigate the safety and tolerability of TT-00920. The secondary objectives of the study were to assess the PK profile of TT-00920 following an oral dose.

Trial Status. We have completed the study in June 2022.

Safety Profile. There were no deaths, SAEs reported during the study. All TEAEs were mild in severity.

Conclusions. The results showed that oral administration of a single dose of TT-00920 tablets of 300 to 800 mg, and multiple doses of TT-00920 of 300 to 500 mg were safe and well tolerated. Clinical PK results showed that over the dose range of 300 to 500 mg, C_{max} of TT 00920 plasma concentrations appeared to increase in a slightly lower than dose-proportional manner and both AUC_{0-t} and $AUC_{0-\infty}$ increased in a dose-proportional manner.

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Licenses, Rights and Obligations

As TT-00920 is internally discovered and developed by us, we maintain the global rights to develop and commercialize TT-00920.

Material Communications

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

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TT-00920 SUCCESSFULLY.

TT-01025: Irreversible VAP-1 Inhibitor

Overview

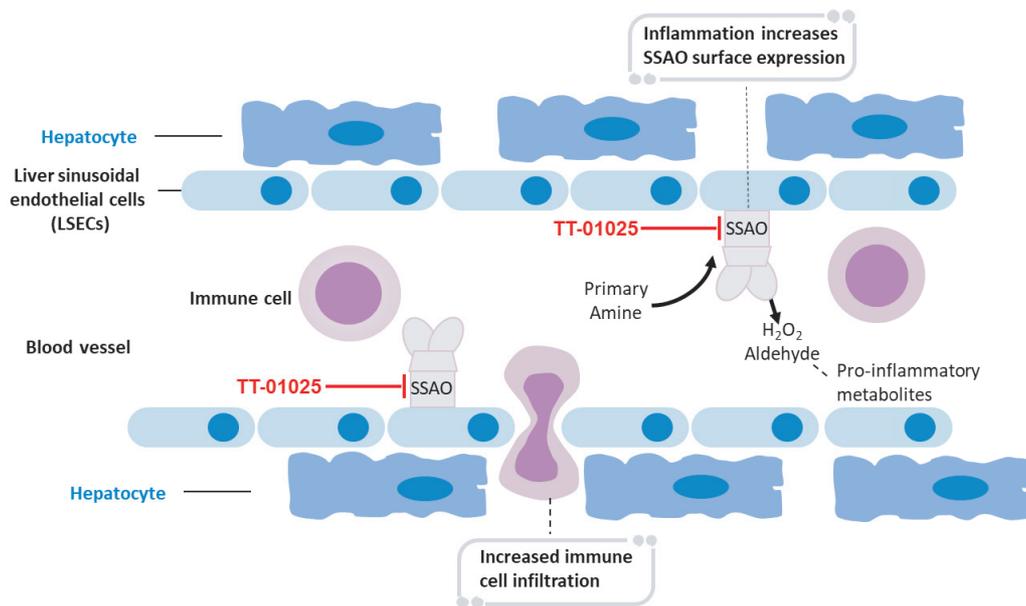
TT-01025 is an internally discovered and developed, irreversible VAP-1 inhibitor, intended as an oral treatment for NASH. We licensed-out TT-01025 to LG Chem and retained the development and commercialization rights in Greater China and Japan. VAP-1 is a novel clinical target for anti-inflammation, and its potential for the treatment of NASH had been demonstrated by a competitor VAP-1 inhibitor, BI-1467335, in a Phase II study. However, according to Frost & Sullivan, the clinical development of BI-1467335 was discontinued due to the risk of drug interaction of the compound, specifically CNS MAO-B inhibition. In a Phase I study (NCT03927209) of BI-1467335 in healthy subjects, significant CNS MAO-B inhibition (72.58%) was found. It is found that concurrent use of any MAO inhibitor may potentially increase the risk of serotonin syndrome including behavior/cognitive symptoms and somatic effects. Preclinical data indicated that two factors contribute to the CNS MAO-B inhibition of BI-1467335, namely high brain penetration and off-target MAO-B inhibition at its effective dose level. In contrast, a head-to-head comparison in preclinical studies showed that TT-01025 has very low brain penetration and highly selective with no significant MAO-B inhibition at 100µM, suggesting the risk of such drug interactions in TT-01025 is minimal. We completed the Phase I study of TT-01025 in healthy subjects in China in April 2022.

Mechanism of Action

VAP-1, also known as semicarbazide sensitive amine oxidase, catalyzes the oxidative conversion of endogenous primary amines to the corresponding cytotoxic aldehydes and hydrogen peroxide. VAP-1 is expressed in the human hepatic endothelium acting as a cell adhesion molecule and plays an important role in leukocyte adhesion and transmigration in the liver. This function is dependent on the amine oxidase enzyme activity of VAP-1. The level of its circulating soluble form (sVAP-1) increases during liver inflammation and is known to correlate with disease severity and the presence of fibrosis in NASH. Genetic or pharmacological inhibition of VAP-1 enzyme activity has shown reduction of oxidative stress and recruitment of inflammatory cells to the liver and also attenuation of fibrosis in multiple preclinical NASH models. The diagram below shows the mechanism of action of TT-01025.

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TT-01025, a VAP-1 inhibitor, reduces immune cell infiltration and oxidative stress



→ Stimulation/Induction/Activation; —| Inhibition

Abbreviations: SSAO=semicarbazide-sensitive amine oxidase; H₂O₂=hydrogen peroxide.

Source: Company data

Market Opportunity and Competition

TT-01025 is intended primarily to treat NASH, a progressive form of non-alcoholic fatty liver disease characterized by hepatic steatosis without alcohol abuse. NASH is characterized by ballooning degeneration and lobular inflammation with or without hepatic fibrosis, in addition to steatosis in the liver. Patients with NASH can progress to cirrhosis and are at increased risk of death resulting from liver disease. According to Frost & Sullivan, in 2023, the prevalence of the NASH reached 386.1 million globally and 42.5 million in China, respectively.

As there is no approved VAP-1 inhibitor drug for NASH treatment, for patients within late-stage NASH, the disease is almost irreversible. In March 2024, the FDA approved Rezdiffra (resmetirom) for the treatment of adults with NASH with moderate to advanced liver scarring (fibrosis), to be used along with diet and exercise. Previously, patients with NASH who also have notable liver scarring did not have a medication that could directly address their liver damage. Rezdiffra's approval will, for the first time, provide a treatment option for these patients, in addition to diet and exercise. In both the U.S. and China, the treatment of NASH can be divided into lifestyle intervention, drug intervention, and surgical intervention. The prevention and treatment of metabolic syndrome, type 2 diabetes mellitus, and other comorbidities are important. Despite the newly approved drug Rezdiffra, NASH treatment still focuses on a multi-mechanistic strategy of combination therapy, given the complexity in pathophysiology and the heterogeneous nature of the disease.

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As of the Latest Practicable Date, there was no VAP-1 inhibitor either approved by the FDA or the NMPA. As of the Latest Practicable Date, there were seven VAP-1 inhibitors at clinical stage globally, but only three were for the treatment of NASH. Meanwhile, as of the Latest Practicable Date, TT-01025 stood out as the only VAP-1 inhibitor that was in clinical trial in China. For more details, see “Industry Overview – Small Molecule Non-Oncology Targeted Therapy – VAP-1 Inhibitor – Competitive Landscape.”

Competitive Advantages

Clear differentiation on low risk of drug interaction

BI-1467335 is an irreversible VAP-1 inhibitor and had been evaluated in Phase II clinical trials for NASH. The Phase II NASH study outcomes demonstrated positive effectiveness, validating the potential of VAP-1 inhibition for NASH indication. However, its clinical development was discontinued following the discovery of substantial drug interactions of the compound in clinical studies.

In a Phase I study (NCT03927209) of BI-1467335 in healthy subjects, significant CNS MAO-B inhibition (72.58%) was found, which contributes to its risk of drug interaction. It is also found that concurrent use of any MAO inhibitor may potentially increase the risk of serotonin syndrome including behavior/cognitive symptoms and somatic effects. Preclinical data indicated that two factors contribute to the CNS MAO-B inhibition of BI-1467335, namely high brain penetration and off-target MAO-B inhibition at its effective dose level. In contrast, TT-01025 exhibited significantly lower brain penetration in rats and remarkable selectivity against other amine oxidases, including MAO-B (>4700-fold), in an *in vitro* biochemical assay, suggesting the risk of such drug interactions in TT-01025 is minimal.

The brain/plasma distribution of BI-1467335 and TT-01025 in rats

Compound	Brain/Plasma ratio
BI-1467335	134%
TT-01025	≤3.1%

Note: Data represents the brain/plasma ratio at T_{max} in rats given an oral dose of 10mg/kg in a head-to-head comparison study.

Source: Company data

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Biochemical IC₅₀ of TT-01025 and BI-1467335 on amine oxidases

Amine Oxidase IC ₅₀ (μM)	BI-1467335	TT-01025
VAP-1	0.006	0.021
MAO-B	5.7	>100
AOC2	7.4	41.4

Source: Company data

CYP enzymes can be inhibited or induced by drugs, resulting in clinically significant drug-drug interactions that can cause unanticipated adverse reactions or therapeutic failures. Comparing with BI-1467335, TT-01025 shows no inhibition on major CYP enzymes (no substantial inhibition at 100μM), indicating that it carries a low risk of drug-drug interaction and is suitable for possible combination studies in patients with NASH.

CYP inhibition of BI-1467335 and TT-01025

CYP inhibition IC ₅₀ (μM)	BI-1467335	TT-01025
1A2	14.1	>100
2C9	24.1	>100
2C19	4.71	>100

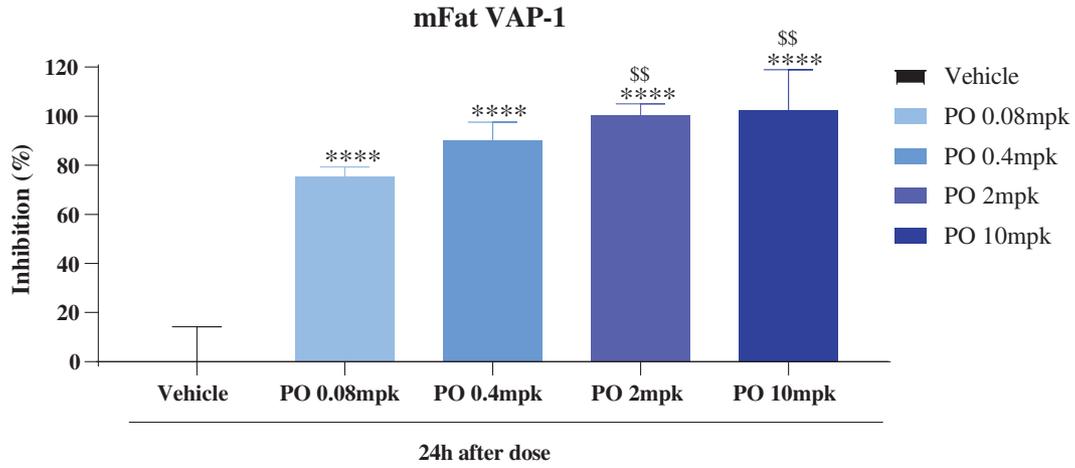
Source: Company data

Compelling preclinical efficacy

The preclinical *in vivo* pharmacodynamic effects of TT-01025 were evaluated after a single oral administration of TT-01025 in normal C57BL/6 mice at 0.08 mg/kg, 0.4 mg/kg, 2 mg/kg and 10 mg/kg. TT-01025 showed a dose-dependent inhibition on epididymis adipose VAP-1 activity for up to 24 hours after dosing, and confirmed a lasting inhibition of VAP-1 *in vivo* (>24 hours). In a model of streptozotocin/high-fat diet induced NASH model in mice, TT-01025 at an oral dose of 10 or 20 mg/kg led to notable improvement in NAS score and liver fibrosis.

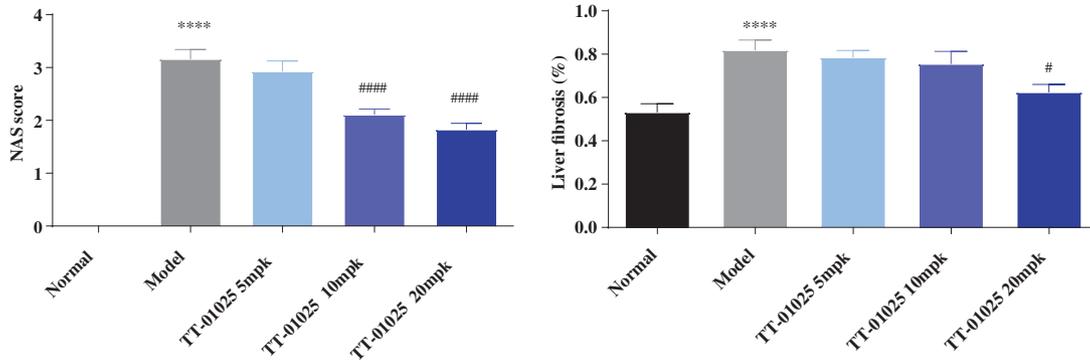
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Dose-dependent VAP-1 Inhibition *In Vivo*



****p<0.001 vs Vehicle, \$\$p<0.01 vs PO 0.08mpk, by one-way ANOVA Dunnett's Test

In Vivo Efficacy Study in NASH Model



NAS Score

Notes: One-way ANOVA, Dunnett's test:
 ***P<0.001 vs. normal group;
 ###P<0.001 vs. model group

Liver Fibrosis

Notes: One-way ANOVA, Dunnett's test:
 ***P<0.001 vs. normal group;
 #P<0.05 vs. model group

Source: Company data

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Summary of Clinical Trial

Phase I clinical trial in China in healthy subjects

Trial Design. This is a first-in-human, randomized, double-blind, placebo-controlled, Phase I SAD and MAD study of TT-01025 in healthy subjects. The study contained two parts, SAD and MAD, each with multiple cohorts dosing orally. SAD included five cohorts. The starting dose in SAD was 10mg. The dose levels for dose escalation were 10mg, 40mg, 100mg, 200mg and 300 mg in the fasted state. MAD comprised of three cohorts. The dose levels in MAD were 20mg, 40mg, 100mg. Subjects received TT-01025 or placebo once daily for seven consecutive days in a fasted state. The primary objectives of the study were to investigate the safety and tolerability of SAD and MAD of TT-01025 in healthy subjects. The secondary objectives were to determine the PK profiles and to evaluate the PD biomarker changes following SAD and MAD of TT-01025 in healthy subjects. The competent authority of this trial is the NMPA.

Trial Status. This trial was completed in April 2022.

Trial results. A total of 36 (single-dose group) and 24 (multiple-dose group) subjects were enrolled in the study. No serious AEs were reported, and no subject discontinued due to an AE. All TEAEs were mild and moderate in intensity. No dose-dependent increase in intensity or frequency of events was observed. TT-01025 was rapidly absorbed after administration. In the SAD study, PK was linear in the range of 100 to 300 mg. Complete inhibition (>90%) of SSAO activity was observed at 0.25 to 0.5 hours post-dose and was maintained 48 to 168 hours post-dose. In the MAD study, steady state was reached by day 5 in the 20mg-100mg dose groups. Negligible accumulation was observed after repeated dosing. PK was linear in the range of 20 to 100 mg. Plasma methylamine appeared to plateau at doses of 20 mg and above. SSAO activity in plasma was persistently inhibited throughout the treatment period. No evident change of methylamine and SSAO activity was observed in the placebo groups.

Conclusion. TT-01025 was safe and well-tolerated at a single dose of up to 300 mg and multiple doses of up to 100 mg. The absorption and elimination occurred rapidly in plasma. Linearity in plasma exposure was observed. TT-01025 inhibited SSAO activity rapidly and persistently in human. The profile of TT-01025 demonstrated suitability for further clinical development.

Licenses, Rights and Obligations

We licensed-out TT-01025 to LG Chem in 2020. LG Chem and we mutually agreed to terminate this license-out arrangement in 2023. We maintain the global rights to develop and commercialize TT-01025.

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Material Communications

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

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TT-01025 SUCCESSFULLY.

PRECLINICAL PRODUCTS

TT-02332: A novel, highly potent, selective NLRP3 inhibitor

Overview

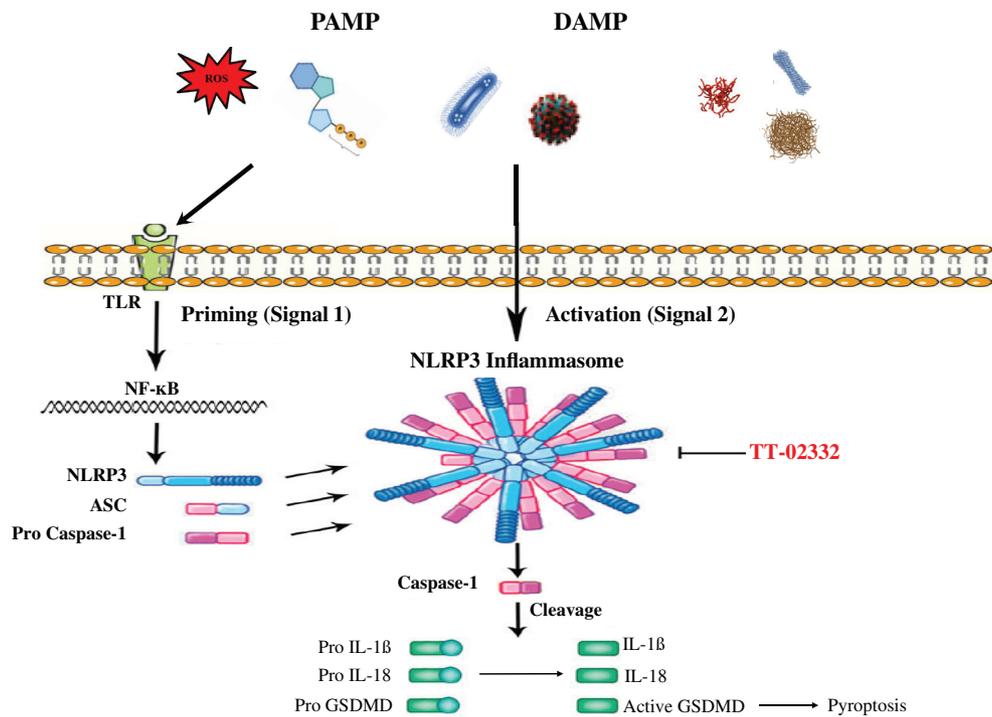
TT-02332 is a novel, highly potent, selective NLRP3 inhibitor that effectively restrains excessive inflammation *in vitro* or *in vivo* with good dose-dependency. TT-02332 shows excellent efficacy in acute inflammation models, indicating its potential application in various metabolic and inflammatory diseases. The differentiated chemical scaffold of TT-02332 may help avoid hepatotoxicity associated with the early clinical NLRP3 inhibitor with sulfonylurea-like structure. We plan to submit IND applications to the FDA and the NMPA in the first half of 2025 and initiate the Phase I clinical trial in the second half of 2025 or first half of 2026.

Mechanism of Action

The NLRP3 inflammasome is a critical component of the innate immune response, activated by various stimuli such as PAMPs, DAMPs, and tissue damage signals. When sensing intracellular damage signal, it triggers the organization of inflammasome complex. This inflammasome complex leads to maturation of IL-1 β , IL-18, and Gasdermin D to promote a downstream inflammatory response as well as pyroptosis. Inappropriate activation of NLRP3 has been implicated in a variety of inflammatory diseases, including inflammatory bowel diseases, metabolic diseases and neurodegenerative diseases. Notably, numerous preclinical and clinical studies have identified the NLRP3 inflammasome as a key therapeutic target in obesity.

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TT-02332 is a novel, highly potent, selective NLRP3 inhibitor that effectively restrains excessive inflammation. The following diagram illustrates the mechanism of action of TT-02332.



Source: Company data

Competitive Advantages

TT-02332, A High Potent and Selective NLRP3 Inhibitor

- Highly potent and selective NLRP3 inhibitor

In vitro assays have shown that TT-02332 exhibits potent inhibition of the NLRP3 inflammasome in human macrophages cell line THP-1, and human whole blood, highlighting its potential clinical efficacy. Moreover, TT-02332 demonstrated excellent selectivity for the NLRP3 over other inflammasomes more than 1000 fold.

Cellular Assay ⁽¹⁾		Activity of TT-02332 IC ₅₀ (nM)
Potency	THP-1	0.6
	Human Whole Blood	1.85
Selectivity	Other inflammasome	>1000 fold

Note:

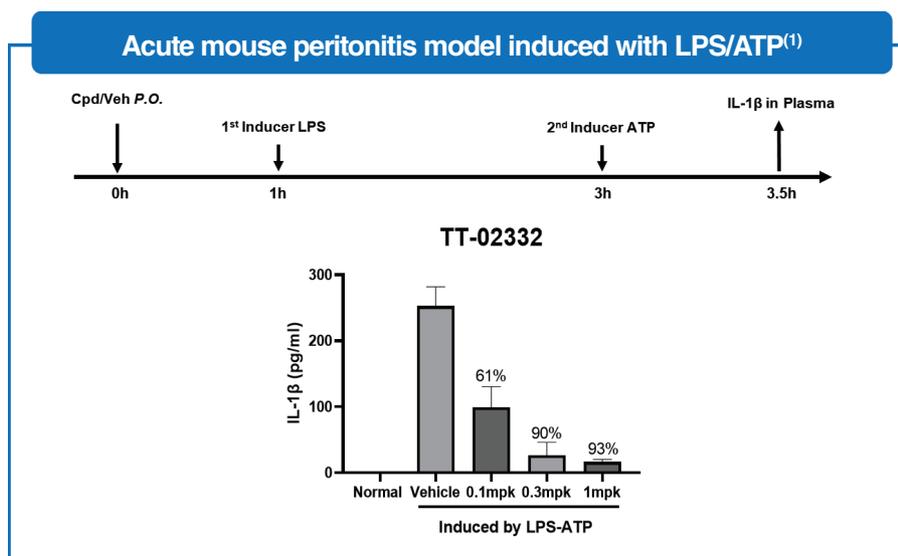
(1) The potency and selectivity results are from cellular assays.

Source: Company Data

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- Excellent dose-dependent PD response in mouse model

In the acute peritonitis model induced by LPS/ATP, TT-02332 demonstrated a remarkable dose-dependent inhibition of the NLRP3 inflammasome *in vivo*. This finding highlighted the potent and effective inhibitory effects of TT-02332 on the NLRP3 inflammasome in a relevant disease model.



Note:

(1) Results are from *in vivo* mouse model.

Source: Company Data

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TT-02332 SUCCESSFULLY.

OUR NON-PIPELINE PRODUCT CANDIDATES

TT-00434

TT-00434 is an internally discovered and developed, potent, and highly selective small-molecule FGFR1/2/3 inhibitor. It is developed for the treatment of gastric cancer and other solid tumors with FGFR1/2/3 alterations. TT-00434 has demonstrated its improved target selectivity, antitumor efficacy, and high potential in combination therapy with other small molecule targeted therapies or chemotherapies. Preclinical studies have shown a favorably high tissue distribution of TT-00434 in the gastrointestinal tract cancers. We have received the IND clearance from the FDA, the NMPA and the TFDA and enrolled the first patient in Taiwan in July 2021. We aim to complete the Phase I clinical trial in the first half of 2024.

TT-ROMI and TT-RIAN

In addition to the above drug candidates, we have been cooperating with Teijin for new targets discovery of TT-ROMI and TT-RIAN. See “– Collaboration and License Agreements – Collaboration with Teijin” for more details.

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COLLABORATION AND LICENSE AGREEMENTS

License-in Agreement with LG Chem

On April 23, 2021, we entered into an exclusive license agreement (the “**License-in Agreement**”) with LG Chem concerning the patents in relation to TT-01688. Pursuant to the License-in Agreement, LG Chem granted to us an exclusive, royalty-bearing license, with the right to grant sublicenses through multiple tiers, under certain know-how and patent rights controlled by LG Chem relating to TT-01688, to use, research develop, manufacture, commercialize and otherwise exploit TT-01688 in Greater China. Currently, it cannot be determined that which company will be the marketing authorization holder of TT-01688 when it gets approved in China. LG Chem is a South Korea-based listed company (051910:Korea SE) principally engaged in the manufacture of petrochemical materials. LG Chem has more than 60 affiliates and approximately 270,000 employees worldwide. LG Chem includes a life sciences division engaged in the business of developing, manufacturing and commercializing pharmaceutical products, and is an independent third party.

In accordance with the License-in Agreement, LG Chem and us established a Joint Steering Committee with equal representation from each party to oversee and coordinate each party’s activities under the License-in Agreement. All decisions of the Joint Steering Committee shall be made by unanimous vote with each of LG Chem and us having one vote. In the event that the Joint Steering Committee cannot reach consensus, the dispute matter shall be referred to the president of the life sciences division of LG Chem and our CEO for resolution.

Pursuant to the License-in Agreement, the intellectual property right of TT-01688 is owned by LG Chem and we obtained exclusive license right of TT-01688 in Greater China. We and LG Chem have the right to make subsequent improvements and have exclusive ownership of each parties’ respective improvements and any intellectual property rights in such improvements that are discovered, generated, developed, invented or created. Subject to the terms and conditions of the agreement, all data generated in connection with any research, development, manufacturing or commercialization activities with respect to TT-01688 conducted by or on behalf of LG Chem or its affiliates or sublicensees, whether such data was generated before or after April 23, 2021 shall be the sole and exclusive property of LG Chem or of its affiliates or sublicensees. All data generated in connection with any research, development, manufacturing or commercialization activities with respect to TT-01688 conducted by or on behalf of us or our affiliates or sublicensees shall be our sole and exclusive property or of our affiliates or sublicensees. Each party shall solely own any project inventions, project know-how and project patent rights made solely by or on behalf of its and/or its affiliates’ employees, agents or contractors. The parties shall jointly own any project inventions, project know-how and project patent rights that are made jointly by employees, agents or independent contractors of one party and/or its affiliates together with employees, agents or independent contractors of the other party and/or its affiliates.

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Under the License-in Agreement, in exchange of our rights, we are required to make various payments to LG Chem, including an upfront payment, milestone payments and royalty payments. We shall make and have made a one-time, non-refundable, non-creditable upfront payment of US\$2 million. We are obliged to pay to LG Chem milestone payments up to an aggregate amount of approximately US\$68 million. Milestone payments comprise development milestone payments, regulatory milestone payments and commercial milestone payments. Specifically, (i) the development milestone payments up to an aggregate amount of US\$7.5 million shall be made by installments upon a clinical trial application approval by the NMPA for TT-01688 and the initiation of Phase II and Phase III clinical trials of TT-01688 for each of first and second indications in Greater China, respectively; (ii) regulatory milestone payments up to an aggregate amount of US\$13 million shall be made upon marketing approvals of TT-01688 for treating ulcerative colitis and any other indications; and (iii) three commercial milestone payments up to an aggregate amount of US\$47.5 million shall be made upon the achievement of specific levels of aggregate annual net sales for TT-01688 products in Greater China. The amount of each commercial milestone payment accounts for no more than 5% of the related annual net sales. In addition, during the applicable royalty term, we will also pay royalties based on annual net sales of TT-01688 in Greater China at progressive rates ranging from a single-digit percentage to a low double-digit percentage. Our royalty obligations remain during the royalty term commencing on a product-by-product basis and jurisdiction-by-jurisdiction basis upon the first commercial sale of any TT-01688 products in Greater China and expiring upon the later of (i) the expiration of all patents licensed to us from LG Chem; (ii) ten years after the first commercial sale; and (iii) the expiration of applicable regulatory exclusivities for TT-01688 in Greater China. As of the Latest Practicable Date, we had paid US\$4.5 million to LG Chem under the License-in Agreement. The License-in Agreement will remain in effect until the expiration of the last to expire of the aforementioned royalty term in Greater China for TT-01688 products. The License-in Agreement may be terminated by either party for the other party's uncured material breach.

As of the Latest Practicable Date, the License-in Agreement had been registered in NIPA.

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Collaboration with Teijin

In October and December 2020, we entered into two collaboration and license agreements (the "Collaboration Agreements") with Teijin Pharma Limited ("Teijin") seeking collaboration with respect to the research of projects (TT-ROMI and TT-RIAN) based upon certain existing hit/lead compounds discovered and controlled by Teijin, to identify compounds that meet the criteria mutually agreed by both parties and to validate the biological targets, with an aim to develop pharmaceutical products that have sufficient efficacy and safety in humans and would be available for commercialization on a global basis. Teijin Pharma Limited is a subsidiary of Teijin Limited (3401:Tokyo), which is a pharmaceutical company engaged in the discovery, development, manufacture, commercialization and marketing of pharmaceutical products, and an independent third party.

Teijin and we agreed to carry out collaboration programs (the "Collaboration Programs") to jointly conduct collaborative research to obtain compounds for the prevention, treatment or cure of certain diseases, disorders or conditions by optimizing the original compounds, and discovering new compounds. Each party shall grant to the other party necessary license to its respective intellectual properties, solely for such other party to conduct the Collaboration Programs and its activities thereunder. The roles and responsibilities of each party in conducting the research projects shall be as follows: (1) for TT-ROMI project, (i) we will conduct medicinal chemistry studies and process development studies; (ii) Teijin will conduct *in silico* studies (including CADD and PKPD simulation), crystallographic and biophysical analyses; (iii) Teijin and we (we will take a leading role) will conduct *in vitro* and *in vivo* pharmacological studies; and (iv) Teijin and we (we will take a leading role) will conduct non-GLP preclinical studies (including ADME physicochemical studies and toxicological studies); (2) for TT-RIAN project, (i) Teijin and we will conduct medicinal chemistry studies and process development studies; (ii) Teijin will conduct structure biology studies; (iii) Teijin and we (Teijin will take a leading role) conduct *in vitro* and *in vivo* pharmacological studies; (iv) Teijin and we (we will take a leading role) conduct non-GLP preclinical studies (including ADME physicochemical studies and toxicological studies); and (v) we will conduct pre-formulation studies.

Upon the expiration of the Collaboration Programs, Teijin granted to us an exclusive, royalty-bearing license under the know-how, patents and interests owned by Teijin relating to the Collaboration Programs, with the rights to sublicense in Greater China, solely for certain purposes as set out in the Collaboration Agreements. We granted to Teijin an exclusive, royal-bearing license under the know-how, patents and interests owned by us relating to the Collaboration Programs, with the right to sublicense in Japan, solely for certain purposes as set out in the Collaboration Agreements. Teijin and us shall jointly have the right to grant to a third party a license, with the right to sublicense outside Japan and Greater China, under any invention or know-how that is invented or discovered in the Collaboration Programs for certain purposes.

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Teijin and us shall jointly and equally own all the rights to inventions and know-how in the Collaboration Programs, and patent applications shall be filed in the names of Teijin and us. Teijin shall have the primary right and authority to prepare, file, prosecute and maintain, in the names of Teijin and us, the patent application in Japan, and shall bear all costs incurred thereunder. We shall have the primary right and authority to prepare, file, prosecute and maintain, in the names of Teijin and us, the patent application that relates in Greater China, and shall bear all costs incurred thereunder. For regions outside China and Japan, Teijin and us shall discuss and determine the responsible party, the regions and countries and other related matters.

Teijin and us shall establish a four-member Joint Research Committee ("Joint Research Committee") with equal representation from each party. The Joint Research Committee shall oversee progress under the Collaboration Programs, review and approve the work plan completed thereunder, make decisions on compound selection or other issues pertaining to the Collaboration Programs; and determine whether the lead candidate criteria have met for the Collaboration Programs. All decisions of the Joint Research Committee shall be made by unanimous vote with each of Teijin and us having one vote. In the event that the Joint Research Committee fails to reach a unanimous decision, such matter may be referred to the senior executive officers of Teijin and us for resolution. If the senior executive officers are not able to resolve such dispute within 30 days, such dispute shall be resolved through binding arbitration. The following sets forth the background of the members in the Joint Research Committee during the Track Record Period:

Member	Background
<i>Joint Research Committee of TT-ROMI Program</i>	
Member A (assigned by Teijin)	Director of Medicinal Chemistry Research Laboratories, medicinal chemist who has more than 20 years of industry experience.
Member B (assigned by Teijin)	Director of Pharmaceutical Discovery Research Laboratories, with expertise in pharmacology and bioinformatics.
Dr. Peng Peng (assigned by us)	Our vice president of project management who has over 15 years of rich experience in drug discovery and development, toxicology and project management, with a focus on oncology.
Member C (assigned by us)	Director of our chemistry department, with over 10 years of experience in medicinal chemistry and process chemistry development.

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<u>Member</u>	<u>Background</u>
<i>Joint Research Committee of TT-RIAN Program</i>	
Member A (assigned by Teijin)	Director of Medicinal Chemistry Research Laboratories, medicinal chemist who has more than 20 years of industry experience.
Member B (assigned by Teijin)	Director of Pharmaceutical Discovery Research Laboratories, with expertise in pharmacology and bioinformatics.
Dr. Sheng Zejuan (assigned by us)	Our vice president of biology who has more than 15 years of experience in drug research and discovery in the U.S. and China.
Member C (assigned by us)	Director of our chemistry department who has over 10 years of experience in medicinal chemistry and process chemistry development.

As of the Latest Practicable Date, we did not have any profit sharing arrangement for the sales of the research projects under the Collaboration Agreement as the collaboration is still at an exploratory phase. The Collaborations Agreements will remain effective until (i) either party enters into any transaction with a third party engaging in competing compound and the breached party does not timely take remedial measures; or (ii) the Collaboration Programs are terminated by either party. The Collaboration Agreements may be terminated by either party or in the event of uncured material breach.

Patent Transfer Agreement with Gentai

In September 2020, we entered into a patent transfer agreement (the “Patent Transfer Agreement”) with Nanjing Gentai Pharmaceutical Technology Co Ltd (南京互泰醫藥技術有限公司) (“Gentai”) whereby Gentai agreed to transfer to us its patent rights and relevant interest in the BTK inhibitors. Gentai is a pharmaceutical company engaged in researching, developing and manufacturing small molecule drugs focusing on cancer treatment, and an independent third party.

Pursuant to the Patent Transfer Agreement, Gentai agreed to transferred to us the patent and the molecule entity of its BTK inhibitors as well as all relevant technology, intellectual property rights, existing and future interests. In addition, Gentai shall not reserve any rights or interests in the BTK inhibitors. After the Patent Transfer Agreement came into force, Gentai and its affiliates shall be prohibited from conducting research and development as well as applying for patent applications in relation to BTK inhibitors for a period of three years. After acquisition of these BTK inhibitors, in 2020, we developed reversible BTK inhibitors which led to the selection of TT-01488 as a high-quality candidate. To protect our IP rights with respect to TT-01488, we have owned issued patents of TT-01488 in China and also filed patent applications in other jurisdictions. See “– Intellectual Property” for more details.

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Under the Patent Transfer Agreement, in exchange of our rights, we shall make transfer payment to Gentai, including an upfront payment, milestone payments and royalty payment. We shall pay and have paid Gentai a one-time, non-refundable, non-creditable upfront payment of RMB1 million. We are obliged to pay to Gentai milestone payments up to an aggregate amount of appropriately RMB129 million. Milestone payments comprise recent key milestone payments, clinical and registration milestone payments, and commercial milestone payments. Specifically, (i) recent key milestone payments up to an aggregate amount of RMB2 million shall be made upon the completion of patent transfer registration and the completion of verification experiments and dose range finding toxicity experiments; (ii) clinical and registration milestone payments up to an aggregate amount of RMB72 million shall be made upon the achievement of related clinical events; and (iii) commercial milestone payments up to an aggregate amount of RMB55 million shall be made upon the achievement of specific levels of aggregate annual net sales of TT-01488 products. The amount of each commercial milestone payment accounts for no more than 1% of the related annual net sales. In addition, during the applicable royalty term, we will also pay royalties based on annual net income of transferred products worldwide at progressive rates ranging from a single-digit to a low double-digit percentage. As of the Latest Practicable Date, we did not make or owe any royalty payments to Gentai. Our royalty obligations remain during the term commencing upon the first commercial sales of any TT-01488 products and expiring upon the later of (i) the expiration of the patent of the compound in China; and (ii) the expiration of the new drug monitoring period. As of the Latest Practicable Date, we had paid RMB7 million to Gentai under the Patent Transfer Agreement.

The Patent Transfer Agreement will remain effective until it is terminated by either party or in the event of uncured material breach. As of the Latest Practicable Date, the patent transfer and relevant filings had been completed.

Collaboration with Roche

In March 2021, we entered into a master clinical supply agreement (the “Master Clinical Supply Agreement”) and its supplements (“CSA Supplement”) with F. Hoffmann-La Roche Ltd (“Roche”) to explore the combination of Tinengotinib and atezolizumab for the treatment of patients in China with biliary tract carcinoma. F. Hoffmann-La Roche Ltd is a subsidiary of Roche Holding AG, an Independent Third Party to us. Roche Holding AG is traded in the United States as a U.S.-dollar denominated American depositary receipt on the OTCQX International Premier market under the stock symbol “RHHBY”.

Pursuant to the Master Clinical Supply Agreement and CSA Supplement, Roche agreed to supply the atezolizumab to us at no cost per our request, for use in clinical studies of the Tinengotinib in combination with the atezolizumab as set forth in our protocol (the “Protocol”). In accordance with the Master Clinical Supply Agreement, we shall prepare the Protocol, and the final draft of the Protocol shall be submitted to Roche for its review. We will perform clinical study with the Protocol, provide written updates regarding the status of the study, summarize the findings of study in a final study report and share with Roche. We may use subcontractors in the performance of the study and activities. Upon Roche’s request, we will

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inform Roche about study sites, or any additions or deletions thereto. All data generated in the performance of any study shall belong to us as the sponsor of the study, and/or our Chinese collaborators (the participating sites of the study).

Subject to compliance with, and to the extent permitted by, the applicable laws and regulations (including privacy laws) and completion of the necessary approval and filing procedures, and based on our agreement with our Chinese collaborators. The data, results and reports generated in connection with the study will be shared with Roche, and Roche and its affiliates are entitled to use such data and results of the study for any lawful purpose.

RESEARCH AND DEVELOPMENT

Our Platform

We believe that fully-integrated in-house R&D capabilities are critically important to our success in global competition. Our fully-integrated in-house R&D capabilities is best illustrated by our fully integrated R&D platform with the aim of identifying drug candidates against evidence-based and novel targets, increasing the speed of development and likelihood of success while reducing the cost of development. Our platform covers a wide spectrum of drug discovery and development functionalities for our drug candidates in the fields of oncology and non-oncology. Our platform facilitates collaboration among different functional groups and feeds into early discovery and research to cultivate promising targets with clinical and commercial potential. Our platform integrates all the necessary capabilities to streamline our target-to-market timeline. These capabilities will be housed in four main functional units: drug discovery, clinical development, CMC and regulatory affairs. These individual functional units have been optimized and great attention has been given to building cross-function integration at key points in the lifecycle of a drug candidate.

Levering our platform, we have discovered and developed a number of product candidates. We are generally responsible for the global development of our internally discovered and developed drug candidates. For our drug candidates, we conduct clinical activities including: (i) coordinating all clinical development activities; (ii) designing the key aspects of the clinical study; (iii) designing and coordinating the selection process for qualified CROs to assist in engaging clinical sites and coordinating clinical studies once commenced; (iv) supervising the clinical studies; and (v) overseeing extensive regulatory outreach and coordination in China, the U.S. and globally.

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Drug Discovery

As of the Latest Practicable Date, our drug discovery team consisted of 66 members, whom had an average of approximately eight and a half years’ experience and had been working on the relevant products for more than four years. Our drug discovery team members expertise in biology, medicinal chemistry, DMPK, CMC and early clinical areas, which support our oncology and non-oncology product development, with 43 members holding doctorate degrees or master degrees. During the drug discovery stage, our R&D medical chemistry team explores new chemical entities, structure-activity-relationship (SAR) analysis based on thorough biological understanding of the disease, and carries out synthesis and structure optimization of the target molecules for potential drug candidates. During the drug evaluation stage, our drug discovery team coordinates and accomplishes preclinical R&D activities in relation to the product candidates’ pharmacology, pharmacokinetics and toxicology. We are able to conduct preclinical R&D activities including product activity screening, studies of cellular functions of product candidates, product biochemical studies and biomolecule detection.

Our robust product pipeline is built by our exceptional drug discovery capabilities through our platform. Leveraging our integrated technology platforms and expertise in biology, chemistry, pharmacology, toxicology and IP knowledge, we have successfully translated innovative targets and molecules into clinical therapeutics. Our drug discovery comprises (i) a target screening and validation approach that screens, validates and develops specific biological targets based on medical needs; (ii) multi-functional technology platforms including synthetic chemistry, analytical chemistry, biology, DMPK, formulation, and toxicology; (iii) supporting systems including intellectual properties and quality assurance; and (iv) translational research that helps to establish stronger disease link between the preclinical data and clinical signal.

Clinical Development

Clinical Development Team

As of the Latest Practicable Date, the clinical development team consisted of 28 scientists and physicians with an average of approximately 10 years’ drug development experience, who lead clinical development strategy development, clinical trial protocol design, clinical trial operation organization, drug safety monitoring, and clinical trial quality control. As of the Latest Practicable Date, 18 members in our clinical development team had obtained doctorate degrees or master degrees. All of them specialized in management of all stages of our clinical trials, including clinical trial design, implementation, drug supply, and the collection and analysis of trial data. We collaborate with top clinical experts in various areas as our principal investigators, leverage the operational capabilities of industry-leading CROs, and rely on well-known academic medical institutions and clinical trial centers in China and abroad to promote the high-quality and efficient implementation of our clinical trials in China, the U.S. and globally.

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Clinical Trial Design and Implementation

The clinical development unit of our platform manages all stages of clinical trials, including protocol design, operation, and the collection and analysis of clinical data. Our rapid trial advancements are driven by (i) our strategic decision to initiate clinical phase trials globally with our outstanding preclinical results, (ii) rigorous trial design, (iii) long-term partnership with numerous hospitals and principal investigators from different regions globally and (iv) professional execution. We employ a clinical-demand-oriented and market-driven approach to our R&D efforts. We identify suitable drug development targets and carry out project evaluation and overall project design based on our development strategies, and explore and establish experimental methodology by coordinating among the different experimental platforms. We carefully select drug development programs by balancing the commercial potential of each drug candidate and its likelihood of successful development, its potential competition and market size.

Our clinical operations unit is also responsible for the selection of trial sites. We select trial sites based on multiple factors, including suitability of on-site facilities, availability of qualified staff and availability of research subjects. We have entered into agreements with numerous hospitals and principal investigators located in China, the U.S., the EU and other regions that can support our clinical trials of different indications at different stages. We believe the size and geographic diversity of these facilities provide us with a significant advantage in implementing large-scale clinical trials and also enable us to conduct multiple clinical trials concurrently. With the support of our partner hospitals, we are capable of recruiting participants from specific populations for studies that would otherwise be difficult to fulfill enrollment.

In 2022 and 2023, we cooperated with 93 and 133 principal investigators, respectively, to conduct the clinical trials of our drug candidates. To the best of our Company’s knowledge, all of our principal investigators are Independent Third Parties.

As of the Latest Practicable Date, we had designed and implemented more than 15 clinical studies in China, the U.S., the EU and other regions. Leveraging our extensive knowledge and experience in clinical trials, our clinical development experts are particularly good at identifying unique therapeutic opportunities for our drug candidates based on the differentiating properties observed in clinical trials and improving clinical plans accordingly. Our team has demonstrated the ability to obtain IND approvals and initiate patient enrollment efficiently. We have initiated the pivotal/registrational Phase II and Phase III clinical trial for Tinengotinib for CCA in China and globally in the second half of 2023.

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Clinical Translational Research

We conduct clinical translational research to assess the effectiveness of treatment, evaluate different ways to customize therapies, and improve personalized medicine guidelines using the new data generated. These insights help further guide us toward new directions in novel drug discovery and efficiently obtain proof of concept results.

We also maintain extensive collaboration with physicians, scientists and key opinion leaders, and further develop products based on their clinical feedback to our drug candidates, whether in terms of indications or potential treatment combinations. We have established a rich network of top tier CROs, research institutions and hospitals, so that our drug candidates can be quickly moved to the clinical stage.

Collaboration with CROs

In line with industry practice, we collaborate with CROs to conduct and support our preclinical and clinical studies. We select our CROs by weighing various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. We engaged 82 and 93 CROs in 2022 and 2023, respectively. To the best of our Company's knowledge, except for PharmaBlock, they are all Independent Third Parties.

The preclinical CROs mainly provide us with services related to preclinical toxicity and safety evaluations, such as animal studies, of our drug candidates in accordance with our study design and under our supervision. We engaged CROs for the clinical trials of our clinical-stage products. CROs generally provide a comprehensive suite of services to assist us in the implementation and management of clinical trials, including trial preparation, source data verification, clinical safety management, data management, and report preparation.

We closely monitor the work of our CROs, and provide specific directions to ensure the quality and efficiency of the trial execution. This approach allows us to leverage the experience of our in-house team to better focus on critical clinical trial elements, such as trial design, data analysis and decision making. All of studies of our drug candidates on human are conducted in compliance with the applicable laws, regulations and in line with the industry standards.

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In 2022 and 2023, the expenses attributable to CROs were RMB110.0 million and RMB192.2 million, respectively, with 72.6% and 73.1% of such expenses attributable to research and development of Tinengotinib. The following table sets forth background and expenses (exclusive of tax) of five largest CROs engaged by us during the Track Record Period:

<u>CRO</u>	<u>Company Background</u>	<u>Expenses (exclusive of tax)</u>
<i>(RMB'000)</i>		
For the year ended December 31, 2022		
CRO A	Based in the U.S., a company providing pharmaceutical sciences, clinical research and regulatory affairs services for pharmaceutical products	47,316
CRO B	Based in the U.S., a U.S. listed company providing innovative and comprehensive laboratory services for pharmaceutical products	18,230
CRO C	Based in the U.S., a company providing genetic diagnostic testing services	5,753
CRO D	Based in Anhui Province, China, a company providing R&D and consulting services for pharmaceutical products	5,123
CRO E	Based in Beijing, China, a PRC and HK listed company providing R&D, CMC and safety assessment services	3,528
<i>(RMB'000)</i>		
<u>CRO</u>	<u>Company Background</u>	<u>Expenses (exclusive of tax)</u>
<i>(RMB'000)</i>		
For the year ended December 31, 2023		
CRO F	Based in the U.S., a company providing contract research and commercial services to pharmaceutical and biotechnology companies	58,172
CRO G	Based in the U.S., a U.S. listed company providing clinical trial management, patient access and technology solutions to pharmaceutical and biotechnology organizations	31,237
CRO D	Based in Anhui Province, China, a company providing R&D and consulting services for pharmaceutical products	26,586

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CRO	Company Background	Expenses (exclusive of tax)
	For the year ended December 31, 2023	<i>(RMB'000)</i>
CRO A	Based in the U.S., a company providing pharmaceutical sciences, clinical research and regulatory affairs services for pharmaceutical products	17,310
CRO C	Based in the U.S., a company providing genetic diagnostic testing services	13,734

We believe our ability to conduct, and to work closely with CROs to conduct multi-center, high-quality and global clinical trials enable us to shorten the time required for drug development by generating the requisite data reliably and efficiently. For additional information of CROs, see “– Raw Materials and Suppliers.”

Chemistry, Manufacture & Controls (“CMC”)

CMC Team

As of the Latest Practicable Date, the CMC team consisted of 31 professionals with an average of nine years’ experience. Our CMC team has established experience in process development, production and quality management from well-known biopharmaceutical and pharmaceutical companies. Among our CMC team members as of the Latest Practicable Date, approximately 54.8% had obtained post-graduate degrees and approximately 6.5% had Ph.D. degrees. Our CMC team specializes in preclinical and clinical support throughout the drug development process. CMC function in our platform plays a critical role in drug development. It is responsible for developing safe, robust, and economically sound production processes for our drug substances and drug products, and ensuring their qualities meet regulatory requirements.

Collaborations with CMOs and CDMOs

As of the Latest Practicable Date, we had not established an internal clinical manufacturing facility. Collaborating with leading CMO and CDMO partners, we currently outsource the production of product candidates to support relevant clinical trials in the U.S., China and other relevant regions. Given the highly sophisticated nature of the drug substance and drug product manufacturing process, we support our CMO and CDMO partners with our extensive CMC know-hows in production, packaging, transportation, and storage of our products. We engaged one CMO in each of 2022 and 2023. We also engaged two CDMOs and one CDMO in 2022 and 2023, respectively. To the best of our Company’s knowledge, none of them have any past or present relationships with our Group, our Directors, our Shareholders

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holding more than 5% of our issued share capital, our senior management or any of their respective associates. Upon receiving marketing approval for Tinengotinib, we plan to outsource commercial-scale manufacturing to recognized CDMOs.

We select our CMO and CDMO partners by reviewing a number of factors, including their quality standard, regulatory compliance, technical expertise, production capacity, geographic proximity, track record and reputation in the industry, reliability in meeting delivery timelines, and the financial terms offered by them. We have established procedures to closely monitor and communicate with our CMO and CDMO partners to ensure their practices meet our internal standards and comply with regulatory guidelines. These include holding regular meetings for project review and technical discussion, constantly exchanging ideas and technical know-how, and timely reviewing all relevant documents and records such as manufacturing batch records and quality control records. Additionally, all intellectual properties generated from the collaboration shall be solely and exclusively owned by us. For additional information of CMOs and CDMOs, see “– Raw Materials and Suppliers.”

In 2022, the expenses attributable to the CMO were RMB0.5 million, which were used for the research and development of TT-00920. In 2023, the expenses attributable to the CMO were RMB0.1 million, which were used for the research and development of TT-01488. The following table sets forth background and expenses (exclusive of tax) of all the CMOs we engaged during the Track Record Period:

Identity	Background	Year Ended December 31,		Total Amount During the Track Record Period
		2022	2023	
		<i>RMB'000</i>	<i>RMB'000</i>	
CMO A	Based in Tianjin, China, a PRC and HK listed company providing one-stop, full-cycle CMC service for innovative drug to its customers worldwide	491	–	491
CMO B	Based in Shanghai, China, a company providing global pharmaceutical companies with full-cycle, one-stop laboratory R&D and manufacturing services for innovative drugs	–	104	104

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In 2022 and 2023, the expenses attributable to CDMOs were RMB28.5 million and RMB8.5 million, respectively, with 88.5% and 85.3% of such expenses attributable to research and development of our core product Tinengotinib. The following table sets forth background and expenses (exclusive of tax) of all the CDMOs we engaged during the Track Record Period:

Identity	Background	Year Ended December 31,		Total Amount During the Track Record Period
		2022	2023	Period
		RMB'000	RMB'000	RMB'000
CDMO A	Based in Jiangsu Province, China, a PRC and HK listed company provides a broad portfolio of R&D and manufacturing services for pharmaceutical products	27,672	8,493	36,165
CDMO B	Based in Zhejiang Province, China, a wholly-owned subsidiary of a PRC listed company. It provides services including the development, manufacturing, risk assessment of APIs, pharmaceutical intermediates, innovative drugs and small molecule compounds	811	–	811

Regulatory Affairs and Compliance

As of the Latest Practicable Date, the regulatory affairs team consisted of 5 professionals with an average of approximately 11 years' experience. Our regulatory affairs team specializes in communication with the FDA, NMPA, EMA, TFDA and other regulatory authorities. Approximately 80.0% of team members as of the Latest Practicable Date had obtained post-graduate degrees and approximately 20.0% held Ph.D. degrees. Our regulatory affairs team is responsible for the regulatory approval process of our drug candidates, including assembling application dossiers for IND and NDA, addressing inquiries from relevant authorities and monitoring our R&D projects to ensure their compliance with relevant regulations. Our regulatory affairs team manages the regulatory submission process for our drug candidates, which require filings to be made to and approved by the relevant authorities before clinical trials and commercialization can be initiated. With our presence and expertise in the U.S., China and the EU, we are able to design our clinical trials in a way to maximize operational efficiency.

In addition, our qualified and experienced quality assurance team is responsible for ensuring that we maintain compliance with all applicable regulations, standards, protocols and internal policies. As of the Latest Practicable Date, our quality assurance team members on average have approximately 10 years of industry experience.

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BUSINESS DEVELOPMENT

To support our long-term strategy and to maximize pipeline assets value, our business development team encompasses the exploration of cooperation opportunities with global and domestic industry players. These opportunities may include research collaboration, co-development, product in-licensing and out-licensing. We have a proven track record of collaborating with biopharmaceutical and biotechnology companies across the globe, which underscores our credibility with global biopharmaceutical and biotechnology companies and paves the way for long-term collaborations. We are exploring opportunities to capitalize our strong R&D capabilities and to maximize the value of our pipeline assets by in-licensing high potential drug candidates to enrich and to supplement our existing drug pipeline and bring first-in-class or best-in-class therapies to the global market. In addition, we are taking advantage of the global network and industry resources of our shareholders, including world-class strategic investors with profound life science expertise.

COMMERCIALIZATION

We plan to formulate a commercialization and marketing plan in anticipation of future product launch. We plan to start with commercialization of Tinengotinib for CCA treatment in China. Patients suffered from this disease often seek medical attention in a handful of hospitals reputed for treatment of CCA. Considering the targeted patient population of Tinengotinib is readily reachable, we are currently poised to establish an in-house commercial team. We believe that an experienced marketing leader will be critical to success in commercialization. We will soon start the hiring process for a potential marketing director to join us, who will lead the marketing strategy and future commercialization plan. Our commercialization team will be responsible for market strategy, product positioning, market access and promotion activities.

Our international commercialization approach centered around international collaboration. Specifically, we look forward to collaborating with world-leading pharmaceutical companies with abundant marketing resources and deep root in local region to maximize the value of Tinengotinib overseas. We expect that upon receiving the marketing approvals, the collaborator will assume responsibility for promoting the product in overseas markets and will also continue to assist Tinengotinib in developing subsequent indications, including, mCRPC, breast cancer, and BTC.

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Leveraging the expertise and industry connections of our team, we plan to market our products primarily through our physician-targeted and patient-targeted marketing strategies. In terms of physician-target marketing strategy, in order to commercialize Tinengotinib to hospitals or physicians in China and globally, we will actively join or organize various academic conferences, including generalized and specialized conferences, and communicate and educate the physicians and patients through reputable cancer-related foundations or associations. In terms of our patient-targeted marketing strategy, we plan to cooperate with patient communities to enhance patient education as well as to increase market awareness of our products and brand name, such as holding lectures to patients. Such marketing efforts are expected to commence several months before the expected approval for the commercialization of a drug candidate. In preparation for the sales of our future approved products, we intend to identify a number of hospitals, clinics and physicians specialized in our targeted therapeutic areas, and visit the sites and physicians for product pre-approval training.

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business. Our future commercial success depends, in part, on our ability to obtain and maintain patent and other intellectual property and proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we (i) owned 30 issued patents in China, and 62 issued patents in the U.S. and other jurisdictions, and (ii) filed 15 published patent applications in China, and 125 published patent applications in the U.S. and other jurisdictions relating to certain of our product candidates and platform technologies. The following table summarizes the details of the material granted patents and filed patent applications by our Company in connection with our clinical and preclinical product candidates:

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<u>Product</u>	<u>Name of Patent</u>	<u>Jurisdiction</u>	<u>Status</u>	<u>Applicant</u>	<u>Patent expiration</u>	<u>Market commercial rights of the Company</u>
	Multi-kinase inhibitor compound, and crystal form and use thereof	China, Australia, Canada, India, Japan, South Korea, Russia, U.S., Brazil, Singapore	Granted	our Company	2037	Ownership
	Methods for treating a cancer mediated by abnormality of multi-kinases	U.S.	Granted	our Company	2038	Ownership
Tinengotinib	Multi-kinase inhibitor compound, and crystal form and use thereof	Europe, Hong Kong	Pending	our Company	N/A	Ownership
	Novel use of Multi-Kinase Inhibitor	China	Granted	our Company	2041	Ownership
	Novel use of Multi-Kinase Inhibitor	Australia, Brazil, Canada, Europe, Japan, South Korea, Russia, Singapore, Taiwan, U.S., Hong Kong	Pending	our Company	N/A	Ownership

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<u>Product</u>	<u>Name of Patent</u>	<u>Jurisdiction</u>	<u>Status</u>	<u>Applicant</u>	<u>Patent expiration</u>	<u>Market commercial rights of the Company</u>
	Method for synthesizing antitumor compound, and intermediates thereof	China, Australia, Brazil, Canada, Europe, India, Japan, South Korea, Russia, Singapore, Taiwan, U.S., Hong Kong	Pending	our Company	N/A	Ownership
	Combined use of Multi-Kinase Inhibitor	China, Europe, Japan, South Korea, Taiwan, U.S., Hong Kong	Pending	our Company	N/A	Ownership
	Pharmaceutical composition and use of Multi-kinase inhibitor	China, Taiwan Europe, Japan, South Korea, U.S.	Pending	our Company	N/A	Ownership
	Novel use of Kinase Inhibitor	China, Taiwan U.S., South Korea, Japan, Australia, Canada, Europe	Pending	our Company	N/A	Ownership

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<u>Product</u>	<u>Name of Patent</u>	<u>Jurisdiction</u>	<u>Status</u>	<u>Applicant</u>	<u>Patent expiration</u>	<u>Market commercial rights of the Company</u>
	Novel quinoline derivative inhibitor	China, Russia, Taiwan, Europe	Granted	our Company	2039	Ownership
TT-00973	Novel quinoline derivative inhibitor	Argentina, Australia, Brazil, Canada, Hong Kong, Indonesia, Japan, South Korea, Malaysia, New Zealand, Singapore, U.S.	Pending	our Company	N/A	Ownership
	Crystal forms, preparation methods, and applications of quinoline derivative inhibitors	China, PCT, Taiwan	Pending	our Company	N/A	Ownership

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Product	Name of Patent	Jurisdiction	Status	Applicant	Patent expiration⁽¹⁾	Market commercial rights of the Company
	Aminonordecane derivative and preparation method therefor and application thereof	China, U.S., Hong Kong, Japan, Russia, Mexico, India, Australia	Granted	our Company	2039	Ownership
	Aminonordecane derivative and preparation method therefor and application thereof	Brazil, Canada, Europe, South Korea, U.S.	Pending	our Company	N/A	Ownership
TT-01488	Aminonordecane derivative and preparation method therefor and application thereof	China	Granted	our Company	2038	Ownership
	Crystal form of imidazopyrazine derivatives, and preparation method and use thereof	China, PCT, Taiwan	Pending	our Company	N/A	Ownership

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<u>Product</u>	<u>Name of Patent</u>	<u>Jurisdiction</u>	<u>Status</u>	<u>Applicant</u>	<u>Patent expiration⁽¹⁾</u>	<u>Market commercial rights of the Company</u>
TT-01688	Sphingosine-1 -phosphate receptor agonists, methods of preparing the same, and pharmaceutical compositions containing the same as an active agent	China, Taiwan	Granted	LG CHEM, LTD.	2034	Exclusive ⁽²⁾

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<u>Product</u>	<u>Name of Patent</u>	<u>Jurisdiction</u>	<u>Status</u>	<u>Applicant</u>	<u>Patent expiration⁽¹⁾</u>	<u>Market commercial rights of the Company</u>
	PDE9 Inhibitor and use thereof	U.S., Taiwan, Australia, China, Indonesia, India, Russia, South Africa, Japan, South Korea, Malaysia	Granted	our Company	2038	Ownership
	PDE9 Inhibitor and use thereof	Brazil, Canada, China, Europe, Hong Kong, New Zealand, Singapore	Pending	our Company	N/A	Ownership
TT-00920	Method for preparing phosphodiesterase inhibitor	China, U.S., Japan, Europe, New Zealand, Russia, South Korea, Australia, Canada, Taiwan	Pending	our Company	N/A	Ownership
	Use of phosphodiesterase inhibitors	China, Russia, Australia, Taiwan, Japan, Canada	Granted	our Company	2040	Ownership

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Product	Name of Patent	Jurisdiction	Status	Applicant	Patent expiration⁽¹⁾	Market commercial rights of the Company
	Use of phosphodiesterase inhibitors	U.S., Malaysia, Indonesia, Singapore, New Zealand, Europe, South Korea, Hong Kong	Pending	our Company	N/A	Ownership
	Crystal form of phosphodiesterase inhibitor, preparation method therefor and use therefore	China, South Africa, Australia, Malaysia, Japan, Canada, Indonesia, Russia, Taiwan.	Granted	our Company	2040	Ownership
	Crystal form of phosphodiesterase inhibitor, preparation method therefor and use therefore	U.S., Brazil, South Korea, Europe, India, Singapore, New Zealand, Hong Kong, Russia	Pending	our Company	N/A	Ownership

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Product	Name of Patent	Jurisdiction	Status	Applicant	Patent expiration⁽¹⁾	Market commercial rights of the Company
	Halogenated allylamine compounds and their applications	China, Taiwan, South Africa, Australia, Russia, Saudi Arabia, Canada, India	Granted	our Company	2040	Ownership
TT-01025	Halogenated allylamine compounds and their applications	Hong Kong , Japan, U.S., Europe, South Korea, Singapore, Brazil, United Arab Emirates, Qatar	Pending	our Company	N/A	Ownership

Abbreviation: PCT=Patent Cooperation Treaty.

Notes:

- (1) 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.
- (2) Pursuant to the License-in Agreement, LG Chem granted to us an exclusive, royalty-bearing license, with the right to grant sublicenses through multiple tiers, under certain know-how and patent rights controlled by LG Chem relating to TT-01688, to use, research develop, manufacture, commercialize and otherwise exploit TT-01688 in Greater China.

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The term of individual patents depends on the legal term for patents in the jurisdictions in which they are granted. In most jurisdictions, the patent term for inventions is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable jurisdiction. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our owned or licensed pending patents in application or any such patents in application that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisers and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we 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.

These agreements may not provide sufficient protection of our trade secret and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secret and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secret and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

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

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We conduct our business under the brand name of “Transthera” or “藥捷安康.” As of the Latest Practicable Date, we had registered 41 trademarks in China, seven trademarks in Hong Kong and 27 trademarks in other jurisdictions. We are also the registered owner of 26 domain names.

We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property or gain access to the intellectual property of others. For details, see “– Collaboration and License Agreements.”

As of the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent.

PRICING

During the Track Record Period and up to the Latest Practicable Date, we had no commercialized drugs on the market either in China or overseas. We have not formulated any definitive pricing policy for our drug candidates yet. When our drug candidates progress to commercialization in the future, we will determine their prices based on various factors, such as current medical needs, our drugs’ pharmacoeconomic evaluation, our production costs, prices of prior line treatment options, competitive landscape and prices of competing drugs (if any), differences in features between our drugs and competing drugs, and health economics in the country to market in. We will conduct extensive market research with KOLs, hospitals, physicians and patients as well as regulatory bodies before pricing our drugs.

Our Core Product, Tinengotinib, is expected to be launched in China first, then in the U.S. and other regions. We will determine the price of Tinengotinib in China considering the factors including estimated demand, production costs, affordability of patients, and the prices of first generation FGFR inhibitors, such as pemigatinib (with the price of USD19,759 and RMB66,547 per 21-day treatment cycle in the U.S. and China, respectively). We will also take into consideration that Tinengotinib is the first FGFR therapeutic agent targeting for CCA patients who have progressed on chemotherapy and prior FGFR inhibitors to enter the market, and if there is any competing drug with respect to drug resistance to FGFR inhibitors, the differences in safety and efficacy and respective benefits between Tinengotinib and any such potential competing drugs. Similar considerations will be taken before market launch when we determine the price of Tinengotinib in the U.S. and other regions. In addition, we will actively negotiate with government authorities for Tinengotinib to be included in the NRDL.

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As of the Latest Practicable Date, there was no guidance price set by the relevant government authorities in relation to our drug candidates. We might sell our drugs to distributors at the prices determined by us from time to time, and might be required to, or choose to, participate in a public tender process to facilitate our distributors’ sales of our drugs to public hospitals. Nonetheless, in China, the government maintains a high level of involvement in the determination of retail prices, as the prices are affected by the bidding and tender processes organized by government agencies and hospitals. Furthermore, if our Core Product or other drug candidates upon commercialization are included in public medical insurance programs, we may face adverse pricing limitations. For more details, see “Risk Factors – Risks Relating to Government Regulations – If we are able to commercialize any of our approved drug candidates, we may face uncertainties from national, provincial or other third-party drug reimbursement practices or unfavorable pricing regulations, which could harm our business and prospects.”

CUSTOMERS

During the Track Record Period, we derived revenue primarily from milestone payments from LG Chem in connection with the out-licensed TT-01025.

To the knowledge of our Directors, none of our Directors, their respective associates or any of our Shareholders holding more than 5% of our issued share capital as of the Latest Practicable Date had an interest in LG Chem.

RAW MATERIALS AND SUPPLIERS

Our suppliers are mainly CROs, CMOs, CDMOs, and equipment providers. We use reputable CROs, CMOs and CDMOs to support our internal team in managing and conducting preclinical and clinical studies of our pipeline candidates in China, the U.S. and other relevant regions. We select our suppliers weighing various factors, such as their qualifications, academic and professional experience, industry reputation and service fees.

We closely supervise these third-party service providers to ensure that they perform their duties in a manner that complies with our protocols and applicable laws and regulations, and that protects the integrity of the data resulting from our trials. Below is a summary of the material terms and conditions of an agreement that we typically enter into with a CRO, CMO, or CDMO (including the agreement we entered into with PharmaBlock):

- *Services.* The CRO, CMO or CDMO provides us with services such as the implementation of a clinical research project or the production of product candidates as specified in the master agreement or a work order.
- *Term.* The CRO, CMO or CDMO is required to perform its services according to the prescribed timeframe set out in the master agreement or a work order.

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- *Payment.* We are required to make payments to the CRO, CMO or CDMO in accordance with the payment schedule agreed by the parties.
- *Confidentiality.* We and the CRO, CMO or CDMO both agree to keep confidential any information in relation to the performance of the master agreement.
- *Intellectual Property.* We own all intellectual property derived from the clinical research project, and we are entitled to apply patent for such intellectual properties.

We also procure raw materials and equipment for the development and manufacture of our product candidates from industry-leading and highly reputable manufacturers and suppliers around the world. We selected our suppliers by considering cost and their quality, capacity, capability, delivery, supplier profile, and regulatory compliance according to our internal purchasing policy, among other factors.

For the years ended December 31, 2022 and 2023, our purchases from our five largest suppliers in aggregate accounted for 52.0% and 48.4% of our total purchases for the respective years, respectively, and our purchases from our largest supplier alone accounted for 20.5% and 19.0% of our total purchases for the respective years, respectively. To the best of knowledge of our Directors, all of our five largest suppliers in each year during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the best knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers in each year during the Track Record Period.

In addition, we believe that adequate alternative sources for such supplies exist and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. Other than the agreements with certain CROs, CMO or CDMOs, we order supplies and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

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The tables below set forth certain information about our five largest suppliers during the Track Record Period:

<u>Supplier</u>	<u>Background</u>	<u>Years of relationship</u>	<u>Product or service supplied</u>	<u>Credit Term</u>	<u>Purchase amount (exclusive of tax)</u>	<u>Percentage of total purchases</u>
					For the year ended December 31, 2022 (RMB'000, except percentages)	
Supplier A	Based in the U.S., a company providing pharmaceutical sciences, clinical research and regulatory affairs services for pharmaceutical products	Since 2018	CRO services	Within 30 days upon receipt of invoice	47,316.0	20.5%
Supplier B	Based in Jiangsu Province, China, a PRC and HK listed company providing a broad portfolio of R&D and manufacturing services for pharmaceutical products	Since 2018	CDMO services	Within 30 days upon receipt of invoice	27,672.4	12.0%
Supplier C	Based in the U.S., a cancer center focused on cancer treatment	Since 2019	Trial site services	Within 30 days upon receipt of invoice	20,688.1	8.9%
Supplier D	Based in the U.S., a U.S. listed company providing innovative and comprehensive laboratory services for pharmaceutical products	Since 2021	CRO services	Within 30 days upon receipt of invoice	18,229.7	7.9%

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<u>Supplier</u>	<u>Background</u>	<u>Years of relationship</u>	<u>Product or service supplied</u>	<u>Credit Term</u>	<u>Purchase amount (exclusive of tax)</u>	<u>Percentage of total purchases</u>
For the year ended December 31, 2022 <i>(RMB'000, except percentages)</i>						
Supplier E	Based in South Korea, a South Korea listed company providing R&D, manufacturing and commercialization services for pharmaceutical products	Since 2021	IP license	Upfront payment: within 45 days upon execution of the contract; milestone payment: within 10 working days upon receipt of invoice	6,208.6	2.7%

<u>Supplier</u>	<u>Background</u>	<u>Years of relationship</u>	<u>Product or service supplied</u>	<u>Credit Term</u>	<u>Purchase amount (exclusive of tax)</u>	<u>Percentage of total purchases</u>
For the year ended December 31, 2023 <i>(RMB'000, except percentages)</i>						
Supplier F	Based in the U.S., a company providing contract research and commercialization services to pharmaceutical and biotechnology organizations	Since 2022	CRO services	Within 30 days upon receipt of invoice	58,171.7	19.0%
Supplier G	Based in the U.S., a U.S. listed company providing clinical trial management, patient access and technology solutions to pharmaceutical and biotechnology organizations	Since 2021	CRO services	Within 30 days upon receipt of invoice	31,236.6	10.2%

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<u>Supplier</u>	<u>Background</u>	<u>Years of relationship</u>	<u>Product or service supplied</u>	<u>Credit Term</u>	Purchase amount (exclusive of tax)	Percentage of total purchases
					For the year ended December 31, 2023 <i>(RMB'000, except percentages)</i>	
Supplier H	Based in Anhui Province, China, a company providing R&D and consulting services for pharmaceutical products	Since 2021	CRO services	Upfront payment: within 10 working days upon the execution of the contract; milestone payment: within 10 working days upon receipt of invoice	26,585.7	8.7%
Supplier A	Based in the U.S., a company providing pharmaceutical sciences, clinical research and regulatory affairs services for pharmaceutical products	Since 2018	CRO services	Within 30 days upon receipt of invoice	17,310.4	5.7%
Supplier C	Based in the U.S., a cancer center focused on cancer treatment	Since 2019	Trial site services	Within 30 days upon receipt of invoice	14,614.5	4.8%

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AWARDS AND RECOGNITIONS

The following table sets forth some of the important accreditations and awards we have received from the relevant authorities and organizations in China during the Track Record Period in recognition of our research and development capabilities:

<u>Year</u>	<u>Accreditation/Award</u>	<u>Accreditation Organization</u>
2023	Hurun Global Unicorn Enterprise	Hurun Research Institute
2023	Innovative Small and Medium-sized Enterprises	Nanjing Municipal Bureau of Industry and Information Technology
2023	The First Prize in the Growth Enterprise Group in Nanjing – The 11th “Entrepreneurship Jiangsu” Science and Technology Entrepreneurship Competition and the 12th China Innovation and Entrepreneurship Competition	Nanjing Science and Technology Bureau
2023	The Second Prize in the Growth Enterprise Group in Jiangsu – The 11th “Entrepreneurship Jiangsu” Science and Technology Entrepreneurship Competition and the 12th China Innovation and Entrepreneurship Competition	Jiangsu Province Science and Technology Entrepreneurship Competition Organizing Committee Office
2023	Excellent Enterprises of the 12th China Innovation and Entrepreneurship Competition (National Competition)	China Innovation and Entrepreneurship Competition Organizing Committee Office
2023	Excellent Enterprises in Jiangsu – The 11th “Entrepreneurship Jiangsu” Science and Technology Entrepreneurship Competition and the 12th China Innovation and Entrepreneurship Competition	Jiangsu Province Science and Technology Entrepreneurship Competition Organizing Committee Office
2023	Top 100 Research and Development Strength of Pharmaceutical Companies in China – 2023 Healthy Industry High-Quality Development Conference and the 8th China Pharmaceutical Research and Innovation Summit	Organizing Committee of the China Pharmaceutical Research and Innovation Summit, Yaozhi.COM, and China Pharmaceuticals

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Year	Accreditation/Award	Accreditation Organization
2023	Potential Unicorn Enterprises in Jiangsu in 2023	Productivity Centre of Jiangsu Province
2023	Promising New Enterprises with Highest Investment Value – 2023 China Biopharmaceutical Industry Chain Innovation Ranking	China Biopharmaceutical Industry Chain Innovation and Transformation Consortium, Nanjing Biopharmaceutical Industry Innovation and Transformation Center, Pharmacodia Database, and Gathering of Pharmaceutical Experts
2023	2023 Deloitte China Medical and Health Rising Star	Deloitte Touche Tohmatsu China
2022	Nanjing Cultivating Unicorn Enterprises in 2022	Nanjing Municipal Commission of Development & Reform
2022	Most Innovative Biotech Enterprises with Strong R&D Capabilities – 2022 China Biopharmaceutical Industry Chain Innovation Ranking	China Biopharmaceutical Industry Chain Innovation and Transformation Consortium, Nanjing Biopharmaceutical Industry Innovation and Transformation Center, Pharmacodia Database, Gathering of Pharmaceutical Experts, China Industrial Securities Co., Ltd., and Editorial Board of Progress in Pharmaceutical Science
2022	Nanjing Engineering Technology Research Center	Nanjing Science and Technology Bureau
2022	Top 100 Research and Development Strength of Pharmaceutical Companies in China – 2022 Healthy Industry High-Quality Development Conference and the 7th China Pharmaceutical Research and Innovation Summit	Organizing Committee of the China Pharmaceutical Research and Innovation Summit, Yaozhi.COM, and China Pharmaceuticals

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COMPETITION

Our industry is highly competitive and subject to rapid and significant change. While we believe that our fully-integrated platform, our robust pipeline of drug candidates in clinical and preclinical trials and our experienced management team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications against which we are developing our drug candidates. These include major pharmaceutical companies, academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future.

EMPLOYEES

As of the Latest Practicable Date, our employees consisted of 124 members in total, including 120 employees in Nanjing, China. The following table sets forth a breakdown of our employees by function as of the Latest Practicable Date:

Function	Number	Percentage
Research & development	94	75.8%
General and administrative	30	24.2%
Total	124	100.0%

Employee Agreements with Key Management and Research Staff

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

Recruitment, Training and Development

To maintain the quality, knowledge and skill levels of our workforce, we provide continuing education and training programs, including internal and external training, for our employees to improve their technical, professional or management skills. We also provide trainings 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 compensation to our employees, particularly our key employees.

Employee Benefits

We have materially complied with the PRC law to make contributions to statutory employee benefit plans (including pension insurance, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries, including bonus up to a maximum amount specified by the local government during the Track Record Period.

BUSINESS

We consider we have maintained good relations with our employees. Our PRC Legal Adviser confirmed during the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes, labor disputes or industrial actions which had a material effect on our business.

LAND AND PROPERTIES

According to Section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong) and Chapter 5 of the Listing Rules, this document is exempted from compliance with the requirements of Section 342(1)(b) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which require a valuation report with respect to all of our interests in land and buildings, for the reason that, as of December 31, 2023, we had no property interest with a carrying amount of 15% or more of our total assets.

Owned Properties

As of the Latest Practicable Date, we owned one parcel of land with a site area of 20,212 sq.m. used for industrial purpose. We have obtained the land use right certificate for such parcel of land.

Leased Properties

As of the Latest Practicable Date, we leased three properties in China with an aggregate GFA of approximately 5,093.62 sq.m. 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. We do not anticipate undue difficulty in renewing our leases upon their expiration.

The following table set forth the details of our leased properties in China as of the Latest Practicable Date:

Location	Type of Property	Address	GFA (sq.m.)	Lease Term	Expiry Date
Nanjing	Offices and R&D	4F, Building 02, Life Science & Technology Island, No. 11, Pharmaceutical Valley Avenue, Jiangbei New District, Nanjing	1,689.04	3 years	May 22, 2026
Nanjing	Offices and R&D	3F, Building 09, Accelerator II, No. 11, Pharmaceutical Valley Avenue, Jiangbei New District, Nanjing	1,950.76	3 years	December 31, 2025
Nanjing	Offices	13F, Convention Center, No. 09, Pharmaceutical Valley Avenue, Jiangbei New District, Nanjing	1,453.82	3 years	June 7, 2027

BUSINESS

OCCUPATIONAL HEALTH, SAFETY AND ENVIRONMENTAL MATTERS

We are subject to various health, safety, social and environmental laws and regulations and our operations are regularly inspected by local government authorities. We believe we have adequate policies ensuring compliance with all health, safety, social and environmental protection regulations. For the years ended December 31, 2022 and 2023, we spent approximately RMB0.3 million and RMB0.3 million with respect to environmental protection, respectively. Our Directors consider that the annual cost of compliance with the applicable health, safety, social and environmental laws and regulations was not material during the Track Record Period and we do not expect the cost of such compliance to be material going forward.

We have been, and will continue to be, highly committed to sustainable corporate responsibility. We are committed to social responsibilities, and consider environmental, social and governance (“ESG”) essential to our continuous development. We focus on areas such as employee responsibility, environment responsibility and public responsibility. Corporate social responsibility is viewed as part of our core growth philosophy that will be pivotal to our ability to create sustainable value for our Shareholders by embracing diversity and public interests. We plan to review our key ESG performance on a regular basis. We may from time to time engage independent professional third parties to help us make necessary improvements.

We have established a set of ESG policies covered under relevant international standards. For environmental matters, we have adopted policies related to (i) reduction of greenhouse gas emissions, (ii) treatment of exhaust gas and solid waste and (iii) conservation of energy, among other aspects. For social matters, we have adopted policies related to (i) product quality, (ii) employee health, promotion, compensation, benefits and training and (iii) employee complaint handling, among other aspects. An ESG working group has been established for developing the Company’s ESG strategy, policy and reporting, including assessing and managing climate-related risks, with oversight provided by the Board. For environmental matters, our ESG working group will be responsible for managing environmental and climate-related risks arising from our business operations. The ESG working will identify key environmental factors, establish operational control requirements and procedures and conduct relevant monitoring and inspections. The ESG working group will also review and update the operational control procedures in accordance with changes to key environmental factors, applicable laws and regulations and compliance assessments.

We are subject to various health, safety, social and environmental laws and regulations and our operations are regularly inspected by local government authorities. For more details, see “Regulatory Overview.” Since we have not yet launched any product, we have not started large-scale commercial production, and product manufacturing is mainly used for clinical trials and research. We do not operate in a highly polluting industry, while the manufacturing process of our product candidates for our clinical trials and research may generate solid and liquid waste and exhaust gas. Our business operations involve the use of hazardous and flammable chemical materials. We engage third-party waste treatment service providers to collect and treat hazardous waste produced in our operations. We select such service providers by considering their quality, industry reputation and compliance with relevant regulatory agencies. We inspect their business licenses, relevant operating permits and certificates for hazardous waste before engaging such service providers and require them to treat and dispose our hazardous waste in accordance with the applicable PRC environmental laws and regulations. The third-party waste treatment service providers issue written records for the transfer of hazardous waste and we keep such records for our internal review and compliance.

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Our general solid and liquid waste were typically processed by qualified entities and we also engage qualified institutions to evaluate the level of exhaust emission and limit its impact on the environment to far below the relevant statutory standard.

In addition, we have assigned dedicated environmental protection personnel and adopted specific environmental protection policies to make our operations more energy efficient and environmentally friendly and to ensure effective compliance with applicable PRC environmental laws and regulations. We have developed internal policies for environmental risk prevention to ensure compliance with the requirements of the applicable national, industrial and local standards, laws, regulations and policies. We will also adopt policies include reporting on the emission level of gas pollutants, waste water and solid waste to our management to the extent applicable and evaluation of such emission levels on a regular basis. If there is any deviation from the applicable emission standard, we will investigate the cause and will take rectification measures accordingly. We will prepare annual plan and report on the management of pollutants and waste and file such report with the relevant environmental authority for review.

We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe work environment for our employees. We have introduced relevant internal policies to ensure the safe storage and disposal of flammable and corrosive materials used in our production processes. We also have appropriate safety equipment and instruments in place. According to our safety management protocols, all of our employees are required to receive safety trainings. We aim to operate our facilities in a manner that protects the environment and the health and safety of our employees and communities. We have implemented company-wide environmental, health and safety policies and standard operating procedures related to waste treatment, process safety management, worker health and safety requirements and emergency planning and response. To further ensure our compliance with applicable environmental protection and health and safety laws and regulations, we (i) have established various guidelines governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes to ensure such guidelines are strictly enforced for the disposal of laboratory materials and wastes; (ii) inspect our equipment and facilities regularly to identify and eliminate safety hazards; (iii) provide regular safety awareness training to our employees; (iv) keep health records for all employees and conduct health examinations before and during their time at the company, especially for employees engaged in work involving occupational hazards; and (v) conduct regular fire safety inspections, maintenance of fire-fighting equipment and regular emergency drills.

In view of the nature of our business, to the best knowledge of our Directors, the climate change will not have any major impact on our business operation. In case of extreme natural weather, we will actively respond to the relevant policies of local government, make contingency plans in addition to the life insurance contributed by our Group to ensure the safety of our staff. In the case of acute physical risks such as direct damage to assets and indirect impacts from supply chain disruption as a result of extreme weather events, we will make the corresponding contingency plans and disaster preparedness plan, we believe that we have the ability to deal with climate crisis. As of the Latest Practicable Date, we had not experienced any material impact on our business operations, strategies or financial performance as a result of environmental, social and climate-related issues.

BUSINESS

Our compliance team is responsible for monitoring and enforcing the compliance of our operations with health, safety, social and environmental protection regulations. This responsibility is executed through training. Our Directors confirm that we have obtained all applicable permits and licenses under PRC environmental laws and regulations that are material to our operations. During the Track Record Period and up to the Latest Practicable Date, we had been in compliance with the relevant PRC laws and regulations in all material aspects, and had not been subject to any material claim or penalty in relation to health, safety, social and environmental protection, or been involved in any significant work place accident or fatality.

We attach great importance to ESG and act proactively to conform with ESG standards. We are committed to minimizing environmental impacts and ensuring sustainability through our entire value chain. Our Directors recognize the importance of good corporate governance to protect the interests of our Shareholders. After the [REDACTED], we will publish an Environmental, Social and Governance Report each year pursuant to Appendix C2 of the Listing Rules to analyze and disclose important environmental, social and governance matters, risk management and the accomplishment of performance objectives.

We will adopt various strategies and measures to identify, assess, manage and mitigate environmental, social and climate-related risks, including but not limited to:

- reviewing and assessing the ESG reports of similar companies in the industry to ensure that all relevant ESG-related risks are identified on a timely basis.
- discussing among management from time to time to ensure all the material ESG areas are recognized and reported.
- discussing with key stakeholders on key ESG principles and practices to ensure that the significant aspects are covered.
- organising a specific ESG risk management process to identify and consider ESG risks and opportunities separate from other business risks and opportunities.
- setting targets for environment KPI, including with regard to emission, pollution and other impact on the environment aimed at reducing emissions and natural resource consumption.

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We will adopt comprehensive measures to mitigate environmental impact from our business, strategy and financial performance in the near, medium and long term, as summarized below:

<u>Focus area</u>	<u>Key measures</u>
Exhaust gas management	<ul style="list-style-type: none">• Adopt exhaust gas treatment system and install active carbon filters
Greenhouse gas management	<ul style="list-style-type: none">• Increase the use of clean energy• Use energy efficient equipment
Sewage management	<ul style="list-style-type: none">• Install sewage treatment system
Solid waste management	<ul style="list-style-type: none">• Require proper handling and disposal of solid waste• Set up hazardous waste storage sites in accordance with relevant standards and establish standardized hazardous waste management system• Engage qualified third-party suppliers for solid waste disposal
Energy and resource conservation	<ul style="list-style-type: none">• Improve energy-saving features such as energy-saving transformers• Conserve water by recycling rain water and installing low-flow valves

Further, we monitor the following metrics to assess and manage the environmental and climate-related risks arising from our business and manufacturing operations:

Resource consumption

- *Electricity consumption.* We monitor our electricity consumption levels and implement measures to improve energy efficiency. For the years ended December 31, 2022 and 2023, our electricity consumption levels were 1.2 million kWh and 1.1 million kWh, respectively.
- *Water consumption.* We monitor our water consumption levels and implement measures to promote water conservation. For the years ended December 31, 2022 and 2023, our water consumption levels were 4,724 tons and 3,426 tons, respectively.

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Pollutant management

- *Exhaust gas discharge.* We monitor our exhaust gas discharge levels on a periodic basis. During the Track Record Period, our daily exhaust gas emissions VOCs concentration was below 21mg/m³, and such exhaust gas was properly treated prior to discharge.
- *Hazardous waste discharge.* We monitor our hazardous waste discharge levels on a periodic basis. For the years ended December 31, 2022 and 2023, our hazardous waste discharge levels were approximately 26.9 tons and 26.1 tons, respectively, and such waste was disposed by qualified third parties.

In setting targets for the KPIs, we have taken into account our respective historical levels during the Track Record Period, and has considered our future business expansion in a thorough and prudent manner with a view of balancing business growth and environmental protection to achieve sustainable development. We will make continuous efforts in working towards the target of reducing our electricity and water consumption, gas emissions and hazardous wastes discharge per thousand dollars of expense by 10% in 2024.

INSURANCE

We maintain insurance policies for adverse events in clinical trials, liabilities of directors, supervisors and senior management, and fixed assets. We currently do not maintain product liability insurance. For more details, see “Risk Factors – Risks Relating to Our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.”

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made, or been the subject of, any material insurance claims.

CERTIFICATES, PERMITS AND LICENSES

As of the Latest Practicable Date, our PRC Legal Adviser confirmed that we had obtained all requisite licenses, approvals and permits from relevant PRC authorities that are material to our operations in the PRC, and such licenses, permits and certifications all remained in full effect. For more details regarding the laws and regulations to which we are subject, see “Regulatory Overview.” We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. To the best knowledge of our PRC Legal Adviser, 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

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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 noncompliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates.

The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

Qualification	Issue Date	Expiration Date
Business License	February 17, 2023	N/A
Customs import and export goods consignee or consignor for the record return receipt (海關進出口貨物收發貨人備案回執)	November 25, 2020	N/A
Enterprise overseas investment certificate (企業境外投資證書)	September 16, 2022	N/A
Notice of filing for overseas investment projects (境外投資項目備案通知書)	September 19, 2022	N/A

LEGAL PROCEEDINGS AND 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. 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

Our PRC Legal Adviser confirmed that during the Track Record Period and up to the Latest Practicable Date, we had complied with applicable PRC laws and regulations in all material aspects. Our Directors confirmed that we were not involved in any material or systematic non-compliance incidents.

Our compliance team is responsible for building, developing and improving our compliance management system to ensure our compliance culture is embedded into every day workflow. The team conducts compliance training for target groups, and identifies, assesses, monitors and reports compliance risks and expectations in a timely manner. For example, we

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provide formal and comprehensive company-level Chinese Civil Code seminar to our employees, followed by on-the-job trainings in order to efficiently get our employees familiarized with their responsibilities and our compliance requirements. Our compliance team will also work with the senior management team to monitor and evaluate the effectiveness of our compliance function and structure to ensure that we comply with the applicable laws and regulations. For example, we will conduct compliance and performance review on our employees periodically against our internal compliance standards to ensure their compliance awareness meets our requirements.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in general market conditions and the regulatory environment of China, the U.S. and other target markets, our ability to develop, manufacture and commercialize our product candidates, and our ability to compete with other pharmaceutical companies. See “Risk Factors” for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to credit, liquidity and currency risks that arise in the normal course of our business.

We have established an audit committee and also adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. The following key principles outline our approach to risk management:

- Our audit committee will oversee and manage the overall risks associated with our business operation, including (i) reviewing and approving our risk management policies to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management’s handling of such risks; (iv) reviewing our corporate risk in light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Company.
- We have established an audit compliance department to be responsible for (i) formulating and updating our risk management policy and targets; (ii) reviewing and approving major risk management issues of our Company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our Company; (v) reviewing the relevant departments’ reporting on key risks and providing feedback; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our Company; (viii) reporting to our audit committee on our material risks; and (ix) cooperating with external auditors in the audit work of the company.

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- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to standardize risk management across our Company and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

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

Internal Control

Our Board of Directors is responsible for establishing and ensuring effective internal controls to safeguard our Shareholder's investment at all times. Our internal control policies set out a framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis.

Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have established anti-bribery and anti-corruption measures, which set forth procedures for identifying potential frauds and corruption, implementing relevant anti-corruption procedures and setting out anti-corruption responsibilities for relevant personnel. We strictly prohibit bribery or other improper payments in any of our business operations. This prohibition applies to all business activities, whether involving government officials, influential personnel or private or public payors. 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. We provide employees with adequate communication channels. If employees have any questions about anticorruption compliance principles, they should promptly contact their supervisor or company compliance team. We encourage employees to take the initiative to seek guidance from us regarding anti-corruption policy principles. We have also put in place whistleblower mechanism so that employees can timely report relevant incidents in time to compliance team according to our anti-corruption measures.

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We plan to maintain strict anti-corruption policies among our employees in our sales and marketing activities and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We have not had any corruption incidents in our history.

- We have established procedures to protect the confidentiality of patients' personal data. We maintain policies which require our personnel to be trained on collecting, and safeguarding personal information. We also require our CROs to have data protection clauses in our agreements with them under which they are responsible for safeguarding data in their possession. Access to clinical trial data has been strictly limited to authorized personnel only according to the good clinical practice and relevant regulations. Additionally, we require external parties and internal employees involved in clinical trials to comply with applicable confidentiality requirements. Data can only be used for the intended purpose, as agreed by the patients and the data usage shall be consistent with the informed consent form. We have a number of ongoing or planned clinical studies. Any transfer of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable data and privacy protection laws.
- We have adopted various measures and procedures regarding each aspect of our business operation, such as protection of intellectual property, environmental protection, and occupational health and safety. We provide periodic training on these measures and procedures to our employees as part of our employee training program. We also constantly monitor the implementation of those measures and procedures through our on-site internal control team for each stage of the product development process.
- Our Directors (who are responsible for monitoring the corporate governance of our Company), with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an audit committee, which (i) makes recommendations to our Directors on the appointment and removal of external auditors; (ii) reviews the financial information and renders advice in respect of financial reporting; and (iii) oversee internal control procedures of our Company.
- We have engaged Central China International Capital Limited as our compliance advisor to provide advice to our Directors and management team. Our Compliance Advisor is expected to, upon our consultation, provide advice and guidance in respect of compliance with the applicable laws and Listing Rules including various requirements of directors' duties and internal control in a timely fashion.

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- We plan to engage a PRC law firm to advise us on and keep us abreast of PRC laws and regulations after the [REDACTED]. We will continue to arrange various trainings sessions to be provided by external legal advisors from time to time when necessary, and/or any appropriate accredited institution to update our Directors, senior management and relevant employees on the latest PRC laws and regulations.
- We will comply with the Corporate Governance Code, except for the deviation from the code provision A.2.1 of the Corporate Governance Code. We have set out respective terms of reference of directors and senior management in compliance with the Corporate Governance Code. For further details, see the section headed “Directors, Supervisors and Senior Management.”
- Our Directors believe that compliance creates value for us and dedicate to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behaviour across the organization, we regularly conduct internal compliance checks, inspections and compliance training.

During the Track Record Period, we have regularly reviewed and enhanced our internal control system.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Dr. Wu is able to exercise approximately 34.29% voting rights in our Company through (i) 47,847,024 Shares directly held by him; (ii) 54,726,152 Shares held by Nanjing Yipu; and (iii) 28,284,453 Shares held by Nanjing Jiminrui. Immediately upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Dr. Wu will be directly and indirectly entitled to exercise approximately [REDACTED]% voting rights in our Company. Therefore, Dr. Wu, Nanjing Yipu and Nanjing Jiminrui will be regarded as our Controlling Shareholders under the Listing Rules upon the [REDACTED]. For background and biographical details of Dr. Wu, please refer to the section headed “Directors, Supervisors and Senior Management – Board of Directors” in this document.

Our Controlling Shareholders have confirmed that, as of the Latest Practicable Date, they did not have any interest in other business, apart from the business of our Company, which competes or is likely to compete, directly or indirectly, with our business, which would require disclosure under Rule 8.10 of the Listing Rules.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

Our Directors consider that we are capable of carrying on our business independently of our Controlling Shareholders and their close associates after the [REDACTED], taking into consideration of the factors below.

Management Independence

Our Board comprises seven Directors, including two executive Directors, two non-executive Directors and three independent non-executive Directors. We believe that our Board as a whole, together with our senior management, is able to perform the managerial role in our Group independently from our Controlling Shareholders for the following considerations:

- (a) each of our Directors is aware of his/her fiduciary duties as a Director which require, among others, that he/she acts for the benefit of and in the best interests of our Company and not allow any conflict between his/her duties as a Director and his/her personal interests;
- (b) our daily management and operation decisions are made by all our executive Directors and senior management, all of whom have substantial experience in the industry in which we are engaged and will be able to make business decisions that are in the best interest of our Group. For details of the industry experience of our senior management, please see the section headed “Directors, Supervisors and Senior Management” in this document;
- (c) we have appointed three independent non-executive Directors, comprising more than one-third of the total members of our Board, who have sufficient knowledge, experience and competence with a view to bringing independent judgment to the decision-making process of our Board;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (d) in the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Group and a Director and/or his/her associate, he/she shall abstain from voting and shall not be counted towards the quorum for the voting; and
- (e) we have adopted a series of corporate governance measures to manage conflicts of interest, if any, between our Group and our Controlling Shareholders which would support our independent management. For further details, please refer to the paragraph headed "Corporate Governance Measures" in this section.

In light of the above, our Directors believe that our Company has sufficient and effective control mechanisms to ensure that our Directors perform their respective duties properly and safeguard the interests of our Company and our Shareholders as a whole.

Operational Independence

We have full rights to make all decisions on, and to carry out, our own business operations independently. We have our own departments specializing in these respective areas which have been in operation and are expected to continue to operate independently from our Controlling Shareholders and their close associates. We hold all the requisite licenses, intellectual property rights and qualifications that are material to carry on our principal business. We also have independent access to suppliers and customers and have sufficient capital, facilities and employees to operate our business independently from our Controlling Shareholders and their close associates.

Based on the above, our Directors believe that we will be able to operate independently from our Controlling Shareholders and their close associates.

Financial Independence

We have an independent financial system. We make financial decisions according to our own business needs and neither our Controlling Shareholders nor their close associates intervene with our use of funds. We have established an independent finance department with a team of financial staff and an independent audit, accounting and financial management system.

In addition, we have been and are capable of obtaining financing from third parties without relying on any guarantee or security provided by our Controlling Shareholders or their close associates. As of the Latest Practicable Date, our Group had no loan, advance or guarantee provided by our Controlling Shareholders or their close associates.

Based on the above, our Directors believe that we are capable of carrying on our business independently of and do not place undue reliance on our Controlling Shareholders and their close associates after the [REDACTED].

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

CORPORATE GOVERNANCE MEASURES

Our Directors recognize the importance of good corporate governance in protecting our Shareholders’ interests. We have adopted the following measures to safeguard good corporate governance standards and to avoid potential conflict of interests between our Group and our Controlling Shareholders:

- (a) where a Shareholders’ meeting is to be held for considering proposed transactions in which our Controlling Shareholders or any of their associates has a material interest, our Controlling Shareholders or their associate will not vote on the relevant resolutions and shall not be counted in the quorum for the voting;
- (b) our Company has established internal control mechanisms to identify connected transactions. Upon the [REDACTED], if our Company enters into connected transactions with our Controlling Shareholders or any of their associates, our Company will comply with the applicable Listing Rules;
- (c) our Board consists of a balanced composition of executive Directors, non-executive Directors and independent non-executive Directors, with independent non-executive Directors representing not less than one-third of our Board to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. Our independent non-executive Directors individually and collectively possess the requisite knowledge and experience to perform their duties. They will review whether there is any conflict of interests between our Group and our Controlling Shareholders and provide impartial and professional advice to protect the interests of our minority Shareholders;
- (d) where our Directors reasonably request the advice of independent professionals, such as financial advisers, the appointment of such independent professionals will be made at our Company’s expenses; and
- (e) we have appointed Central China International Capital Limited as our compliance adviser to provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules, including various requirements relating to corporate governance.

Based on the above, our Directors believe that sufficient corporate governance measures have been put in place to manage conflicts of interest that may arise between our Group and our Controlling Shareholders and to protect our Shareholders’ interests as a whole after the [REDACTED].

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and without taking into account any H Shares which may be issued pursuant to the exercise of the [REDACTED], the following persons will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to our Company and the Hong Kong Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company:

Name of Shareholder	Nature of Interest	Description of Shares	Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)		
			Number of Shares	Approximate percentage of interest in the Unlisted Shares/H Shares (as appropriate) ⁽¹⁾ (%)	Approximate percentage of interest in the Company ⁽¹⁾ (%)
Nanjing Yipu ⁽²⁾	Beneficial owner	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
Nanjing Jiminrui ⁽²⁾	Beneficial owner	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
		H Shares	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Wu ⁽²⁾	Beneficial owner	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
		Interest in controlled corporations	[REDACTED]	[REDACTED]	[REDACTED]
Genecare Development ⁽³⁾	Beneficial owner	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
		H Shares	[REDACTED]	[REDACTED]	[REDACTED]
Morningside Venture (I) Investments Limited ⁽³⁾	Interest in controlled corporations	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
Morningside Bio-Ventures Limited ⁽³⁾	Interest in controlled corporations	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
Morningside Holdings (Asia) Limited ⁽³⁾	Interest in controlled corporations	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
FIIF II ⁽⁴⁾	Beneficial owner	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
CS Capital Co., Ltd. (國投招商投資管理有限公司) ⁽⁴⁾	Interest in controlled corporations	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
PharmaBlock	Beneficial owner	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
CPE Investment ⁽⁵⁾	Beneficial owner	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
Cayenne Private Enterprise IV Limited (“Cayenne Private”) ⁽⁵⁾	Interest in controlled corporations	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
CPEChina Fund IV, L.P. (“CPEChina”) ⁽⁵⁾	Interest in controlled corporations	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
CPE Funds IV Limited (“CPE Funds IV”) ⁽⁵⁾	Interest in controlled corporations	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
CPE Management International Limited (“CPE Management”) ⁽⁵⁾	Interest in controlled corporations	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
CPE Management International II Limited (“CPE Management II”) ⁽⁵⁾	Interest in controlled corporations	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理 有限公司) ⁽⁶⁾	Interest in controlled corporations	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
SDIC Venture Capital Co., Ltd (國投創業投資管理有限公司) ⁽⁷⁾	Interest in controlled corporations	H Shares	[REDACTED]	[REDACTED]	[REDACTED]
Shanghai Guoxin ⁽⁸⁾	Beneficial owner	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]
Shanghai State-owned Assets Management Co., Ltd. (上海國有資產經營有限公司) (“Shanghai State-owned Asset”) ⁽⁸⁾	Interest in controlled corporations	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of Interest	Description of Shares	Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)		
			Number of Shares	Approximate percentage of interest in the Unlisted Shares/H Shares (as appropriate) ⁽¹⁾ (%)	Approximate percentage of interest in the Company ⁽¹⁾ (%)
Shanghai International Group Co., Ltd. (上海國際集團有限公司) (“Shanghai International”) ⁽⁸⁾	Interest in controlled corporations	Unlisted Shares	[REDACTED]	[REDACTED]	[REDACTED]

Notes:

- (1) The calculation is based on the total number of [REDACTED] Unlisted Shares and [REDACTED] H Shares in issue upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised) comprising (i) an aggregate of [REDACTED] H Shares to be converted from the Unlisted Shares and (ii) [REDACTED] H Shares to be issued pursuant to the [REDACTED] (assuming the [REDACTED] is not exercised).
- (2) Dr. Wu is the general partner of Nanjing Yipu and Nanjing Jiminrui and is responsible for the management of Nanjing Yipu and Nanjing Jiminrui. As such, Dr. Wu is deemed to be interested in the [REDACTED] Shares held by Nanjing Yipu and [REDACTED] Shares held by Nanjing Jiminrui under the SFO.
- (3) As of the Latest Practicable Date, the sole shareholder of Genecare Development was Morningside Venture (I) Investments Limited which was wholly owned by Morningside Bio-Ventures Limited. Morningside Bio-Ventures Limited was wholly owned by Morningside Holdings (Asia) Limited, a member of Morningside group ultimately owned by a family trust established by Madam Chan Tan Ching Fen. As such, each of Morningside Venture (I) Investments Limited, Morningside Bio-Ventures Limited and Morningside Holdings (Asia) Limited was deemed to be interested in the Shares in which Genecare Development was interested under the SFO.
- (4) CS Capital Co., Ltd. (國投招商投資管理有限公司) is the general partner of FIIF II and is responsible for its management. As such, it is deemed to be interested in the [REDACTED] Shares held by FIIF II under the SFO.
- (5) CPE Investment is wholly owned by Cayenne Private which is controlled by CPEChina whose general partner is CPE Funds IV. CPE Funds IV is wholly owned by CPE Management, which is a wholly-owned subsidiary of CPE Management II. As such, each of Cayenne Private, CPEChina, CPE Funds IV, CPE Management and CPE Management II is deemed to be interested in the [REDACTED] Shares held by CPE Investment under the SFO.
- (6) GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理有限公司) is the general partner of GP Healthcare Capital Phase II and GP Healthcare Capital Phase III. As such, it is deemed to be interested in the [REDACTED] Shares held by GP Healthcare Capital Phase II and the [REDACTED] Shares held by GP Healthcare Capital Phase III.
- (7) SDIC Venture Capital Co., Ltd (國投創業投資管理有限公司) is the general partner of SDICVC Ningbo Fund and holds 91% interest in SDIC (Guangdong) Venture Capital Management Co., Ltd (國投(廣東)創業投資管理有限公司), which in turn is the general partner of SDIC Greater Bay Area Fund. As such, it is deemed to be interested in the [REDACTED] Shares held by SDICVC Ningbo Fund and the [REDACTED] Shares held by SDIC Greater Bay Area Fund.
- (8) As of the Latest Practicable Date, Shanghai Guoxin is wholly owned by Shanghai State-owned Asset. Shanghai State-owned Asset is wholly owned by Shanghai International, which in turn is wholly owned by Shanghai State-owned Assets Supervision and Administration Commission (上海市國有資產監督管理委員會). As such, each of Shanghai State-owned Asset and Shanghai International is deemed to be interested in the [REDACTED] Shares held by Shanghai Guoxin.

SUBSTANTIAL SHAREHOLDERS

Save as disclosed herein, our Directors are not aware of any persons who will, immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), without taking into account the [REDACTED] that may be taken up under the [REDACTED], have interests or short positions in Shares or underlying Shares which would fall to be disclosed under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company.

SHARE CAPITAL

This section presents certain information regarding our share capital prior to and upon the completion of the [REDACTED].

As of the Latest Practicable Date, the registered share capital of our Company was RMB381,616,633 comprising 381,616,633 Unlisted Shares with a nominal value of RMB1.00 each.

UPON COMPLETION OF THE [REDACTED]

Immediately upon completion of the [REDACTED], assuming the [REDACTED] is not exercised, the share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate percentage of the total issued share capital (%)
Unlisted Shares in issue	95,230,960	[REDACTED]
H Shares to be converted from Unlisted Shares	286,385,673	[REDACTED]
H Shares to be [REDACTED] pursuant to the [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Total	<u>[REDACTED]</u>	<u>100.00</u>

Immediately upon completion of the [REDACTED], assuming the [REDACTED] is fully exercised, the share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate percentage of the total issued share capital (%)
Unlisted Shares in issue	95,230,960	[REDACTED]
H Shares to be converted from Unlisted Shares	286,385,673	[REDACTED]
H Shares to be issued pursuant to the [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Total	<u>[REDACTED]</u>	<u>100.00</u>

SHARE CAPITAL

RANKING

Upon completion of the [REDACTED] and conversion of 286,385,673 Unlisted Shares into H Shares, our Shares will consist of Unlisted Shares and H Shares, which represent the same class of Shares. Both Unlisted Shares and H Shares are ordinary shares in the share capital of our Company. Apart from certain qualified domestic institutional investors in the PRC, certain qualified PRC investors under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect, and other persons who are entitled to hold our H Shares pursuant to relevant PRC laws and regulations or upon approvals of any competent authorities, H Shares generally cannot be subscribed by or traded among legal and natural persons of the PRC.

Unlisted Shares and H Shares are regarded as one class of shares under our Articles of Association, and Unlisted Shares and H Shares will rank *pari passu* with each other in all other respects and, in particular, will rank equally for all dividends or distributions declared, paid or made after the date of this document. All dividends in respect of our Shares are to be declared and paid by us in Hong Kong dollars or Renminbi. Other than cash, dividends could also be paid in the form of shares or a combination of cash and shares.

CONVERSION OF OUR UNLISTED SHARES INTO H SHARES

All our Unlisted Shares are not [REDACTED] or [REDACTED] on any stock exchange. The holders of our Unlisted Shares may convert their Shares into H Shares provided such conversion shall have gone through any requisite internal approval process and complied with the regulations prescribed by the securities regulatory authorities of the State Council and the regulations, requirements and procedures prescribed by the overseas stock exchange(s) and have been approved by the securities regulatory authorities of the State Council, including the CSRC. The [REDACTED] of such converted Shares on the Hong Kong Stock Exchange will also require the approval of the Hong Kong Stock Exchange.

Based on the procedures for the conversion of our Unlisted Shares into H Shares as disclosed in this section, we can apply for the [REDACTED] of all or any portion of our Unlisted Shares on the Hong Kong Stock Exchange as H Shares in advance of any proposed conversion to ensure that the conversion process can be completed promptly upon notice to the Hong Kong Stock Exchange and delivery of Shares for entry on the [REDACTED]. As any [REDACTED] of additional Shares after our initial [REDACTED] on the Hong Kong Stock Exchange is ordinarily considered by the Hong Kong Stock Exchange to be a purely administrative matter, it will not require such prior application for [REDACTED] at the time of our initial [REDACTED] in Hong Kong.

No class Shareholder voting is required for the [REDACTED] and [REDACTED] of the converted Shares on the Hong Kong Stock Exchange. Any application for [REDACTED] of the converted Shares on the Hong Kong Stock Exchange after our initial [REDACTED] is subject to prior notification by way of announcement to inform Shareholders and the public of such proposed conversion.

SHARE CAPITAL

After all the requisite approvals have been obtained, the following procedure will need to be completed in order to effect the conversion: the relevant Unlisted Shares will be withdrawn from the Unlisted Share register and we will re-register such Shares on our [REDACTED] maintained in Hong Kong and instruct the [REDACTED] to issue H Share certificates. Registration on our [REDACTED] will be conditional on (a) our [REDACTED] lodging with the Hong Kong Stock Exchange a letter confirming the proper entry of the relevant H Shares on the [REDACTED] of members and the due dispatch of H Share certificates; and (b) the admission of the H Shares to trade on the Hong Kong Stock Exchange in compliance with the Listing Rules, the General Rules of CCASS and the CCASS Operational Procedures in force from time to time. Until the converted shares are re-registered on our [REDACTED], such Shares would not be [REDACTED] as H Shares.

RESTRICTION ON TRANSFER OF SHARES ISSUED PRIOR TO [REDACTED] DATE

Pursuant to the PRC Company Law, our Shares issued prior to the [REDACTED] shall not be transferred within one year from the [REDACTED] Date.

REGISTRATION OF SHARES NOT [REDACTED] ON THE OVERSEAS STOCK EXCHANGE

According to the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》), domestic shareholders of unlisted shares shall, in accordance with the relevant business rules of the CSDC, handle the transfer registration of shares, complete the procedures of share registration and stock listing in accordance with the relevant regulations of the Hong Kong market, and disclose information in accordance with the law and regulations. The H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with the CSDC of the shares related to the application has been completed.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board consists of seven Directors, with two executive Directors, two non-executive Directors and three independent non-executive Directors. Our Board serves a term of three years and is responsible and has general powers for the management and conduct of our business.

The table below sets out certain information in respect of the members of the Board.

Name	Age	Position	Date of appointment as Director	Date of joining our Group	Role and responsibilities	Relationship with other Directors, Supervisors and senior management
Dr. Frank Wu (吳永謙)	61	Chairman of the Board, executive Director and chief executive officer	May 10, 2016	June 10, 2016	Responsible for the overall strategic planning, business direction and operational management	None
Mr. Wu Di (吳笛)	45	Executive Director and vice president	March 16, 2020	January 13, 2017	Responsible for strategy and business development of our Company	None
Ms. Jia Zhongxin (賈中新)	65	Non-executive Director	September 11, 2018	September 11, 2018	Responsible for providing guidance on corporate strategy and governance to our Company	None
Dr. Yi Hua (易華)	49	Non-executive Director	March 16, 2020	March 16, 2020	Responsible for providing guidance on corporate strategy and governance to our Company	None
Ms. Chui Hoi Yam (徐海音)	57	Independent non-executive Director	October 17, 2022	October 17, 2022	Supervising and providing independent opinion to our Board	None
Ms. Zheng Zhelan (鄭哲蘭)	54	Independent non-executive Director	October 17, 2022	October 17, 2022	Supervising and providing independent opinion to our Board	None
Mr. Li Shu Pai (李書湃)	47	Independent non-executive Director	June 17, 2021	June 17, 2021	Supervising and providing independent opinion to our Board	None

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

The following sets forth the biographies of our Directors:

Executive Directors

Dr. Frank Wu (吳永謙), previously known as Wu Yong-qian, aged 61, is the chairman of the Board, executive Director and chief executive officer of our Company. He joined our Company on June 10, 2016 and has been participating in the daily operations of our Company since then. Dr. Wu has been the chairman of the Board since November 18, 2016. Dr. Wu is primarily responsible for the overall strategic planning, business direction and operational management. Dr. Wu has more than 27 years of experience in the biopharmaceutical industry.

Prior to joining our Company, Dr. Wu joined Sihuan Pharmaceutical Holdings Group Ltd. (四環醫藥控股集團有限公司), a comprehensive pharmaceutical company engaged in R&D, manufacture and sales of medicine listed on the Main Board of the Stock Exchange (stock code: 0460) (“**Sihuan Pharmaceutical**”) in 2011. Dr. Wu served as the senior vice president of project management of Shandong Xuanzhu Biopharmaceutical Co., Ltd. (山東軒竹醫藥科技有限公司) (“**Shandong Xuanzhu Biopharmaceutical**”), a wholly owned subsidiary of Sihuan Pharmaceutical at that time, from January 2011 to December 2012, and as the general manager Shandong Xuanzhu Biopharmaceutical from January 2013 to May 2016, where he was primarily responsible for the overall management and operations of the company. He was the chief scientific officer of Sihuan Pharmaceutical from 2014 to 2015. He also worked for five years at Boehringer Ingelheim Pharmaceuticals Inc., where he was responsible for the research projects in immunology and cardiovascular drug. Moreover, he was employed by Guilford Pharmaceuticals, Inc. from November 1996 to June 2005.

Dr. Wu has been granted several certificates and recognitions in the industry and the community. He was a member of prestigious American Chemistry Society Division of Medicinal Chemistry long range planning committee from 2008 to 2010. He was appointed as an editor of Chinese Journal of New Drugs (中國新藥雜誌) in 2014 and an editor of Progress in Pharmaceutical Sciences (藥學進展) in 2020. He was a member of the first session (*years 2015-2019*) of the “Drug Development Committee” of the China Pharmaceutical Innovation and Research Development Association (中國醫藥創新促進會). He was a visiting professor at the School of Pharmacy of Sun Yat-sen University (中山大學) from May 2014 to May 2017.

Dr. Wu obtained his bachelor’s degree in chemistry from Nanjing University (南京大學) in the PRC in July 1985. He further obtained his doctor’s degree in philosophy from Wayne State University in the U.S. in May 1993 and was appointed as a postdoctoral fellow in the biochemistry department from Brandeis University in the U.S. from January 1994 to December 1995.

Mr. Wu Di (吳笛), aged 45, is the executive Director and vice president of our Company. He joined the company on January 13, 2017, and has been responsible for strategy and business development of our Company since then. He was appointed as an executive Director on March 16, 2020. Mr. Wu has more than 18 years of experience in the biopharmaceutical industry.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Prior to joining our Company, Mr. Wu was the business development director of Shandong Xuanzhu Biopharmaceutical, a pharmaceutical R&D company, and he was responsible for the international business development from January 2015 to January 2017. And before that, he was also employed as a regular full-time employee at Boehringer Ingelheim Pharmaceuticals Inc., a company primarily engaged in a U.S. corporation principally engaged in scientific research in order to develop and market ethical pharmaceuticals until January 2015.

Mr. Wu obtained his bachelor’s degree in science from the Peking University (北京大學) in the PRC in July 2001. He further obtained his master’s degree in science from the University of Nebraska in the U.S. in July 2005. He also obtained another master’s degree in business administration in the New York University in the U.S. in September 2015.

Non-executive Directors

Ms. Jia Zhongxin (賈中新), aged 65, is a non-executive Director of our Company. She was appointed as non-executive Director on September 11, 2018, and has been serving as the strategic consultant of our Company since September 11, 2018 and was primarily responsible for providing guidance on corporate strategy and governance to our Company. Ms. Jia has profound experience in the biopharmaceutical industry.

Prior to joining our Company, Ms. Jia was the chief operating officer of Sihuan Pharmaceutical, and she was responsible for the research and development, manufacturing and marketing of the group from December 2007 to June 2017. She has held various managerial positions in several companies. Between January 2006 and November 2007, Ms. Jia headed the biomedical department of China Baoan Group Co., Ltd. (中國寶安集團股份有限公司) and was also chairwoman of Shenzhen Daphne Pharmaceutical Co., Ltd. (深圳大佛藥業有限公司). Prior to that, she was the general manager of Wuhan Ma Ying Long Pharmaceutical Co., Ltd. (武漢馬應龍醫藥有限公司) and chairman of Wuhan Ma Ying Long Chained Pharmacies Co., Ltd. (武漢馬應龍大藥房連鎖股份有限公司) from November 2002 to December 2005.

Ms. Jia obtained a Bachelor in medicinal chemistry in 1982 from the Medical Department of Peking University (北京大學) (formerly known as Beijing Medicine College, Beijing Medical University (北京醫科大學 – 北京醫學院)) and a Master in Business Administration from the University of South Australia in 2004 through remote learning.

Ms. Jia obtained the registered qualification certificate of licensed pharmacist (執業藥師資格證書) approved and authorized by Ministry of Personnel and State Drug Administration of the PRC in September 2000. She was awarded the title of senior engineer (高級工程師) approved and authorized by Shandong Pharmaceutical Engineering Technical Post Senior Evaluation Committee (山東省醫藥工程技術職務高級評審委員會) in December 1993. She was awarded the title of senior engineer of pharmaceutical research (藥研高級工程師) approved and authorized by Personnel Department of Guangdong Province (廣東省人事廳) in June 2002.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. Yi Hua (易華), aged 49, is a non-executive Director of our Company. He was appointed as non-executive Director on March 16, 2020. He is primarily responsible for the corporate strategy and governance. Dr. Yi has profound experience in the biopharmaceutical industry.

Beginning in April 2017, he was with SDIC Fund Management (Shanghai) Co., Ltd. (國投創新投資管理(上海)有限公司), a stated-owned professional private equity management organization where he currently serves as an executive director and he is responsible for equity investments. Dr. Yi also served as a director of HMT (Xiamen) New Technical Materials Co., Ltd. (華懋(廈門)新材料科技股份有限公司(HMT)) from November 2020 to November 2023, a company listed on the Shanghai Stock Exchange (stock code: 603306).

Prior to joining our Company, Dr. Yi was the investment manager at CoStone Asset Management Co., Ltd. (基石資產管理股份有限公司), an investment firm in China, and he was responsible for equity investments from October 2014 to April 2017.

Dr. Yi obtained his doctor’s degree in analytical chemistry from the East China Normal University (華東師範大學) in the PRC in July 2005. He further obtained his post-doctoral degree from ENS Cachan (currently known as Ecole normale superieure Paris-Saclay) in France in September 2009.

Independent Non-executive Directors

Ms. Chui Hoi Yam (徐海音), aged 57, is an independent non-executive Director of our Company. She was appointed as independent non-executive Director since October 17, 2022. She is primarily responsible for supervising and providing independent opinion to our Board. Ms. Chui has accumulated more than 20 years of experience in corporate management.

Prior to joining our Company, Ms. Chui has been serving as an independent non-executive director of Everest Medicines Limited (雲頂新耀有限公司), a biotech company and listed on the Main Board of the Stock Exchange (stock code: 1952) since January 2023. She served as an independent non- executive director of China biotech services holdings limited (中國生物科技服務控股有限公司), a biotech company and listed on the Main Board of the Stock Exchange (stock code: 8037) from December 2022 to June 2024. Ms. Chui served as a director and general manager of Hapharm Group Co., Ltd. (哈藥集團股份有限公司) from March 2019 to August 2022, a company principally engaged in pharmaceutical manufacturing and listed on the Shanghai Stock Exchange (stock code: 600664), and she was responsible for the overall management. She served as a president of Novartis from March 2012 to March 2016, an international biotechnology company, and she was responsible for the overall management. Ms. Chui also served as a senior vice president of China Hewlett-Packard Co., Ltd (中國惠普有限公司) from March 2010 to March 2012, an international high-technology company, and she was responsible for supervising overall operations. In addition, She served as a senior director of Pfizer Investments Ltd. (輝瑞投資有限公司) from November 2004 to March 2010, a subsidiary of Pfizer Inc., and she was responsible for department’s overall management. In addition, Ms. Chui has been a chairwoman of the board of Neuma Biology Ltd. (靈知生物技術(蘇州)有限公司) since November 2023.

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Ms. Chui obtained her bachelor’s degree of economics from Peking University (北京大學) in the PRC in July 1990. She further obtain her master’s degree of finance from Peking University (北京大學) in the PRC in July 2001.

Ms. Zheng Zhelan (鄭哲蘭), aged 54, is an independent non-executive Director of our Company. She was appointed as independent non-executive Director since October 17, 2022. She is primarily responsible for supervising and providing independent opinion to our Board. Ms. Zheng has accumulated more than 27 years of experience in legal industry.

Prior to joining our Company, Ms. Zheng has been serving as a partner of Grandall Law Firm (Shanghai) (國浩律師(上海)事務所) since November 2016, and she is responsible for the overall management of the law firm. She also served as an associate of Grandall Law Firm (Nanjing) (國浩律師(南京)事務所), and she was responsible for capital markets related works law firm. In addition, she also served as an associate of Nanjing Yonghe Law Firm (南京永和律師事務所) from November 1997 to November 1999.

In addition, she also has extensive experience in government agencies and social organizations, including: (i) a member of the Ethics Committee of Nanjing High-tech Hospital (南京市高新醫院倫理委員會委員) since March 2018; (ii) a member of the Ethics Review Committee of Nanjing Jiangbei New Area Medical Association (南京江北新區醫學會倫理審查委員會委員) since July 2021; and (iii) a member of the Committee of Nanjing Drum Tower Hospital (南京鼓樓醫院倫理委員會委員) since December 2023.

Ms. Zheng obtained her bachelor’s degree of economics law from Nanjing University (南京大學) in the PRC in July 1991. She further obtain her master’s degree in law from Nanjing University (南京大學) in the PRC in July 2002.

Mr. Li Shu Pai (李書湃), former name Lee Shu Paai (李書湃), aged 47, is an independent non-executive Director of our Company. He was appointed as independent non-executive Director since June 17, 2021. He is primarily responsible for supervising and providing independent opinion to our Board. Mr. Li has accumulated more than 20 years of experience in finance, investment, and accounting.

Prior to joining our Company, Mr. Li has been serving as the chief financial officer and company secretary of Meilleure Health International Industry Group Limited since July 2019, a company principally engaged in the healthcare-related business, trading business, property-related business and equity investment business and listed on the Main Board of the Stock Exchange (stock code: 2327). Mr. Li was the independent non-executive Director of Comtec Solar Systems Group Limited from February to March 2021, a company principally engaged in design, development, manufacturing and marketing of solar wafers and listed on the Main Board of the Stock Exchange (stock code: 0712). Mr. Li was the chief financial officer and company secretary of Perfectech International Holdings Limited (威發國際集團有限公司) and was mainly responsible for the financial management, compliance and risk management of the Group, and he undertook the duties of secretary and relevant duty thereof, reporting to the director of the group from December 2016 to September 2018, a company principally engaged

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

in manufacture and sales of toy products and listed on the Main Board of the Stock Exchange (stock code: 0765). Mr. Li served as the chief financial officer and joint company secretary of Chutian Dragon Corporation Limited (楚天龍股份有限公司) and was mainly responsible for account, finance, investor relationship, company secretary and corporate governance from July 2015 to December 2016, a company principally engaged in integrated smart card solution provider and data management. Mr. Li was appointed as the chief financial officer of R2 Games Co., Limited (深圳燦和兄弟網絡科技有限公司) and was mainly responsible for account, finance, internal control, investor relationships and corporate governance from August 2014 to June 2015, a company principally engaged in online game operator and the wholly-owned subsidiary of Beijing Can Brother Technologies Co., Ltd., a company quoted on National Equities Exchange and Quotations (stock code: 430052). Mr. Li served as the deputy chief financial officer of Beijing Tong Ren Tang Chinese Medicine Co., Ltd and was mainly responsible for handling investor relations, finance, compliance and corporate governance from September 2011 to December 2013, a company principally engaged in traditional Chinese medicine and listed on the Main Board of the Stock Exchange (stock code: 3613). Mr. Li served as an associate of BNP Paribas Capital (Asia Pacific) Limited from July 2010 to August 2011. Mr. Li served as an associate of Corporate Finance Department of BOCI Asia Limited from August 2007 to July 2009. Mr. Li worked in PricewaterhouseCoopers as an associate and from September 2001 to October 2006 and was later promoted to manager from October 2006 to August 2007.

Mr. Li obtained his bachelor’s degree of business administration in accountancy from City University of Hong Kong in November 2001. Mr. Li obtained his master’s degree in business administration from The Hong Kong University of Science and Technology in June 2014.

Mr. Li was admitted as a Certified Public Accountant and a fellow of the Hong Kong Institute of Certified Public Accountants in October 2004 and February 2012, respectively. Mr. Li was also admitted as a member and a fellow of Association of Chartered Certified Accountants in July 2012 and July 2017, respectively.

General

Each of our Directors has confirmed that:

- (1) he/she obtained the legal advice referred to under Rule 3.09D of the Listing Rules in April 2024, and understood his/her obligations as a director of a [REDACTED];
- (2) save as disclosed in the paragraph headed “Appendix VI – Statutory and General Information – Further Information about Our Directors, Supervisors and Substantial Shareholders – 1. Disclosure of Interests” in this document, he/she has no interest in the Shares within the meaning of Part XV of the SFO as at the Latest Practicable Date;

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

- (3) save as disclosed above, he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to and as at the Latest Practicable Date;
- (4) other than being a Director, none of our Directors has any relationship with any other Directors, Supervisors, senior management or substantial Shareholders of our Company; and
- (5) he/she did not complete his/her education programs as disclosed in this section by way of attendance of long distance learning or online courses.

Each of our independent non-executive Directors has confirmed:

- (1) his/her independence after taking into consideration each of the factors referred to under Rules 3.13(1) to 3.13(8) of the Listing Rules;
- (2) that he/she does not have any past or present financial or other interest in the business of our Company or our subsidiaries, or any connection with any core connected person of our Company; and
- (3) there are no other factors which may affect his/her independence at the time of his/her appointment as our independent non-executive Director.

Save as disclosed in this document, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries:

- (1) there is no other matter with respect to the appointment of our Directors that needs to be brought to the attention to the Shareholders as of the Latest Practicable Date; and
- (2) there is no other information relating to our Directors that is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as of the Latest Practicable Date.

From time to time, our non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biotechnology industries. However, as these non-executive Directors are neither our Controlling Shareholders, executive directors, nor members of our senior management team, we do not believe that their interests in such companies, including as directors, would render us incapable of carrying on our business independently from other companies in which they may hold a role, including a directorship, from time to time.

SUPERVISORS

Our Supervisory Committee comprises three members. Our Supervisors serve a term of three years and may be re-elected for successive reappointments. The functions and duties of the Supervisory Committee include reviewing financial reports, business reports and profit distribution plans prepared by the Board and overseeing the financial and business performance of our Company. They are also entitled to appoint certified public accountants and practicing auditors to re-examine our Company's financial information where necessary.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

The following table sets out information in respect of the Supervisors.

Name	Age	Position	Date of appointment as Supervisor	Date of joining our Company	Role and responsibilities	Relationship with other Directors, Supervisors and senior management
Ms. Zhao Weili (趙衛麗)	42	Chairwoman of Supervisory Board (employees' representative Supervisor)	June 17, 2021	April 17, 2017	Responsible for monitoring of the financial affairs of our Company, supervising the performance of our Directors and members of senior management and performing other supervisory duties as a Supervisor	None
Mr. Mei Jianghua (梅江華)	46	Shareholders' representative Supervisor	March 16, 2020	March 16, 2020	Responsible for monitoring of the financial affairs of our Company, supervising the performance of our Directors and members of senior management and performing other supervisory duties as a Supervisor	None
Ms. Pang Yajing (龐亞京)	39	Shareholders' representative Supervisor	July 16, 2021	September 14, 2018	Responsible for monitoring of the financial affairs of our Company, supervising the performance of our Directors and members of senior management and performing other supervisory duties as a Supervisor	None

Ms. Zhao Weili (趙衛麗), aged 42, is the Chairwoman of Supervisory Board. She joined our Company as the deputy director of Intellectual Property Department in April 17, 2017. She was primarily responsible for the overall management of patent related work until April 2020 when she was promoted to the director of the department and since April 2020, she has been primarily responsible for the overall management of intellectual property rights. She also serves as the Chairman of our Supervisory Board since June 17, 2021, and is primarily responsible for monitoring of the financial affairs of our Company, supervising the performance of our Directors and members of senior management and performing other supervisory duties as a Supervisor.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Prior to joining our Company, Ms. Zhao worked as a member of the patent affairs department of Shandong Xuanzhu Biopharmaceutical from January 2008 to June 2012, a pharmaceutical R&D company, and designated as the head of the patent affairs department from July 2012 to March 2017, mainly responsible for domestic and foreign patent drafting, filing and granting. In addition, she was also responsible for the strategic layout of product patents.

Ms. Zhao received a bachelor’s degree in Chinese pharmacology in July 2006 and a master’s degree in pharmaceutical chemistry in June 2018 from Shandong University of Traditional Chinese Medicine (山東中醫藥大學) in the PRC. She also received a master degree of business administration in November 2023 from Maastricht School of management in Netherlands.

Ms. Zhao obtained the patent attorney qualification certificate (專利代理人資格) from the National Intellectual Property Administration in January 2013.

Mr. Mei Jianghua (梅江華), aged 46, is a shareholders’ representative Supervisor. He was appointed as a Supervisor of our Company on March 16, 2020 and is primarily responsible for monitoring of the financial affairs of our Company, supervising the performance of our Directors and members of senior management and performing other supervisory duties as a Supervisor.

Prior to joining our Company, Mr. Mei has been serving as investment director of Shanghai Grandyangtze Capital Co., Ltd. (上海長江國弘投資管理有限公司) since May 2012, an equity investment company, and was responsible for investment in the medical industry. He also worked in Kaishi Changjiang Investment Management Ltd., (凱石長江投資管理有限公司) from March 2011 to May 2012. He also worked in Roche China Development Co., Ltd. (羅氏研發(中國)有限公司) from December 2004 to August 2010, a drug development company. He worked in Shanghai Institute of Materia Medica, Chinese academy of Sciences (中國科學院上海藥物研究所) from September 2003 to December 2004, a scientific research organization.

Mr. Mei obtained his bachelor’s degree in chemistry in June 2000 and a master’s degree in chemistry in March 2003 from Zhejiang University (浙江大學) in the PRC. He also obtained another master’s degree in business administration in March 2015 from Shanghai Jiao Tong University (上海交通大學) in the PRC.

Ms. Pang Yajing (龐亞京), aged 39, is a shareholders’ representative Supervisor. She has joined our Company as the head of quality assurance department since September 14, 2018, was appointed as a supervisor of our Company on July 16, 2021. She is primarily responsible for monitoring of the financial affairs of our Company, supervising the performance of our Directors and members of senior management and performing other supervisory duties as a Supervisor.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Prior to joining our Company, Ms. Pang worked at Shandong Xuanzhu Biopharmaceutical from July 2011 to September 2018, a pharmaceutical R&D company, with her last position as the head of quality assurance department, where she was responsible for the daily management of the quality assurance department.

Ms. Pang obtained her bachelor’s degree in pharmacy from Hebei University (河北大學) in the PRC in July 2008. She obtained her master’s degree in pharmacognosics from the Shandong University of Traditional Chinese Medicine (山東中醫藥大學) in the PRC in July 2011. She also obtained the qualification of engineer in new drug development approved by Jinan Human Resources and Social Security Bureau (濟南市人力資源和社會保障局) in August 2015.

General

Each of our Supervisors has confirmed that:

- (1) save as disclosed above, he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to and as at the Latest Practicable Date;
- (2) other than being a Supervisor, none of our Supervisors has any relationship with any other Directors, Supervisors, senior management or substantial Shareholders of our Company; and
- (3) he/she did not complete his/her education programs as disclosed in this section by way of attendance of long distance learning or online courses.

Save as disclosed in this document, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries:

- (1) there is no other matter with respect to the appointment of our Supervisors that needs to be brought to the attention to the Shareholders as of the Latest Practicable Date; and
- (2) there is no other information relating to our Supervisors that is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as of the Latest Practicable Date.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management and operation of our business. The table below sets out certain information in respect of the senior management of our Group.

Name	Age	Position	Date of appointment as Senior management	Date of joining our Group	Role and responsibilities	Relationship with other Directors, Supervisors and senior management
Dr. Frank Wu (吳永謙)	61	Chairman of the Board, executive Director and chief executive officer	November 18, 2016	June 10, 2016	Responsible for the overall strategic planning, business direction and operational management	None
Mr. Wu Di (吳笛)	45	Executive Director and vice president	March 16, 2020	January 13, 2017	Responsible for strategy and business development	None
Dr. Fan Jing (樊菁)	60	Chief medical officer of our Company and chief operating officer of TransThera US	November 1, 2022	November 1, 2022	Responsible for clinical and regulatory affairs	None
Ms. Cui Songxi (崔松喜)	53	Vice president of operations	August 2, 2021	July 1, 2020	Responsible for human resources, governmental and administrative management, IT, property control and EHS (environment, health and safety)	None
Dr. Peng Peng (彭鵬)	51	Vice president of project management	June 17, 2021	November 14, 2016	Responsible for company project management, DMPK R&D and oncology pipeline development	None
Dr. Sheng Zejuan (盛澤娟)	49	Vice president of biology department	August 2, 2021	October 9, 2017	Responsible for biology and pharmacology R&D and non-oncology pipeline development	None

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position	Date of appointment as Senior management	Date of joining our Group	Role and responsibilities	Relationship with other Directors, Supervisors and senior management
Dr. Sun Caixia (孫彩霞)	42	Clinical executive director	August 2, 2021	June 1, 2020	Responsible for clinical trial management	None
Ms. Feng Jie (馮潔)	38	Secretary of the Board	August 2, 2021	July 1, 2021	Responsible for investor relation management, financing and corporate governance	None

Dr. Frank Wu (吳永謙), see “– Board of Directors – Executive Directors” for details.

Mr. Wu Di (吳笛), see “– Board of Directors – Executive Directors” for details.

Dr. Fan Jing (樊菁), aged 60, is a chief medical officer of our Company and a chief operating officer of TransThera US, one of our subsidiaries. Dr. Fan joined our Group on November 1, 2022. She is primarily responsible for clinical and regulatory affairs.

Prior to joining our Group, Dr. Fan served as a lead clinical scientist of GlaxoSmithKline from September 1999 to September 2005, an international clinical company, and she was responsible for multiple clinical phase I-IV including small molecule target compounds. She also served as an associated director of Bristol-Myers Squibb Company from October 2005 to December 2007, a global biotechnology company, and was responsible for clinical development for registration phase III studies and Phase I study. Dr. Fan also served as a director of Array Biopharma from March 2008 to September 2008, a global biotechnology company, and was responsible for developing strategy and clinical development plan. She also served as a director of Elsay Co., Ltd. from October 2008 to June 2013, a global biotechnology company, and was responsible for phase I-III studies. Dr. Fan also served as a senior global clinical program leader of Boehringer-Ingelheim from July 2013 to October 2017, a global science-led biopharmaceutical company, and was responsible for global clinical development. She also served as a global clinical lead of AstraZeneca from November 2017 to August 2019, a global biopharmaceutical company, and was responsible for developing and executing strategy and clinical development plan for Immuno-Oncology products products. Dr. Fan also served as a vice president of Blueprint Medicine, a global biotechnology company, and was responsible for clinical development. In addition, she also served as a chief clinical officer of NeoImmuneTech, Inc, a global biopharmaceutical company, and was responsible for clinical development, clinical operations, pharmacovigilance and biostats.

Dr. Fan obtained the bachelor’s degree of clinical medicine from Jiangxi Medical College (江西醫學院) (now known as Nanchang University Jiangxi Medical College (南昌大學江西醫學院)) in the PRC in July 1985 and further obtained the master’s degree of biophysics and physiology from Sun Yat-sen University of Medical Sciences (中山醫科大學) (now known as Sun Yat-sen University (中山大學)) in the PRC in July 1991. Dr. Fan completed her postdoctoral training at Georgetown University, School of Medicine in the United States in September 1997.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Ms. Cui Songxi (崔松喜), aged 53, is the vice president of operations of our Company. Ms. Cui joined our Company in July 1, 2020 and has been redesignated as vice president of operations since August 2, 2021. She is responsible for human resources, governmental and administrative management, IT, property control and EHS (environment, health and safety).

Prior to joining our Company, Ms. Cui was appointed by Nanjing Economic Development for New and High Technology Co., Ltd. (南京高新技術經濟開發總公司) (currently known as Nanjing Jiangbei New District Industrial Investment Group Co., Ltd. (南京江北新區產業投資集團有限公司)) as the deputy manager of the merchants department of the company in March 2007, and was re-designated as the deputy director of investment promotion department of the company in March 2012, re-designated as the deputy director of the investment promotion bureau of Nanjing Hi-Tech Zone Administrative Committee (南京高新區投資促進局) in July 2016, re-designated as the deputy director or the Economic Development bureau of Nanjing Municipal Jiangbei New Area Administrative Committee (南京江北新區管委會經濟發展局) in June 2017 and until June 2020 with her last position as the deputy chief of the Management Office of Jiangbei New Area Industrial Technology Research and Innovation Park (江北新區產業技術研創園管理辦公室). She also worked at Nanjing Putian Wangzhi Electronics Co., Ltd (南京普天王之電子有限公司), a CDMA cell phone production company from December 2001 to September 2003. She worked at Nanjing Sharp Electronics Co., Ltd (南京夏普電子有限公司), an electronics production company from April 2000 to November 2001. She worked at Jinling Heren Real Estate Development Co., Ltd. (金陵和仁房地產開發有限公司), a real estate company from May 1996 to December 1998. She also worked at Nanyu Glass Co., Ltd (南宇玻璃有限公司), a float glass production company from January 1995 to September 1995.

Ms. Cui obtained her undergraduate certificate of graduation in Chinese from Yanbian University (延邊大學) in the PRC in June 1994. She completed the basic Japanese language course at Tokyo Riverside School in September 1998. She obtained her master's degree in economics from Tokyo Metropolitan University in Japan in October 2000.

In addition, Ms. Cui obtained the certificate of Level-1 Japanese-Language Proficiency in February 1999.

Dr. Peng Peng (彭鵬), aged 51, has joined our Company since November 14, 2016. Dr. Peng has been redesignated as the vice president of project management since June 17, 2021. He is responsible for company project management, DMPK R&D and oncology pipeline development.

Prior to joining our Company, Dr. Peng served as an executive director of biology department in Shandong Xuanzhu Biopharmaceutical from April 2011 to November 2016, a pharmaceutical R&D company, and was responsible for the overall operations and management of the department. He also worked at Crown Bioscience Technology (Beijing) (中美冠科生物技術(北京)有限公司) from May 2009 to April 2011, a global contract research organization (CRO) providing discovery, preclinical and translational platforms and services to advance oncology and immuno-oncology with his last position as an associate director where he was primarily responsible for the protein science and antibody technology.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. Peng obtained his bachelor’s degree in science in July 1996 and a master’s degree in molecular biology in July 1999 from the China Agricultural University (中國農業大學) in the PRC. He also obtained his doctor’s degree in molecular cellular and developmental biology from the University of Michigan in the U.S. in August 2005.

Dr. Peng obtained the qualification of professorate senior engineer approved by the department of Human Resources and Social Security of Jiangsu Province (江蘇省人力資源和社會保障廳) since November 2018.

Dr. Sheng Zejuan (盛澤娟), aged 49, is the vice president of biology department of our Company. Dr. Sheng joined our Company in October 9, 2017. She is responsible for biology and pharmacology R&D and non-oncology pipeline development. She has more than 15 years of experience in the biopharmaceutical industry.

Prior to joining our Company, Dr. Sheng served as a senior director of biology in Shandong Xuanzhu Biopharmaceutical from March 2015 to September 2017, a pharmaceutical R&D company. Dr. Sheng also served as a senior research associate in Genentech Inc. from May 2008 to March 2015, a biotechnology company where she was primarily responsible for research in neuroscience.

Dr. Sheng obtained her graduation certificate of undergraduate degree in microbiology from Wuhan University (武漢大學) in the PRC in July 1994. She obtained her master’s degree in science from Fudan University (復旦大學) in the PRC in July 1997. She also obtained her doctor’s degree in molecular and cell biology from University of California, Berkeley in the U.S. in December 2007.

Dr. Sun Caixia (孫彩霞), aged 42, is the clinical executive director of our Company. Dr. Sun joined our Company in June 1, 2020 and has been redesignated as the clinical executive director since August 2, 2021. She is responsible for clinical trial management and team building. She has more than 10 years of experience in the biopharmaceutical industry.

Prior to joining our Company, she joined Suzhou Yabao Pharmaceutical R&D Co., Ltd. (蘇州亞寶藥物研發有限公司), a new drug research company held by Yabao Pharmaceutical Group Co., Ltd. (亞寶藥業集團股份有限公司) (a company listed on Shanghai Stock Exchange with the stock code: 600351), and was designated as the director of clinical research in March 2018, where she was responsible for clinical development until May 2020. She worked as the director of medical marketing of Jiangsu Wanbang Biopharmaceuticals Marketing Co., Ltd. (江蘇萬邦醫藥營銷有限公司), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (上海復星醫藥(集團)股份有限公司) (a company listed on the Main Board of the Stock Exchange with stock code: 2196 and Shanghai Stock Exchange with stock code: 600196), and was responsible for the medical marketing department from February 2014 to January 2017. She worked at Jiangsu Simcere Pharmaceutical R&D Co., Ltd. (江蘇先聲藥物研究有限公司), a new drug research company held by Simcere Pharmaceutical Group Limited (先聲藥業集團有限公司) (a company listed on the Main Board of the Stock Exchange with the stock code: 2096) from June 2010 to December 2013.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. Sun obtained her doctor’s degree in internal medicine from Nanjing University (南京大學) in the PRC in June 2010.

Ms. Feng Jie (馮潔), aged 38, is the secretary of the board and the joint company secretary of our Company. Ms. Feng joined our Company on July 1, 2021 and has been redesignated as the company secretary since August 2, 2021. She is responsible for investor relation management, financing and corporate governance of our Company. Prior to joining our Company, Ms. Feng served as a joint company secretary of Simcere Pharmaceutical Group Limited (先聲藥業集團有限公司), a pharmaceutical company listed on the Main Board of the Stock Exchange (stock code: 2096), she worked there from July 2010 to June 2021.

Ms. Feng obtained both her bachelor’s degree in engineering from the National Life Science and Technology Talent Training Base (國家生命科學與技術人才培養基地) and a master’ degree in social and administrative pharmacy from China Pharmaceutical University (中國藥科大學) in the PRC in July 2008 and in June 2010, respectively. She obtained another master’s degree in corporate governance from the Hong Kong Metropolitan University (previously known as Open University of Hong Kong) in August 2018.

She was admitted as an associate of The Hong Kong Chartered Governance Institute (previously known as the Hong Kong Institute of Chartered Secretaries), an associate of the Chartered Governance Institute (previously known as the Institute of Chartered Secretaries and Administrators) in November 2018. She obtained the qualification certificate of Secretary of the Board by the Shanghai Stock Exchange.

General

Save as disclosed above, each of our senior management members has confirmed that:

- (1) he/she does not hold any other positions in our Company as at the Latest Practicable Date;
- (2) save as being a member of the Company’s senior management, and the selected participants of the Employee Incentive Schemes, he/she does not have any other relationship with any Directors, substantial shareholders of our Company or other members of senior management of our Company as at the Latest Practicable Date;
- (3) save as disclosed above, he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to the Latest Practicable Date and as at the Latest Practicable Date; and
- (4) he/she has not completed their respective education programs as disclosed in this section by way of attendance of long distance learning or online courses.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

JOINT COMPANY SECRETARIES

Ms. Feng Jie (馮潔), see “– Senior Management” for details.

Ms. Wong Tik (黃荻), aged 52, has over 25 years of experience in accounting and corporate secretarial field. Ms. Wong has worked and acted as the company secretary for a number of companies listed on the Stock Exchange. Ms. Wong is currently the head of the Listed Company Secretary Services Department of GIL (HK) Limited (a corporate services provider). Ms. Wong also served as the company secretary of Sim Technology Group Limited (晨訊科技集團有限公司) (a company listed on the Stock Exchange with the stock code: 2000) from February 2008 to June 2017 and Xingfa Aluminium Holdings Limited (興發鋁業控股有限公司) a company listed on the Stock Exchange with the stock code: 0098) from March 2018 to February 2021.

Ms. Wong obtained the Honours Diploma in Accounting from Hong Kong Shue Yan College in Hong Kong in 1995 and is a member of the Hong Kong Institute of Certified Public Accountants.

COMPLIANCE ADVISER

We have appointed Central China International Capital Limited as our compliance adviser pursuant to Rule 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the compliance adviser will advise us on the following circumstances:

- before the publication of any regulatory announcements, circulars or financial reports;
- where a transaction, which might be a notifiable or connected transaction under Chapters 14 and 14A of the Listing Rules is contemplated, including share issues and share repurchases;
- where our Company proposes to use the [REDACTED] from the [REDACTED] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- where the Stock Exchange makes an inquiry of our Company regarding unusual price movement and trading volume or other issues under Rule 13.10 of the Listing Rules.

The terms of the appointment shall commence on the [REDACTED] and end on the date which we distribute our annual report of our financial results for first full the financial year commencing after the [REDACTED].

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD COMMITTEES

We have established the following committees on our Board: the Audit committee, the Remuneration and Appraisal committee and the Nomination committee and the Strategy Committee. The committees operate in accordance with the terms of reference established by our Board.

Audit Committee

The Company has established an audit committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph D.3 of Part 2 of the Corporate Governance Code as set out in Appendix C.1 to the Listing Rules (the “**Corporate Governance Code**”). The audit committee consists of Mr. Li Shu Pai (李書滢), Ms. Zheng Zhelan (鄭哲蘭) and Ms. Jia Zhongxin (賈中新), with Mr. Li Shu Pai (李書滢) serving as the chairman. Mr. Li Shu Pai (李書滢) holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the audit committee are to assist our Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of our Company, overseeing the audit process, and performing other duties and responsibilities as assigned by our Board.

Remuneration and Appraisal Committee

The Company has established a remuneration and appraisal committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of Part 2 of the Corporate Governance Code. The remuneration and appraisal committee consists of Ms. Zheng Zhelan (鄭哲蘭), Ms. Chui Hoi Yam (徐海音) and Ms. Jia Zhongxin (賈中新), with Ms. Zheng Zhelan (鄭哲蘭) serving as the chairman. The primary duties of the remuneration and appraisal committee include, but are not limited to, the following: (i) making recommendations to our Board on our policy and structure for all remuneration of Directors and senior management and on the establishment of a formal and transparent procedure for developing policy on such remuneration; (ii) determining the specific remuneration packages of all Directors and senior management; and (iii) reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by our Board from time to time.

Nomination Committee

The Company has established a nomination committee with written terms of reference in compliance with Rule 3.27A of the Listing Rules and paragraph B.3 of Part 2 of the Corporate Governance Code. The nomination committee consists of Ms. Chui Hoi Yam (徐海音), Ms. Zheng Zhelan (鄭哲蘭) and Dr. Frank Wu (吳永謙), with Ms. Chui Hoi Yam (徐海音) serving as the chairman. The primary functions of the nomination committee include, without limitation, reviewing the structure, size and composition of our Board, assessing the independence of independent non-executive Directors and making recommendations to our Board on matters relating to the appointment of Directors.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Strategy Committee

The Company has established the Strategy Committee, which consists of Dr. Frank Wu (吳永謙), Ms. Chui Hoi Yam (徐海音) and Ms. Jia Zhongxin (賈中新). Dr. Frank Wu (吳永謙) is the chairman of the Strategy Committee. The primary duties of the Strategy Committee are to research and make recommendations on our Company’s long-term development strategies and major investment decisions.

CORPORATE GOVERNANCE

Code Provision C.2.1 of the Corporate Governance Code

Dr. Wu is our chairman of the Board and chief executive officer of our Company. He has over 27 years of science and leadership experience in biopharmaceutical companies. Dr. Wu is in charge of overall strategic planning and decision-making, execution, operation and management of our Company. While this will constitute a deviation from code provision C.2.1 of the Corporate Governance Code, our Board considers that vesting the roles of both chairman of the Board and chief executive officer all in Dr. Wu has the benefit of ensuring consistent leadership and more effective and efficient overall strategic planning of our Company. The balance of power and authority is ensured by the operation of our Board, which comprises experienced and diverse individuals. Our Board currently comprises two non-executive Directors and three independent non-executive Directors as compared to two executive Directors. Therefore, our Board possesses an independent element in its composition. Save as disclosed above, our Company intends to comply with all code provisions under the Corporate Governance Code after the [REDACTED].

Save as disclosed above, our Company intends to comply with all code provisions under the Corporate Governance Code after the [REDACTED].

Board Diversity

We have adopted a board diversity policy (the “**Board Diversity Policy**”) to enhance the effectiveness of our Board and to maintain a high standard of corporate governance. Pursuant to the Board Diversity Policy, in reviewing and assessing suitable candidates to serve as a Director of the Company, the Nomination Committee will consider a range of diversity perspectives with reference to the Company’s business model and specific needs, including but not limited to gender, age, language, cultural and educational background, professional qualifications, skills, knowledge, industry and regional experience and/or length of service.

Our Directors have a balanced mixed of knowledge and skills, including but not limited to overall business management, finance and accounting, research and development, and investment. They obtained degrees in various majors including biotechnology, engineering, chemistry, economics, law, clinical studies, etc. Furthermore, our Board has a relatively wide range of ages, ranging from 45 years old to 65 years old and consists of 4 male members and 3 female members. The Board of Directors is of the view that our Board satisfies the Board

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Diversity Policy. The Nomination Committee is responsible for reviewing the diversity of the Board, reviewing the Board Diversity Policy from time to time, developing and reviewing measurable objectives for implementing the Board Diversity Policy, and monitoring the progress on achieving these measurable objectives in order to ensure that the policy remains effective. The Company will (i) disclose the biographical details of each Director and (ii) report on the implementation of the Board Diversity Policy (including whether we have achieved board diversity) in its annual corporate governance report. Our Company also intends to promote gender diversity when recruiting staff at the mid to senior level so that our Company will have a pipeline of female senior management and potential successors to the Board. We believe that such merit-based selection process with reference to our diversity policy and the nature of our business will be in the best interests of our Company and our Shareholders as a whole.

COMPETITION

Each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract and (ii) a confidentiality agreement with our senior management members and other key personnel (other than Directors). Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

Confidentiality

- *Confidentiality obligations.* The employee shall, during the course of employment with our Company and thereafter, keep in confidence all technical, operational information or trade secrets belonging to the Company or other third parties to whom our Company owes confidentiality obligations. Without our Company's prior consent, the employee shall not leak, disclose, publish, announce, issue, teach, transfer or otherwise make available to any third party (including employees who are not privy to such trade secrets) any such trade secrets of our Company or the aforementioned third parties in any manner and shall not utilize such trade secret beyond his or her scope of work.

Ownership of intellectual work products

- *Acknowledgement:* The employee acknowledges and agrees that our Company shall own all intellectual work products he or she produces during the course of employment with our Company for the purposes of undertaking their duties and responsibilities.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Non-competition

- *Non-competition obligation during employment term.* During the term of his/her employment with our Company, unless with our Company's prior consent, the employee shall not engage in any business that competes with or are similar to that of our Company's business.

Compensation for breach of covenants

- If the employee breaches the obligations under the confidentiality and intellectual property agreements, our Company shall be entitled to recover from the employee any losses incurred and any profits earned by the employee as a result of the breaches.

COMPENSATION OF DIRECTORS AND MANAGEMENT

Our Directors receive compensation in the form of fees, salaries, bonuses, other allowances and benefits in kind, including the Company's contribution to the pension scheme on their behalf. Our Directors' remuneration is determined with reference to the relevant Director's experience and qualifications, level of responsibility, performance and the time devoted to our business, and the prevailing market conditions.

The aggregate amount of remuneration of directors which was recorded for the years ended December 31, 2022 and 2023 were approximately RMB8.1 million and RMB11.8 million, respectively.

It is estimated that remuneration and benefits in kind (excluding any possible payment of discretionary bonus) equivalent to approximately RMB0.89 million in aggregate will be paid and granted to our Directors by us in respect of the financial year ending December 31, 2024 under arrangements in force at the date of this document.

The five highest paid employees during the years ended December 31, 2022 and 2023 included one and two directors, respectively, and the aggregate amount of remuneration recorded who are neither a director nor chief executives of our Company were approximately RMB12.5 million and RMB12.9 million, respectively.

During the Track Record Period, (i) no remuneration was paid to our Directors or the five highest paid individuals as an inducement to join, or upon joining our Company, (ii) no compensation was paid to, or receivable by, our Directors or past Directors or the five highest paid individuals for the loss of office as director of any member of our Company or any other office in connection with the management of the affairs of any member of our Company, and (iii) none of our Directors waived any emoluments.

Except as disclosed above, no other payments have been paid, or are payable, by our Company to our Directors, Supervisors or the five highest paid individuals of our Company during the Track Record Period.

For additional information on Directors' remuneration during the Track Record Period as well as information on the highest paid individuals, please see Notes 11 and 12 of the Accountants' Report set out in Appendix I to this document.

FINANCIAL INFORMATION

You should read the following discussion and analysis in conjunction with our financial statements included in the Accountants' Report in Appendix I to this document, together with the accompanying notes. Our financial information has been prepared in accordance with IFRSs, which may differ in material aspects from generally accepted accounting principles in other jurisdictions. You should read the entire Accountants' Report and not merely rely on the information contained in this section.

The following discussion and analysis contain forward-looking statements that reflect the current views with respect to future events and financial performance. These statements are based on assumptions and analysis made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate under the circumstances. However, whether the actual outcome and developments will meet our expectations and predictions depends on a number of risks and uncertainties over which we do not have control. For details, see "Forward-looking Statements" and "Risk Factors."

OVERVIEW

We are a clinical demand-oriented, registrational clinical-stage biopharmaceutical company focusing on discovering and developing innovative small molecule therapies for oncology, inflammatory and cardiometabolic diseases. Our mission is to deliver innovative and differentiated treatment solutions to patients worldwide, guided by our core value of harnessing original technology as the driving force behind our business. Leveraging our fully-integrated in-house R&D system, we have built a pipeline of six clinical-stage product candidates and one preclinical product candidate, and we plan to continue expanding our pipeline. Further aided by in-depth study of translational medicine and drug design, we aim to develop first-in-class or best-in-class drug candidates strategically positioned to meet urgent clinical needs on a global scale.

Our mission and core value are best evident by our Core Product Tinengotinib (TT-00420), which was internally discovered through our thorough exploration of the foundational mechanisms of correlation between biological science and target diseases. As a registrational clinical-stage, potential first-in-class, potent MTK inhibitor primarily targeting three key pathways (namely, FGFR/VEGFR, JAK and Aurora kinases), Tinengotinib has the potential to address the unmet clinical needs in a variety of relapsed or refractory, drug-resistant solid tumors, including CCA, prostate cancer, breast cancer, BTC and pan-FGFR solid tumors. It was granted Breakthrough Therapy Designation by the NMPA and Fast-Track Designation by the FDA for the treatment of CCA. It was also granted Orphan Drug Designation by both the FDA for the treatment of CCA and by the EMA for the treatment of BTC. The encouraging clinical data of Tinengotinib have been published or presented orally at major international medical conferences such as the American Society of Clinical Oncology, the European Society of Medical Oncology, the San Antonio Breast Cancer Symposium, and American Association for Cancer Research.

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Leveraging our strong drug development expertise and BD capabilities, we adopt a global business strategy composed of global R&D positioning and collaboration activities. As of the Latest Practicable Date, we were developing our Core Product under IND approvals from the FDA, the NMPA, the EMA, the MFDS, the MHRA and the TFDA, and another five pipeline products under IND approvals from the NMPA and/or the FDA. We have established collaborations with world-renowned biopharmaceutical companies, including LG Chem (South Korea), Teijin (Japan), EA Pharmaceuticals (Japan), and F. Hoffmann-La Roche Ltd (Switzerland). Through these international collaborations, we have gained access to a spectrum of innovative technologies and international clinical development resources, positioning us for future global commercialization.

We currently have no products approved for commercial sale and have not generated any revenue from product sales. We were not profitable and incurred operating losses during the Track Record Period. For the years ended December 31, 2022 and 2023, we incurred loss of RMB251.9 million and RMB343.4 million, respectively. We recorded losses as a result of the significant research and development costs and administrative expenses incurred during the Track Record Period.

We expect to incur significant amount of expenses and operating losses for at least the next several years as we further our preclinical research efforts, continue the clinical development, and seek regulatory approvals for our drug candidates before launching these products to the market. Subsequent to the [REDACTED], we expect to also incur costs associated with operating as a public company. We expect that our financial performance will fluctuate periodically due to the development status of our drug candidates, regulatory approval timeline and commercialization of our future approved drugs.

BASIS OF PREPARATION

Our Company was incorporated as a limited liability company in Nanjing, Jiangsu Province, PRC on April 15, 2014. For more details, see “History, Development and Corporate Structure.”

Our historical financial information has been prepared in accordance with IFRSs, which comprise all standards and interpretations approved by the IASB. All IFRSs effective for the accounting period commencing from January 1, 2023, together with the relevant transitional provisions, have been early adopted by us in the preparation of the historical financial information throughout the Track Record Period.

Our historical financial information has been prepared under the historical cost convention, except for financial assets at fair value through profit or loss which have been measured at fair value.

Our consolidated statements of profit or loss and comprehensive income and statements of cash flows for the years ended December 31, 2022 and 2023 and our consolidated statements of financial position as of December 31, 2022 and 2023 have been derived from the Accountants’ Report included in Appendix I to this document.

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MAJOR FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations, financial condition and the period-to-period comparability of our financial results are principally affected by the following factors:

Our Ability to Successfully Develop Our Drug Candidates

Our business and results of operations depend on our ability to successfully develop our drug candidates. As of the Latest Practicable Date, we had developed an innovative and differentiated pipeline of three drug candidates focused on oncology diseases and another four drug candidates focused on inflammatory and cardiometabolic diseases, with a total of six assets at the clinical stage. For more information on the development status of our various drug candidates, see “Business – Our Product Pipeline.” Our business and results of operations depend on our drug candidates demonstrating favorable safety and efficacy clinical trial results, and our ability to obtain the requisite regulatory approvals for our drug candidates to initiate clinical trials, or to advance to the next stage of clinical development. For more details, see “Risk Factors – Risks Relating to Clinical Development of Our Drug Candidates – Our business and financial prospects depend substantially on the success of our clinical- and preclinical-stage drug candidates and our ability to identify additional drug candidates, complete their clinical development, obtain their regulatory approvals or achieve their commercialization.”

Our Ability to Successfully Commercialize Our Drug Candidates

As of the Latest Practicable Date, all of our drug candidates were in clinical development or preclinical development. We currently have no product approved for commercial sale and have not generated any revenue from product sales. However, we expect to commercialize one or more of our drug candidates over the coming years as they move towards the final stages of development. Our ability to generate revenue depends on our ability to obtain regulatory approvals for and to commercialize our drug candidates, establish manufacturing capabilities and sales channels, and undertake extensive sales and marketing activities. If our drug candidates fail to achieve the degree of market acceptance that we anticipate, we may not be able to generate revenue as expected. For more details, see “Risk Factors – Risks Relating to Manufacturing and Commercialization of Our Drug Candidates – We have no track record and limited experience in commercialization of products. If we are unable to build or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our future products or sell our future products, which will materially affect our ability to generate product sales revenue.”

Our Collaboration Partnership

During the Track Record Period, we collaborated with our global partners who are leading pharmaceutical companies, including LG Chem, Roche, Teijin, and EA Pharma. For more details, see “Business – Collaboration and License Agreements.”

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However, we may not achieve the revenue and cost synergies expected from these collaborations since these synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. For more details, see “Risk Factors – Risks Relating to Our Reliance on Third Parties – We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.”

Funding for Our Operations

During the Track Record Period, we funded our operations primarily through equity financing. We expect to fund our future operations primarily with existing cash and cash equivalents, and net [REDACTED] from the [REDACTED]. Going forward, we expect to primarily fund our operations with revenue generated from sales of our commercialized drug products in the event of the successful commercialization of one or more of our drug candidates. However, with the continuing expansion of our business, we may require further funding through public or private [REDACTED], debt financing, collaboration and licensing arrangements or other sources. Any fluctuation in the funding for our operations will impact our cash flow plan and our results of operations.

Our Research and Development Costs

We believe our ability to successfully develop drug candidates is the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality drug candidates requires significant investments of financial resources over a prolonged period of time, and our core strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of preclinical and clinical stage drug candidates has been steadily advancing and expanding. Our operations have consumed substantial amounts of cash since our inception. Our research and development costs were RMB262.5 million and RMB344.5 million in 2022 and 2023, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical assets, continue research and development of our preclinical assets and initiate additional clinical trials of, and seek regulatory approvals for, these and other future drug candidates. These expenditures may include the following, among others:

- expenses incurred for payments to CROs, investigators and clinical trial sites that conduct our clinical studies;
- employee related expenses, including salaries, benefits and share-based payment expenses;
- licensing fees to collaboration partners;
- costs of acquiring, developing, and manufacturing clinical study materials;

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- facilities, depreciation, and other expenses, which include office leases and other overhead expenses; and
- costs associated with preclinical activities and regulatory approvals.

MATERIAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles that conform with IFRSs issued by the IASB. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Our most material accounting policies and significant judgments and estimates are summarized below. See Note 3 and Note 4 to the Accountants' Report in Appendix I to this document for a description of our material accounting policies, and significant judgments and estimates.

Research and Development Costs

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Leases

We assess at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Company as A Lessee

We apply a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. We recognize lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

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(a) *Right-of-use assets*

We recognize right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets. The leased office buildings are depreciated over 3 years. The land use rights are depreciated over 50 years.

If ownership of the leased asset transfers to us at the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) *Lease liabilities*

Lease liabilities are recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by us and payments of penalties for terminating the lease, if the lease term reflects we exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognized as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, we use its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate) or a change in the assessment of an option to purchase the underlying asset.

(c) *Short-term leases and leases of low-value assets*

We apply the short-term lease recognition exemption to its short-term leases of office buildings (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment that is considered to be of low value.

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Lease payments on short-term leases and leases of low-value assets are recognized as an expense on a straight-line basis over the lease term.

Fair Value Measurement

We measure our financial assets at fair value at the end of each year or period of the Track Record Period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by us. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

We use valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognized in the financial statements on a recurring basis, we determine whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each year or period of the Track Record Period.

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Investments and Other Financial Assets

Initial Recognition and Measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortized cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and our business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which we have applied the practical expedient of not adjusting the effect of a significant financing component, we initially measure a financial asset at its fair value, plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which we have applied the practical expedient are measured at the transaction price determined under IFRS 15 “Revenue from contracts with customers” (“**IFRS 15**”).

In order for a financial asset to be classified and measured at amortized cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding. Financial assets with cash flows that are not solely payments of principal and interest are classified and measured at fair value through profit or loss, irrespective of the business model.

Our business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortized cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

Purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace are recognized on the trade date, that is, the date that the Group commits to purchase or sell the asset.

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Subsequent Measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial Assets at Amortized Cost (Debt Instruments)

Financial assets at amortized cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in the statement of profit or loss when the asset is derecognized, modified or impaired.

Financial Assets at Fair Value through Profit or Loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognized in the statement of profit or loss.

Revenue Recognition

Revenue from Contracts with Customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which we will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between us and the customer at contract inception. When the contract contains a financing component which provides us with a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

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We entered into a licensing arrangement with a customer, under which we grant a license of the drug formula to the customer, including the right to produce and sell products based on the drug formula in predetermined areas during commercialization stage. While we and our customer will conduct clinical trials in the predetermined areas respectively, we are obligated to provide certain clinical trial support services to the customer. Such clinical trial support services include helping with the preparation of the investigational new drug application plan and filing to the regulatory, providing regular updates to the customer regarding our development and the manufacture of licensed compounds and licensed products in our territory and etc.

We considered that the grant the licenses of the drug formula and the clinical trial supporting services are separate performance obligations since they are distinct from each other according to the contract.

The performance obligation of the licensing is satisfied at the point in time when we provide the customers with a right to use the formula as it exists at the point in time at which the license is granted, since we considered that it would not undertake activities that significantly affect the drug formula and all the licensing contract only provided the customer with a right to use the drug formula.

The performance obligation of providing clinical trials support services is satisfied over the period of development as the customer simultaneously receives and consumes the benefits provided by our performance as we perform. Progress is measured by passage of time with respect to the total estimated time for the development.

We are entitled to an upfront payment and various milestone payments during the development stage and sale-based royalties during commercialization stage. Most of the considerations entitled by us are variable considerations and we estimate such variable considerations based on the most likely amount. As majority of the considerations are highly susceptible to factors outside the Company's influence, the variable considerations are constrained until uncertainties associated with the variable considerations are subsequently resolved. At the end of each year or period of the Track Record Period, we re-evaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catchup basis, which would affect revenues and earnings in the period of adjustment. Consideration is allocated to the two performance obligations based on the stand-alone selling prices which consider the pricing by competitors for similar products or services as well as the costs and margins.

Contract Liabilities

A contract liability is recognized when a payment is received or a payment is due (whichever is earlier) from a customer before the Company transfers the related goods or services. Contract liabilities are recognized as revenue when the Company performs under the contract (i.e., transfers control of the related goods or services to the customer).

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Other Income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Share-based Payments

A share incentive plan (the “**2017 share incentive plan**”) was approved by our shareholders on March 16, 2017 and became effective on the same day. Options under the 2017 share incentive plan were granted to the employees who contribute to our success. A new share incentive plan, which was approved by our shareholders on January 7, 2021 and became effective on March 1, 2021 (the “**2021 share incentive plan**”, together with the 2017 share incentive plan, the “**Share Incentive Plan**”).

In March 2023, a new share incentive plan (the “**2023 share incentive plan**”) was approved by our shareholders. The 2023 share incentive plan is a replacement of the Share Incentive Plan.

For more details, please see Note 27 to the Accountants’ Report in Appendix I to this document.

Our employees (including directors) receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (“**equity-settled transactions**”).

The cost of equity-settled transactions with employees is measured by reference to the fair value at the grant date.

The cost of equity-settled transactions is recognized in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each year or period of the Track Record Period until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other

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conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognized. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognized as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognized for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. This includes any award where non-vesting conditions within the control of either us or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Judgments

In the process of applying our accounting policies, our management has made the following judgments, apart from those involving estimations, which have the most significant effect on the amounts recognized in the financial statements:

Research and Development Costs

All research costs are charged to the statement of profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, our intention to complete and our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred. Determining the amounts of development costs to be capitalized requires the use of judgments and estimation. We currently expense all the milestone and upfront payments under the drug license agreements.

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Estimation Uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each year or period of the Track Record Period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Share-based Payments

We has set up the share incentive plans for our directors and employees.

Estimating the fair value for share-based payment transactions requires the determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires the determination of the most appropriate inputs to the valuation model including volatility and dividend yield and making assumptions about them.

The assumptions and models used for estimating the fair value for share-based payment transactions are disclosed in Note 27 to the Accountants’ Report set out in Appendix I to this document.

DESCRIPTION OF CERTAIN SELECTED ITEMS OF CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The table below sets forth the components of our consolidated statements of profit or loss and other comprehensive income for the years indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Revenue	124	1,181
Cost of sales	—	—
	124	1,181
Gross profit	124	1,181
Other income	18,733	22,491
Other gains	42,017	17,105
Other expenses	(157)	(221)
Research and development costs	(262,511)	(344,475)
Administrative expenses	(49,946)	(39,219)
Impairment losses on financial assets	(23)	(8)
Finance costs	(181)	(248)
	(251,944)	(343,394)
LOSS BEFORE TAX	(251,944)	(343,394)
Income tax expenses	—	—
	(251,944)	(343,394)
LOSS FOR THE YEAR	(251,944)	(343,394)
Other comprehensive gain/(loss) for the year	(193)	189
	(252,137)	(343,205)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(252,137)	(343,205)

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Revenue

During the Track Record Period, we recognized revenue primarily from the milestone payments in connection with our out-licensed product, TT-01025.

Cost of Sales

During the Track Record Period, our cost of sales was nil as our revenue was primarily recognized from the milestone payments in connection with our out-licensed product, TT-01025, while we did not incur any costs related to the licensing agreement for TT-01025 during the Track Record Period.

Gross Profit and Gross Profit Margin

Our gross profit was RMB0.1 million and RMB1.2 million, respectively for the years ended December 31, 2022 and 2023. Our gross profit margin was 100% for the years ended December 31, 2022 and 2023, because no cost of sales was recorded for the same periods.

Other Income

During the Track Record Period, our other income primarily consisted of government grants and bank interest income. The government grants mainly represented the grants received from the local governments to compensate us for the expenses incurred in connection with our research and clinical trial activities.

The following table sets forth the components of our other income for the periods indicated:

	Years Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Government grants	12,714	10,329
Bank interest income	6,015	12,162
Others	4	–
Total	18,733	22,491

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Other Gains

Our other gains primarily represented (i) fair value gain on financial assets at fair value through profits or losses (“FVTPL”); and (ii) net foreign exchange gains. During the Track Record Period, our fair value gains on financial assets at FVTPL represented realized gains on the wealth management products we purchased primarily from commercial banks. For more details, see “– Discussion of Certain Selected Items from the Consolidated Statements of Financial Position – Financial Assets at FVTPL.” We recorded net foreign exchange gains during the Track Record Period primarily in connection with our bank deposits denominated in U.S. dollars.

The following table sets forth the components of our other gains for the periods indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Fair value gain on financial assets at FVTPL	14,302	14,094
Foreign exchange gains, net	27,715	3,011
Total	42,017	17,105

Research and Development Costs

During the Track Record Period, our research and development costs mainly consisted of (i) clinical trial expenses and preclinical research expenses related to services provided by CROs, CMOs, CDMOs and other service providers during the research and development of our pipeline products; (ii) employee benefit expenses, which primarily included the salaries and welfare for the research and development employees; (iii) share-based payment expenses to our research and development team; (iv) material expenses used for research and development of our drug candidates; (v) depreciation and amortization relating to our equipment; (vi) licensing fees paid to our licensor, LG Chem, regarding our in-licensed drug candidate, TT-01688; and (vii) other expenses, mainly including office expenses and traveling expenses.

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The following table provides a breakdown of our research and development costs for the periods indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Clinical trial expenses	165,329	259,605
Employee benefit expenses	45,857	51,240
Preclinical research expenses	24,991	9,842
Share-based payment expenses	4,464	7,638
Licensing fees	6,830	–
Material expenses	3,760	5,433
Depreciation and amortization	5,884	4,387
Others	5,396	6,330
Total	262,511	344,475

Our research and development costs attributable to our Core Product were RMB167.1 million and RMB236.4 million, in 2022 and 2023, respectively, accounting for 63.7% and 68.6% of our total research and development costs and 53.5% and 61.6% of our total operating expenses (i.e. research and development costs and administrative expenses) in the respective period.

The following table sets forth the clinical development expenses attributable to the Core Product (namely, research and development costs, excluding employee benefit expenses, share-based payment expenses and depreciation and amortization) during the Track Record Period:

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Preclinical	12,968	3,264
Phase I	76,129	48,045
Phase II	59,958	88,739
Phase III	–	69,171
Total	149,055	209,219

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Administrative Expenses

During the Track Record Period, our administrative expenses consisted of (i) employee benefit expenses, including salaries and welfare for administrative employees; (ii) professional fees; (iii) share-based payment expenses to our management and administrative personnel; (iv) depreciation and amortization; (v) lease and utilities expenses; (vi) travel expenses; and (vii) other costs, including office expenses and other expenses in connection with administrative activities. Our professional fees during the Track Record Period mainly comprise (i) fees and expenses of our legal advisers, reporting accountants and other professional service providers in relation to our 2021 HKEX [REDACTED] Application and potential A share [REDACTED], and (ii) fees incurred for business, tax and legal consultation in the ordinary course of our business.

The following table provides a breakdown of our administrative expenses for the periods indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Employee benefit expenses	14,712	17,201
Professional fees	25,151	7,821
Share-based payment expenses	2,546	7,145
Depreciation and amortization	3,091	3,016
Lease and utilities expenses	1,400	1,199
Travel expenses	125	405
Others	2,921	2,432
	49,946	39,219
Total		

Finance Costs

During the Track Record Period, our finance costs consisted of interest on lease liabilities. We recorded finance costs of RMB0.2 million and RMB0.2 million in 2022 and 2023, respectively.

Income Tax Expenses

During the Track Record Period, we had no income tax expenses. Our Directors confirm that during the Track Record Period, we had made all the required tax filings and had paid all outstanding tax liabilities with the relevant tax authorities in the relevant jurisdictions and we are not aware of any outstanding or potential disputes with such tax authorities.

FINANCIAL INFORMATION

PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022

Revenue

Our revenue increased from RMB0.1 million for the year ended December 31, 2022 to RMB1.2 million for the year ended December 31, 2023, primarily because we recognized all our contract liabilities as revenue in 2023.

Other Income

Our other income increased by RMB3.8 million from RMB18.7 million for the year ended December 31, 2022 to RMB22.5 million for the year ended December 31, 2023, primarily due to an increase in bank interest income of RMB6.1 million mainly attributable to an increase in our average balance of bank deposits.

Other Gains

Our other gains decreased by RMB24.9 million from RMB42.0 million for the year ended December 31, 2022 to RMB17.1 million for the year ended December 31, 2023, primarily due to a decrease in net foreign exchange gains of RMB24.7 million mainly attributable to the fluctuations in the exchange rate of the U.S. dollars against Renminbi.

Research and Development Costs

Our research and development costs increased by RMB82.0 million from RMB262.5 million for the year ended December 31, 2022 to RMB344.5 million for the year ended December 31, 2023, primarily due to (i) an increase in clinical trial expenses of RMB94.3 million mainly driven by the advancement of clinical trials of Tinengotinib and TT-01688, (ii) an increase in employee benefit expenses of RMB5.4 million mainly attributable to an increase in employee headcount, and (iii) an increase in share-based payment expenses of RMB3.2 million attributable to the new grants under the 2023 share incentive plan.

Administrative Expenses

Our administrative expenses decreased by RMB10.7 million from RMB49.9 million for the year ended December 31, 2022 to RMB39.2 million for the year ended December 31, 2023, primarily due to a decrease in professional fees of RMB17.3 million mainly attributable to expenses incurred in relation to 2021 HKEX [REDACTED] Application recognized in 2022. This decrease was partially offset by an increase in share-based payment expenses of RMB4.6 million mainly attributable to the new grants under the 2023 share incentive plan.

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Loss for the Year

For the reasons described above, our loss for the year increased by RMB91.5 million from RMB251.9 million for the year ended December 31, 2022 to RMB343.4 million for the year ended December 31, 2023.

TAXATION

We are subject to income tax on an entity basis on profit arising in or derived from the jurisdictions in which we are domiciled and operate.

China

Under the Law of the PRC on Enterprise Income Tax (the “**EIT Law**”) and Implementation Regulation of the EIT Law, our estimated tax rate is 25% during the Track Record Period. No China income tax was provided for as our Company was in loss position and had no estimated assessable profits during the Track Record Period.

Hong Kong

Our subsidiary incorporated in Hong Kong is subject to income tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong during the Track Record Period. No Hong Kong profits tax was provided for as our Group did not generate any assessable profits arising in Hong Kong during the Track Record Period.

The United States

Our subsidiary incorporated in the United States is subject to the federal statutory income tax at the rate of 21% and subject to the corporate income tax of the State of Delaware at the rate of 8.7% on any estimated assessable profits arising in the United States during the Track Record Period. No United States profits tax was provided for as our Group did not generate any assessable profits arising in the United States during the Track Record Period.

FINANCIAL INFORMATION

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The following table sets forth selected items from our consolidated statements of financial position as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
NON-CURRENT ASSETS		
Property, plant and equipment	12,029	11,639
Intangible assets	997	982
Right-of-use assets	2,469	19,982
Prepayments for other receivables and other assets	11,831	8,886
	27,326	41,489
CURRENT ASSETS		
Inventories	245	160
Prepayments, other receivables and other assets	35,295	7,271
Financial assets at FVTPL	–	341,541
Pledged and short-term bank deposits	142,841	–
Cash and cash equivalents	983,934	496,629
	1,162,315	845,601
CURRENT LIABILITIES		
Trade payables	72,238	78,578
Other payables and accruals	21,942	20,527
Contract liabilities	196	–
Lease liabilities	2,688	3,457
	97,064	102,562
NET CURRENT ASSETS	1,065,251	743,039
TOTAL ASSETS LESS CURRENT LIABILITIES	1,092,577	784,528

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	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
NON-CURRENT LIABILITIES		
Lease liabilities	–	1,350
Contract liabilities	978	–
Total non-current liabilities	978	1,350
Net assets	1,091,599	783,178
EQUITY		
Share capital	379,954	381,617
Reserves	711,645	401,561
Total equity	1,091,599	783,178

Property, Plant and Equipment

Our property, plant and equipment primarily consisted of lab equipment, construction in progress, leasehold improvements, motor vehicles and electronic equipment. Our property, plant and equipment remained relatively stable at RMB12.0 million as of December 31, 2022 and RMB11.6 million as of December 31, 2023.

Right-of-use Assets

Our right-of-use assets consisted of our rights to use underlying leased premises and land use rights, which are measured at cost less any accumulated depreciation and impairment losses, and adjusted for any reimbursement of lease liability. Our right-of-use assets increased from RMB2.5 million as of December 31, 2022 to RMB20.0 million as of December 31, 2023, primarily due to the new land use rights we purchased in March 2023.

FINANCIAL INFORMATION

Prepayments, Other Receivables and Other Assets

Our prepayments, other receivables and other assets primarily consisted of (i) prepayments, representing the prepaid research and development expenses; (ii) prepayments for purchase of land use rights; (iii) deferred [REDACTED], representing the portion of [REDACTED] which will be capitalized upon the completion of the [REDACTED]; (iv) value-added tax recoverable, representing value-added tax paid by us on purchases that are deductible against future value-added tax payable; and (v) deposits mainly paid for office leases.

The following table sets forth the components of our prepayments, other receivables and other assets as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Non-current		
Prepayments for purchase of land use right	7,580	–
Deposits	2,520	2,390
Value-added tax recoverable	1,731	6,496
	11,831	8,886
Current		
Accrued interest on short-term bank deposits	604	–
Prepayments	30,862	5,951
Deposits	418	548
Other receivables	468	633
Deferred [REDACTED]	[REDACTED]	[REDACTED]
Allowance for the expected credit losses	(23)	(31)
	35,295	7,271
Total	47,126	16,157

Our prepayments, other receivables and other assets decreased from RMB47.1 million as of December 31, 2022 to RMB16.2 million as of December 31, 2023, primarily due to (i) a decrease in our prepayment of RMB24.9 million mainly resulting from the fulfillment of contractual obligations of our third-party contracting service providers driven by the advancement of our research and development activities; and (ii) a decrease in prepayments for purchase of land use right of RMB7.6 million as the acquisition of such land use right was completed in 2023.

FINANCIAL INFORMATION

Financial Assets at FVTPL

Our financial assets at FVTPL during the Track Record Period represented the wealth management products we purchased. All wealth management products we purchased during the Track Record Period were approved by our senior management team, subject to an annual cap approved by the Board. As of December 31, 2022 and 2023, we recorded financial assets at FVTPL of nil and RMB341.5 million, respectively.

As of December 31, 2022, our financial assets at FVTPL were nil because all of the wealth management products we purchased in 2022 had been redeemed at maturity. As of December 31, 2023, we had five principal protected structured deposits issued by China CITIC Bank, Bank of Nanjing and China Merchants Bank and another wealth management product issued by CITIC Securities Company Limited, with principal amounts ranging from RMB10.0 million to RMB80.0 million. These products had expected annual return rates ranging from 2.5% to 3.8%. All structured deposits had fixed maturity terms between 90 and 96 days, and the one wealth management product had a principal amount of RMB10.0 million and a fixed maturity term of 360 days. As of the Latest Practicable Date, the wealth management products we purchased in 2023 had been redeemed.

The three issuing banks are all A-share listed banks and China CITIC Bank and China Merchants Bank are also H-share listed banks. Specifically, China CITIC Bank’s credit ratings are Ba2 as assigned by Moody’s and BBB+ as assigned by Standard & Poor’s. China Merchants Bank’s credit ratings are A- as assigned by Fitch’s, A2 as assigned by Moody’s and BBB+ as assigned by Standard & Poor’s. Bank of Nanjing’s credit rating is Ba2 as assigned by Moody’s. CITIC Securities Company Limited is A-share and H-share listed company. Its credit ratings are Baa3 as assigned by Moody’s and BBB+ as assigned by Standard & Poor’s. As these issuing institutions are all reputable financial institutions and the wealth management products we purchased are all principal protected or low-risk, we believe we are exposed to very limited credit/default risk. We will continue to apply the same approach and keep our risk exposure low while utilizing our temporarily unused cash.

Our senior management team and the finance department are mainly responsible for making, implementing and supervising our investment decisions. We have implemented the following treasury policies and internal authorization controls:

- We have formulated the Standardized Management Protocol for Funds Management (《資金管理標準管理規程》) to control our process of investment in wealth management products;
- Our Board reviews and approves the annual cap of our investment in wealth management products;
- Our senior management team is responsible for the overall planning and approval of our investment in wealth management products;

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- Our finance department is responsible for the analysis and research of investment in wealth management products, as well as the long-term routine management of such investment;
- Investments in wealth management products could be made when we have surplus cash that is not required for our short-term working capital purposes and in no event beyond the amount authorized by our senior management team.

Prior to making an investment, we ensure that there remains sufficient working capital for our business needs, operating activities, research and development and capital expenditures even after purchasing such wealth management products. We adopt a prudent approach in selecting wealth management products. Our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, such as the duration of the investment and the expected returns. To control our risk exposure, we have in the past sought, and may continue in the future to seek other low-risk wealth management products with terms no longer than twelve months and may continue to invest in similar wealth management products using our surplus cash. We understand that upon [REDACTED], the investments in such financial assets may constitute notifiable transactions under Chapter 14 of the Listing Rules and our Directors confirm that any such investment would only be made after compliance with the Listing Rules as well as other relevant laws and regulations, if applicable.

Short-Term Bank Deposits

Our short-term bank deposits represent our deposits with initial terms of over three months. Our short-term bank deposits decreased from RMB139.4 million as of December 31, 2022 to nil as of December 31, 2023, primarily because all of our short-term bank deposits matured at the end of 2023.

Cash and Cash Equivalents

Our cash and cash equivalents primarily consisted of our cash and bank balances.

The following table below sets forth a breakdown of our cash and cash equivalents by currency type as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Denominated in:		
– RMB	870,283	417,883
– USD	112,823	77,622
– JPY	828	1,124
Total	983,934	496,629

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Our cash and cash equivalents decreased from RMB983.9 million as of December 31, 2022 to RMB496.6 million as of December 31, 2023. For an analysis on cash flows during the Track Record Period, see “– Liquidity and Capital Resources.”

Trade Payables

Our trade payables mainly related to our purchases of materials and third-party contracting services in relation to our research and development activities. Our trade payables increased from RMB72.2 million as of December 31, 2022 to RMB78.6 million as of December 31, 2023, primarily driven by the advancement of our research and development activities. Our credit terms on trade payables normally ranged from 10 to 30 days.

The following table sets forth an aging analysis of our trade payables as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Within 1 year	72,238	78,578
Total	72,238	78,578

As of April 30, 2024, RMB33.8 million, or 43.1% of our trade payables as of December 31, 2023 had been subsequently settled.

Other Payables and Accruals

Our other payables and accruals primarily consisted of (i) conditional government grant received but not yet recognized, which, when complied with the conditions, will be charged to other income; and (ii) staff salaries, bonuses and welfare payables.

The following table sets forth a breakdown of our other payables and accruals as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Government grant	6,400	6,400
Staff salaries, bonuses and welfare payables	14,686	13,611
Other tax payables	102	85
Other payables	754	431
Total	21,942	20,527

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Contract Liabilities

Our contract liabilities during the Track Record Period represented the advanced payments received from our licensee in relation to our out-licensed product, TT-01025 according to the relevant license-out agreement. As of December 31, 2022 and 2023, we recorded contract liabilities of RMB1.2 million and nil, respectively. We recognized all our contract liabilities as revenue in 2023 as result of the termination of license-out agreement in 2023.

Lease Liabilities

The following table sets forth our lease liabilities as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Current	2,688	3,457
Non-current	–	1,350
Total	2,688	4,807

KEY FINANCIAL RATIO

The table below sets forth our key financial ratio as of the dates indicated:

	As of December 31,	
	2022	2023
Current ratio ⁽¹⁾	12.0	8.2

Note:

(1) Current ratio represents current assets divided by current liabilities as of the same dates.

Our current ratio decreased from 12.0 as of December 31, 2022 to 8.2 as of December 31, 2023, primarily due to a decrease in our current assets, which was mainly attributable to (i) a decrease in our cash and cash equivalents, and (ii) a decrease in short-term bank deposits. Such changes were primarily driven by our increasing spending on research and development activities as we advanced our clinical trials in 2023.

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LIQUIDITY AND CAPITAL RESOURCES

Net Current Assets

	As of December 31,		As of April 30,
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(Unaudited)</i>
CURRENT ASSETS			
Inventories	245	160	228
Prepayments, other receivables and other assets	35,295	7,271	8,938
Financial assets at FVTPL	–	341,541	346,744
Pledged and short-term bank deposits	142,841	–	–
Cash and cash equivalents	983,934	496,629	411,353
Total current assets	1,162,315	845,601	767,263
CURRENT LIABILITIES			
Trade payables	72,238	78,578	66,102
Other payables and accruals	21,942	20,527	8,900
Contract liabilities	196	–	–
Lease liabilities	2,688	3,457	1,727
Total current liabilities	97,064	102,562	76,729
NET CURRENT ASSETS	1,065,251	743,039	690,533

Our net current assets decreased from RMB1,065.3 million as of December 31, 2022 to RMB743.0 million as of December 31, 2023, primarily due to (i) a decrease in cash and cash equivalents of RMB487.3 million, and (ii) a decrease in pledged and short-term bank deposits of RMB142.8 million, partially offset by an increase in financial assets at FVTPL of RMB341.5 million.

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As a development-stage biopharmaceutical company, we incurred negative cash flows from our operations during the Track Record Period. During the Track Record Period, our primary uses of cash were to fund the development of our drug pipeline, clinical trials, procurement of services, payment for the purchase of plant and equipment, administrative expenses and other recurring expenses.

The following table provides information regarding our cash flows for the years indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Cash outflows from operating activities before movements in working capital	(289,458)	(355,067)
Changes in working capital	47,190	27,585
Interest received	5,379	8,156
	(236,889)	(319,326)
Net cash flows used in operating activities	(236,889)	(319,326)
Net cash flows from/(used in) investing activities	209,231	(186,938)
Net cash flows from financing activities	235,436	15,759
	207,778	(490,505)
Net increase in cash and cash equivalents	207,778	(490,505)
Cash and cash equivalents at beginning of the year	748,634	983,934
Effect of foreign exchange rate changes, net	27,522	3,200
	983,934	496,629
Cash and cash equivalents at end of the year	983,934	496,629

Operating Activities

In 2023, our net cash used in operating activities was RMB319.3 million, which was primarily attributable to our loss before tax of RMB343.4 million, adjusted for non-cash and non-operating items, including (i) equity-settled share-based payment of RMB14.8 million; and (ii) fair value gain on financial assets at FVTPL of RMB14.1 million. The amount was further adjusted by the positive effect of changes in working capital, which mainly comprised a decrease in prepayment, other receivable and other assets of RMB23.7 million.

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In 2022, our net cash used in operating activities was RMB236.9 million, which was primarily attributable to our loss before tax of RMB251.9 million, adjusted for non-cash and non-operating items, including (i) net foreign exchange differences of RMB33.4 million; and (ii) fair value gain on financial assets at FVTPL of RMB14.3 million. The amount was further adjusted by the positive effect of changes in working capital, which mainly comprised an increase in trade payables of RMB33.6 million.

We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. In view of our net operating cash outflows throughout the Track Record Period, we plan to improve such position by (i) rapidly advancing our pipeline products towards commercialization to generate revenue from product sales. In particular, we have initiated a pivotal Phase II clinical trial of Tinengotinib for the treatment of CCA in China and we enrolled the first patient in November 2023. We have also initiated a Phase III registrational clinical trial of Tinengotinib for the treatment of CCA in certain regions outside China, and we enrolled the first patient in December 2023 in the U.S.; (ii) adopting comprehensive measures to effectively control our costs and operating expenses, primarily including research and development costs and administrative expenses. For example, we would share the pharmacology models for different projects to split costs; (iii) enhancing working capital management efficiency. For example, we plan to adopt technological solutions to optimize our operational process and enhance our efficiency; and (iv) successfully launching the [REDACTED] to obtain the [REDACTED].

Investing Activities

In 2023, our net cash used in investing activities was RMB186.9 million, primarily as a result of purchase of financial assets at FVTPL of RMB2,690.9 million, partially offset by (i) proceeds from maturity of financial assets at FVTPL of RMB2,363.5 million, and (ii) proceeds from maturity of short-term bank deposits of RMB148.8 million.

In 2022, our net cash generated from investing activities was RMB209.2 million, primarily as a result of proceeds from maturity of financial assets at FVTPL of RMB2,254.8 million, partially offset by (i) purchases of financial assets at FVTPL of RMB1,900.0 million; and (ii) purchases of short-term bank deposits of RMB316.5 million.

Financing Activities

In 2023, our net cash generated from financing activities was RMB15.8 million, primarily as a result of proceeds from Series D+ instruments of RMB20.0 million (see “History, Development and Corporate Structure – Corporate Development and Shareholding Changes of Our Company – Subsequent Capital Changes and Equity Transfers.”)

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In 2022, our net cash generated from financing activities was RMB235.4 million, primarily as a result of proceeds from Series D+ instruments of RMB240.0 million.

CASH OPERATING COSTS

The following table sets forth key information relating to our cash operating costs for the years indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
R&D costs		
<i>R&D costs for our Core Product</i>		
– Preclinical research expenses	12,500	2,400
– Clinical trial expenses	133,401	202,368
– Employee benefit expenses	15,097	22,536
– Material expenses	496	826
– Others ⁽¹⁾	2,658	3,625
<i>R&D costs for our other drug candidates</i>		
– Preclinical research expenses	12,491	7,442
– Licensing fees	6,830	–
– Clinical trial expenses	31,928	57,237
– Employee benefit expenses	30,760	28,704
– Material expenses	3,264	4,607
– Others	2,738	2,705
Workforce employment costs⁽²⁾	14,712	17,201
Non-income taxes, royalties and other governmental charges	157	110

Notes:

- (1) Others primarily represent office expenses and travel expenses;
- (2) Workforce employment costs represent general and administrative staff costs comprising mainly salaries and benefits.

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INDEBTEDNESS

As of December 31, 2022 and 2023, and April 30, 2024, except as disclosed in the table below, we did not have any outstanding mortgages, charges, debentures, other issued debt capital, bank overdrafts, borrowings, liabilities under acceptance or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities. Since April 30, 2024, the latest practicable date for the purpose of the indebtedness statement, and up to the date of this document, there had been no material adverse change in our indebtedness.

The following table sets forth the breakdown of our indebtedness as of dates indicated:

	As of December 31,		As of April 30,
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(Unaudited)</i>
CURRENT			
Lease liabilities	2,688	3,457	1,727
NON-CURRENT			
Lease liabilities	–	1,350	1,231
Total	2,688	4,807	2,958

Our Directors confirm that there have been no material defaults in our payment of trade or non-trade payables, or material breaches of covenants of our indebtedness during the Track Record Period and up to the date of this document.

WORKING CAPITAL CONFIRMATION

Our Directors are of the opinion that, taking into account (i) the financial resources available to our Company, including cash and cash equivalents of RMB496.6 million as of December 31, 2023, financial assets at FVTPL of RMB341.5 million as of December 31, 2023, available financing facilities and the estimated [REDACTED] from the [REDACTED], (ii) the expected commercialization timetable of our Core Product, and (iii) our cash burn rate, we will have sufficient working capital to cover at least 125% of our costs, including research and development costs and administrative expenses, for at least the next twelve months from the date of this document.

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Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, and (ii) capital expenditures, which includes purchase of property, equipment and plant and purchase of intangible assets. Taking into account our cash and cash equivalents and financial assets at FVTPL as of December 31, 2023, assuming an average cash burn rate going forward of 1.5 times the average level in 2022 and 2023, we estimate that we will be able to maintain our financial viability for [REDACTED] months or, if we take into account the estimated net [REDACTED] from the [REDACTED], [REDACTED] months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

CAPITAL EXPENDITURE

We regularly incur capital expenditures to expand our operations, upgrade our facilities, enhance our development capabilities and increase our operating efficiency. Our capital expenditures during the Track Record Period primarily consisted of expenditures on the purchase of lab equipment and construction in progress. Historically, we have funded our capital expenditures mainly through equity financing.

The following table sets forth our capital expenditures for the years indicated:

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Purchase of items of property, plant and equipment	2,019	3,486
Purchase of other intangible assets	229	262
Total	2,248	3,748

CAPITAL COMMITMENTS

We had the following capital commitments as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Authorized, but not provided for:		
Purchase of land use right	7,580	–
Construction design	2,288	3,617
Total	9,868	3,617

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OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

MARKET RISK DISCLOSURE

We are exposed to a variety of financial risks, including foreign currency risk, credit risk and liquidity risk as set out below. We manage and monitor these risks to ensure that appropriate measures can be implemented in a timely and effective manner. For further details, see Note 33 to the Accountants' Report in Appendix I to this document. The discussion below provides a summary of our market risks.

Foreign Currency Risk

Foreign currency risk means the risk relating to the fluctuation of fair value or future cash flows of financial instruments which arises from changes in exchange rates.

We have transactional currency exposures. Such exposures arise from currencies other than the units' functional currencies. For further details, including relevant sensitivity analysis, see Note 33 to the Accountant's Report in Appendix I to this document.

Credit Risk

We trade only with recognized and creditworthy third parties. It is our policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and our exposure to bad debts is not significant. For more details, including the credit quality and the maximum exposure to credit risk based on our credit policy, see Note 33 to the Accountants' Report in Appendix I to this document.

Liquidity Risk

We monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance the operations and mitigate the effects of fluctuations in cash flows. For more details, including the maturity profile of our financial liabilities, see Note 33 to the Accountants' Report in Appendix I to this document.

FINANCIAL INFORMATION

TRANSACTIONS WITH RELATED PARTIES

We had the following transactions during the Track Record Period, and the following table sets forth our transactions with related parties for the years indicated.

	Year Ended December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Purchases of goods and services		
PharmaBlock Sciences (Nanjing), Inc.	49	1,049
Total	49	1,049

Note:

- (1) Representing purchases of raw materials and drugs for our research and development activities.

The following table sets forth the outstanding balances with related parties as of the date indicated.

	As of December 31,	
	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables due to a shareholder:		
PharmaBlock Sciences (Nanjing), Inc.	–	38
Total	–	38

Other than disclosed in the table above, we did not have any material related-party transactions during the Track Record Period.

It is the view of our Directors that each of the above transactions during the Track Record Period (i) was conducted in the ordinary course of business and on an arm’s length basis and on normal commercial terms between the relevant parties, and (ii) did not distort our results of operations over the Track Record Period or made our historical results over the Track Record Period not reflective of our expectations for our future performance.

FINANCIAL INFORMATION

DIVIDEND

No dividend has been paid or declared by our Company during the Track Record Period. We currently expect to retain all future earnings for use in the operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the near future. Any declaration and payment as well as the amount of dividends will be subject to our Articles of Association and the PRC Company Law. The declaration and payment of any dividends in the future will be determined by our Board, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. Our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution.

As confirmed by our PRC Legal Adviser, according to the PRC law, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for, and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the near future. There is no assurance that dividends of any amount will be declared to be distributed in any year.

DISTRIBUTABLE RESERVES

As of December 31, 2023, we did not have any distributable reserves.

[REDACTED] EXPENSES

Our [REDACTED] mainly include [REDACTED] fees and [REDACTED] and professional fees paid to legal advisers and the Reporting Accountants for their services rendered in relation to the [REDACTED] and the [REDACTED]. Assuming full payment of the discretionary incentive fee, the estimated total [REDACTED] (based on the mid-point of our indicative [REDACTED] for the [REDACTED] and assuming that the [REDACTED] is not exercised) for the [REDACTED] are approximately [REDACTED] million and are expected to represent approximately [REDACTED] of the gross [REDACTED] of the [REDACTED], comprising of (i) [REDACTED]-related expenses, including [REDACTED] commission and other expenses, of [REDACTED] million; and (ii) non-[REDACTED]-related expenses of [REDACTED] million, including (a) fees paid and payable to our legal advisers and Reporting Accountants of [REDACTED] million; and (b) other fees and expenses, including sponsor fees, of [REDACTED] million. During the Track Record Period, we incurred [REDACTED] of [REDACTED] million which were attributable to the [REDACTED] of Shares and will be deducted from equity upon the [REDACTED]. We expect to incur [REDACTED] of approximately [REDACTED] million after the Track Record Period, of which an estimated amount of [REDACTED] million is expected to be recognized as administrative expenses and the remaining amount of [REDACTED] million is expected to be recognized directly as a deduction from equity upon the [REDACTED].

FINANCIAL INFORMATION

UNAUDITED [REDACTED] STATEMENT OF ADJUSTED NET TANGIBLE ASSETS

[REDACTED]

FINANCIAL INFORMATION

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or trading position since December 31, 2023 (being the date on which the latest audited consolidated financial information of our Company was prepared) and there is no event since December 31, 2023 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, except as otherwise disclosed in this document, as of the Latest Practicable Date, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS AND PROSPECTS

For a detailed description of our future plans, please see “Business – Our Strategies.”

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately [REDACTED] million, after deducting [REDACTED] fees and estimated expenses payable by us in connection with the [REDACTED], assuming the [REDACTED] being not exercised and an [REDACTED] of [REDACTED] per Share (being the mid-point of the [REDACTED] stated in this document). If the [REDACTED] is set at [REDACTED] per Share (being the high-end of the [REDACTED] stated in this document), the net [REDACTED] from the [REDACTED] will increase by approximately [REDACTED] million. If the [REDACTED] is set at [REDACTED] per Share (being the low-end of the [REDACTED] stated in this document), the net [REDACTED] from the [REDACTED] will decrease by approximately [REDACTED] million.

We intend to use the net [REDACTED] from the [REDACTED] as follows, assuming the [REDACTED] is not exercised and assuming an [REDACTED] of [REDACTED] per Share, being the mid-point of the [REDACTED] stated in this document:

- (i) approximately [61.0]%, or [REDACTED] million, will be allocated to fund the research and development of our Core Product, Tinengotinib, as follows:
 - [7.9]%, or [REDACTED], will be used for funding the ongoing pivotal Phase II clinical trial of Tinengotinib monotherapy for the treatment of CCA in China. We anticipate to complete this trial in the second half of 2025;
 - [36.9]%, or [REDACTED], will be used for funding the ongoing multi-regional registrational Phase III clinical trial of Tinengotinib monotherapy for the treatment of CCA. We anticipate to complete patient enrollment in the second half of 2026;
 - [5.8]%, or [REDACTED], will be used for funding the planned Phase II clinical trial of Tinengotinib in combination with NHT for the treatment of mCRPC in China. We anticipate to commence this trial in the first half of 2025; and
 - [10.4]%, or [REDACTED], will be used for funding the ongoing Phase Ib/II clinical trial of Tinengotinib in combination with atezolizumab for the treatment of BTC and for funding the planned Phase II/III clinical trial of Tinengotinib in combination with immunotherapy for BTC in China. We anticipate to complete the Phase Ib/II clinical trial in the fourth quarter of 2024 and initiate the Phase II/III clinical trial in 2025.

See “Business – Our Product Pipeline – Core Product: Tinengotinib – Potential First-in-class, Unique MTK Inhibitor – Clinical Development Plan.”

FUTURE PLANS AND USE OF [REDACTED]

- (ii) approximately [20.4]%, or [REDACTED] million, will be allocated to fund the research and development of our other pipeline products, of which:
- approximately [7.8]% or [REDACTED], will be allocated to fund the ongoing Phase I clinical trial and planned Phase II clinical trial of TT-00973 in patients with solid tumors in China. We expect to complete the Phase I clinical trial in the first half of 2026 and initiate the Phase II clinical trial in the second half of 2026. See “Business – Other Oncology Pipeline Products – TT-00973: AXL/FLT3 Inhibitor – Clinical Development Plan;”
 - approximately [6.5]% or [REDACTED], will be allocated to fund the ongoing Phase I clinical trial and planned Phase II clinical trial of TT-01488 in patients with B-cell malignancies in China. We expect to obtain the results of the primary endpoint of the Phase I clinical trial in the second half of 2025 and then initiate the Phase II clinical trial in the first half of 2026. See “Business – Other Oncology Pipeline Products – TT-01488: Non-covalent, Reversible BTK Inhibitor – Clinical Development Plan;”
 - approximately [1.4]% or [REDACTED], will be allocated to fund the ongoing Phase Ib clinical trial of TT-01688 for UC and the ongoing Phase II clinical trial of TT-01688 for AD in China, which we expect to complete in the second half of 2024. See “Business – Non-Oncology Pipeline Products – TT-01688: Highly Selective, Oral S1P1 Modulator – Clinical Development Plan;” and
 - approximately [4.7]% or [REDACTED], will be allocated to fund the ongoing preclinical IND enabling studies and planned Phase I clinical trial of TT-02332. We plan to submit IND applications to the FDA and NMPA of TT-02332 in the first half of 2025 and initiate the Phase I clinical trial in the second half of 2025 or first half of 2026.
- (iii) approximately [8.6]% or [REDACTED], will be allocated for establishment of our commercialization network, including the establishment of our own commercial team for promotion and sales; and
- (iv) approximately [10.0]%, or [REDACTED], will be allocated for our general working capital and general corporate purposes.

The above allocation of the net [REDACTED] from the [REDACTED] will be adjusted on a pro rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the indicative [REDACTED] stated in this document.

FUTURE PLANS AND USE OF [REDACTED]

If the [REDACTED] is exercised in full, the net [REDACTED] that we will receive will be approximately [REDACTED] million, assuming an [REDACTED] of [REDACTED] per Share (being the mid-point of the indicative [REDACTED]). In the event that the [REDACTED] is exercised in full, we intend to apply the additional net [REDACTED] to the above purposes in the proportions stated above.

To the extent that our net [REDACTED] are not sufficient to fund the purposes set out above, we intend to fund the balance through a variety of means, including cash generated from operations, bank loans and other borrowings. To the extent that the net [REDACTED] from the [REDACTED] are not immediately applied to the above purposes and to the extent permitted by applicable law and regulations, we will only deposit the net [REDACTED] in short-term deposits in licensed banks or other authorized financial institutions (as defined under the Securities and Futures Ordinance or the applicable laws in the PRC).

In the event of any material change in our use of net [REDACTED] of the [REDACTED] from the purposes described above or in our allocation of the net [REDACTED] among the purposes described above, a formal announcement will be made.

[REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report, prepared for inclusion in this document, received from the independent reporting accountants of the Group, Ernst & Young, Certified Public Accountants, Hong Kong.

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF TRANSTHERA SCIENCES (NANJING), INC. AND CITIC SECURITIES (HONG KONG) LIMITED AND HUATAI FINANCIAL HOLDINGS (HONG KONG) LIMITED

Introduction

We report on the historical financial information of TransThera Sciences (Nanjing), Inc. (the “Company” and previously known as Nanjing TransThera Biosciences Co., Ltd.) and its subsidiaries (together, the “Group”) set out on pages I-[●] to I-[●], which comprises the consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2022 and 2023 (the “Relevant Periods”), and the consolidated statements of financial position of the Group as at 31 December 2022 and 2023 and the statements of financial position of the Company as at 31 December 2022 and 2023 and material accounting policy information and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages I-[●] to I-[●] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [date] (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

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ACCOUNTANTS’ REPORT

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the financial position of the Group as at 31 December 2022 and 2023 and the Company as at 31 December 2022 and 2023 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

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ACCOUNTANTS' REPORT

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to note 14 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

[●]

Certified Public Accountants

Hong Kong

[date]

APPENDIX I

ACCOUNTANTS’ REPORT

I. HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the HKICPA (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	<i>Notes</i>	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
REVENUE	6	124	1,181
Cost of sales		–	–
Gross profit		124	1,181
Other income	7	18,733	22,491
Other gains	7	42,017	17,105
Other expenses	8	(157)	(221)
Research and development costs		(262,511)	(344,475)
Administrative expenses		(49,946)	(39,219)
Impairment losses on financial assets		(23)	(8)
Finance costs	10	(181)	(248)
LOSS BEFORE TAX	9	(251,944)	(343,394)
Income tax expenses	13	–	–
LOSS FOR THE YEAR AND ATTRIBUTABLE TO OWNERS OF THE COMPANY		(251,944)	(343,394)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY			
Basic and diluted (RMB)	15	(0.70)	(0.90)

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ACCOUNTANTS' REPORT

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	Year ended 31 December 2022 RMB'000	Year ended 31 December 2023 RMB'000
LOSS FOR THE YEAR	<u>(251,944)</u>	<u>(343,394)</u>
OTHER COMPREHENSIVE LOSS		
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>(193)</u>	<u>189</u>
OTHER COMPREHENSIVE LOSS FOR THE YEAR	<u>(193)</u>	<u>189</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR AND ATTRIBUTABLE TO OWNERS OF THE COMPANY	<u>(252,137)</u>	<u>(343,205)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	<i>Notes</i>	31 December 2022 RMB’000	31 December 2023 RMB’000
NON-CURRENT ASSETS			
Property, plant and equipment	<i>16</i>	12,029	11,639
Intangible assets	<i>17</i>	997	982
Right-of-use assets	<i>18</i>	2,469	19,982
Prepayments, other receivables and other assets	<i>20</i>	11,831	8,886
Total non-current assets		<u>27,326</u>	<u>41,489</u>
CURRENT ASSETS			
Inventories		245	160
Prepayments, other receivables and other assets	<i>20</i>	35,295	7,271
Financial assets at fair value through profit or loss	<i>21</i>	–	341,541
Pledged and short-term bank deposits	<i>22</i>	142,841	–
Cash and cash equivalents	<i>22</i>	983,934	496,629
Total current assets		<u>1,162,315</u>	<u>845,601</u>
CURRENT LIABILITIES			
Trade payables	<i>23</i>	72,238	78,578
Other payables and accruals	<i>23</i>	21,942	20,527
Contract liabilities	<i>24</i>	196	–
Lease liabilities	<i>18</i>	2,688	3,457
Total current liabilities		<u>97,064</u>	<u>102,562</u>
NET CURRENT ASSETS		<u>1,065,251</u>	<u>743,039</u>
TOTAL ASSETS LESS CURRENT LIABILITIES		<u>1,092,577</u>	<u>784,528</u>
NON-CURRENT LIABILITIES			
Lease liabilities	<i>18</i>	–	1,350
Contract liabilities	<i>24</i>	978	–
Total non-current liabilities		<u>978</u>	<u>1,350</u>
Net assets		<u>1,091,599</u>	<u>783,178</u>
EQUITY			
Share capital	<i>25</i>	379,954	381,617
Reserves	<i>26</i>	711,645	401,561
Total equity		<u>1,091,599</u>	<u>783,178</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2022

			Foreign currency				
	<i>Notes</i>	Share capital	Share premium*	translation reserve*	Other reserves*	Accumulated losses*	Total
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
		<i>(note 25)</i>	<i>(note 26)</i>	<i>(note 27)</i>	<i>(note 26)</i>		
At 1 January 2022		204,383	1,490,486	–	(68,840)	(529,303)	1,096,726
Loss for the year		–	–	–	–	(251,944)	(251,944)
Exchange differences on translation of foreign operations		–	–	(193)	–	–	(193)
Total comprehensive loss for the year		–	–	(193)	–	(251,944)	(252,137)
Capital contribution from series D+ investors	25	19,954	220,046	–	–	–	240,000
Conversion from share premium to share capital	25	155,617	(155,617)	–	–	–	–
Equity-settled share-based transactions	27	–	–	–	7,010	–	7,010
At 31 December 2022		<u>379,954</u>	<u>1,554,915</u>	<u>(193)</u>	<u>(61,830)</u>	<u>(781,247)</u>	<u>1,091,599</u>

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ACCOUNTANTS’ REPORT

Year ended 31 December 2023

			Foreign currency		Accumulated	
	Share capital	Share premium*	translation reserve*	Other reserves*	losses*	Total
Notes	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
	(note 25)	(note 26)	(note 26)	(note 26)		
At 1 January 2023	379,954	1,554,915	(193)	(61,830)	(781,247)	1,091,599
Loss for the year	-	-	-	-	(343,394)	(343,394)
Exchange differences on translation of foreign operations	-	-	189	-	-	189
Total comprehensive income for the year	-	-	189	-	(343,394)	(343,205)
Capital contribution from series D+ investors	25 1,663	18,337	-	-	-	20,000
Equity-settled share-based transactions	27 -	-	-	14,784	-	14,784
At 31 December 2023	<u>381,617</u>	<u>1,573,252</u>	<u>(4)</u>	<u>(47,046)</u>	<u>(1,124,641)</u>	<u>783,178</u>

* These reserve accounts represent the consolidated reserves of RMB711,645,000 and RMB401,561,000 in the consolidated statements of financial position as at 31 December 2022 and 2023, respectively.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS

	<i>Notes</i>	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
CASH FLOWS USED IN OPERATING ACTIVITIES			
Loss before tax		(251,944)	(343,394)
Adjustments for:			
Finance costs	<i>10</i>	181	248
Bank Interest income	<i>7</i>	(6,015)	(12,162)
Depreciation of property, plant and equipment	<i>16</i>	6,070	3,655
Depreciation of right-of-use assets	<i>18</i>	2,665	3,487
Amortisation of intangible assets	<i>17</i>	241	262
Equity-settled share-based payments	<i>27</i>	7,010	14,784
Loss on disposal of property, plant and equipment	<i>8</i>	5	1
Impairment losses on financial assets		23	8
Fair value gain on financial assets at fair value through profit or loss	<i>7</i>	(14,302)	(14,094)
Foreign exchange differences, net		(33,392)	(7,862)
Decrease/(increase) in inventories		(86)	85
Decrease/(increase) in prepayments, other receivable and other assets		6,386	23,749
Increase/(decrease) in trade payables		33,576	6,340
Increase/(decrease) in other payables and accruals		7,438	(1,415)
Increase/(decrease) in contract liabilities		(124)	(1,174)
Cash used in operations		(242,268)	(327,482)
Interest received		5,379	8,156
Net cash flows used in operating activities		(236,889)	(319,326)

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ACCOUNTANTS’ REPORT

	<i>Notes</i>	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
CASH FLOWS FROM INVESTING ACTIVITIES			
Payments for purchase of land use right		(7,580)	(8,042)
Payments for performance bonds for investment construction		(2,000)	–
Purchases of items of property, plant and equipment		(2,019)	(3,486)
Purchases of other intangible assets		(229)	(262)
Purchases of financial assets at fair value through profit or loss		(1,900,000)	(2,690,900)
Purchases of short-term bank deposits		(316,504)	–
Proceeds from maturity of financial assets at fair value through profit or loss		2,254,753	2,363,453
Proceeds from maturity of short-term bank deposits		182,809	148,789
Proceeds from maturity of pledged deposits		–	3,510
Disposal of property, plant and equipment		1	–
		<u>209,231</u>	<u>(186,938)</u>
Net cash flows from/(used in) investing activities		<u>209,231</u>	<u>(186,938)</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from series D+ instruments	26	240,000	20,000
Lease payments	18	(2,090)	(3,507)
Payments of [REDACTED] expense		<u>[REDACTED]</u>	<u>[REDACTED]</u>
Net cash flows from financing activities		<u>235,436</u>	<u>15,759</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS			
		207,778	(490,505)
Cash and cash equivalents at beginning of year		748,634	983,934
Effect of foreign exchange rate changes, net		<u>27,522</u>	<u>3,200</u>
CASH AND CASH EQUIVALENTS AT END OF YEAR	22	<u><u>983,934</u></u>	<u><u>496,629</u></u>

APPENDIX I

ACCOUNTANTS’ REPORT

		Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS			
Cash and bank balances	22	1,126,775	496,629
Less: Pledged and short-term bank deposits	22	<u>(142,841)</u>	<u>–</u>
Cash and cash equivalents as stated in the consolidated statements of cash flows and financial position	22	<u>983,934</u>	<u>496,629</u>

APPENDIX I

ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	<i>Notes</i>	31 December 2022 RMB’000	31 December 2023 RMB’000
NON-CURRENT ASSETS			
Property, plant and equipment	<i>16</i>	11,999	11,618
Intangible assets	<i>17</i>	997	982
Right-of-use assets	<i>18</i>	2,469	19,982
Investments in subsidiaries	<i>19</i>	10,682	25,359
Prepayments, other receivables and other assets	<i>20</i>	11,831	8,886
Total non-current assets		<u>37,978</u>	<u>66,827</u>
CURRENT ASSETS			
Inventories		245	160
Prepayments, other receivables and other assets	<i>20</i>	35,295	7,059
Financial assets at fair value through profit or loss	<i>21</i>	–	341,541
Pledged and short-term bank deposits	<i>22</i>	142,841	–
Cash and cash equivalents	<i>22</i>	975,191	488,714
Total current assets		<u>1,153,572</u>	<u>837,474</u>
CURRENT LIABILITIES			
Trade payables	<i>23</i>	72,238	78,578
Other payables and accruals	<i>23</i>	19,315	20,175
Contract liabilities	<i>24</i>	196	–
Lease liabilities	<i>18</i>	2,688	3,457
Total current liabilities		<u>94,437</u>	<u>102,210</u>
NET CURRENT ASSETS		<u>1,059,135</u>	<u>735,264</u>
TOTAL ASSETS LESS CURRENT LIABILITIES		<u>1,097,113</u>	<u>802,091</u>
NON-CURRENT LIABILITIES			
Lease liabilities	<i>18</i>	–	1,350
Contract liabilities	<i>24</i>	978	–
Total non-current liabilities		<u>978</u>	<u>1,350</u>
Net assets		<u>1,096,135</u>	<u>800,741</u>
EQUITY			
Share capital	<i>25</i>	379,954	381,617
Reserves	<i>26</i>	716,181	419,124
Total equity		<u>1,096,135</u>	<u>800,741</u>

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II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

The Company was established in Nanjing, Jiangsu Province, People’s Republic of China (the “PRC”) on 15 April 2014 as a limited liability company. The Company was converted into a joint stock company with limited liability in July 2021 and its name was changed from Nanjing TransThera Biosciences Co., Ltd. (南京藥捷安康生物科技有限公司) to TransThera Sciences (Nanjing), Inc. (藥捷安康(南京)科技股份有限公司). The registered office of the Company is located at 3rd Floor, 9th Building, Accelerator Phase 2 of Biotech and Pharmaceutical Valley, Jiangbei New Area, Nanjing, Jiangsu Province, PRC.

During the Relevant Periods, the Group is principally engaged in the research and development of pharmaceutical products.

The statutory financial statements of the Company for the year ended 31 December 2022 were prepared in accordance with the PRC Generally Accepted Accounting Principles and were audited by Jiang Su Nan Jing Jiuchen Certified Public Accountants LLP (江蘇南京九辰會計師事務所(普通合夥)). The statutory financial statements of the Company for the year ended 31 December 2023 were prepared in accordance with the PRC Generally Accepted Accounting Principles and were audited by BDO China Shu Lun Pan Certified Public Accountants LLP.

As at the date of this report, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies, (or, if incorporated outside Hong Kong, have substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are set out below:

Name	Place and date of incorporation/ establishment and place of operations	Nominal value of registered share capital/issued ordinary shares	Percentage of equity interest attributable to the Company		Principal activities
			Direct	Indirect	
TransThera Sciences (HK) Limited	Hong Kong 18 August 2022	HKD10,000	100%	–	Investment holding
TransThera Sciences (US) Inc.	Delaware, United States of America 19 September 2022	USD5,000	–	100%	Research and development of pharmaceutical products

As at the date of this report, the statutory financial statements of TransThera Sciences (HK) Limited for the period from 18 August 2022 (date of incorporation) to 31 December 2023 prepared under Hong Kong Small and Medium-sized Entity Financial Reporting Standard (“SME-FRS”) were audited by Wiselite CPA Limited Certified Public Accountants, no audited financial statements were prepared for TransThera Sciences (US) Inc.

2.1 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (“IASB”).

All IFRSs effective for the accounting period commencing from 1 January 2023, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods.

The Historical Financial Information has been prepared under the historical cost convention, except for financial assets at fair value through profit or loss which have been measured at fair value.

Basis of consolidation

The Historical Financial Information includes the financial information of the Company and its subsidiaries for the Relevant Periods. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

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Generally, there is a presumption that a majority of voting rights results in control. When the Company has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the Company and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises the related assets (including goodwill), liabilities, any non-controlling interest and the exchange fluctuation reserve; and recognises the fair value of any investment retained and any resulting surplus or deficit in the statement of profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

2.2 ISSUED BUT NOT YET EFFECTIVE IFRSs

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in the Historical Financial Information.

Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ³
Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i> ¹
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current (the “2020 Amendments”)</i> ^{1, 4}
Amendments to IAS 1	<i>Non-current Liabilities with Covenants (the “2022 Amendments”)</i> ^{1, 4}
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i> ¹
Amendments to IAS 21	<i>Lack of Exchangeability</i> ²

¹ Effective for annual periods beginning on or after 1 January 2024

² Effective for annual periods beginning on or after 1 January 2025

³ No mandatory effective date yet determined but available for adoption

⁴ As a consequence of the 2020 Amendments and 2022 Amendments, Hong Kong Interpretation 5 Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause was revised to align the corresponding wording with no change in conclusion

The Group is in the process of making an assessment of the impact of these new or revised IFRSs upon initial application. Up to now, the Group considers that these new or revised standards will not have a significant impact on the Group’s financial statements.

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3. MATERIAL ACCOUNTING POLICIES

Fair value measurement

The Group measures its financial assets at fair value at the end of each reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories and financial assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to the statement of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each reporting period as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to the statement of profit or loss in the period in which it arises.

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Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person's family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
 - (iii) the entity and the Group are joint ventures of the same third party;
 - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
 - (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
 - (vi) the entity is controlled or jointly controlled by a person identified in (a);
 - (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
 - (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used and estimated useful life for this purpose are as follows:

Lab equipment	18%
Electronic equipment	30%
Motor vehicles	18%
Leasehold improvements	Over the lease term

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Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in the statement profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents a building under construction, which is stated at cost less any impairment losses, and is not depreciated. It is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at each financial year end. The principal annual rate used for this purpose is as follows:

Software	20%
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Research and development costs

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Office buildings	3 years
Land-use rights	50 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

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(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of office buildings (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment that is considered to be of low value.

Lease payments on short-term leases and leases of low-value assets are recognised as an expense on a straight-line basis over the lease term.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value, plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

Purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace are recognized on the trade date, that is, the date that the Group commits to purchase or sell the asset.

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Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in the statement of profit or loss when the asset is derecognized, modified or impaired.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognized in the statement of profit or loss.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group’s consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information. The Group considers that there has been a significant increase in credit risk when contractual payments are more than 30 days past due.

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The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Debt investments at fair value through other comprehensive income and financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and contract assets which apply the simplified approach as detailed below.

- Stage 1 – Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs
- Stage 2 – Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs
- Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as loans and borrowings, payables, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade and other payables and lease liabilities.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost (trade and other payables and borrowings)

After initial recognition, trade and other payables, and interest-bearing borrowings are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in the statement of profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss.

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Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in the statement of profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average basis. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

Cash and cash equivalents in the statement of financial position comprise cash on hand and at banks, and short-term highly liquid deposits with a maturity of generally within three months that are readily convertible into known amounts of cash, subject to an insignificant risk of changes in value and held for the purpose of meeting short-term cash commitments.

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and at banks, and short-term deposits as defined above, less bank overdrafts which are repayable on demand and form an integral part of the Group's cash management.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside the statement of profit or loss is recognised outside the statement of profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of the reporting period between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

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Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each reporting period and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to the statement of profit or loss over the expected useful life of the relevant asset by equal annual instalments.

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

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When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognised under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

The Company entered into a licensing arrangement with a customer, under which the Company grants a license of the drug formula to the customer, including the right to produce and sell products based on the drug formula in predetermined areas during commercialization stage. While the Company and the customer will conduct clinical trials in the predetermined areas respectively, the Company is obligated to provide certain clinical trial support services to the customer. Such clinical trial support services include helping with the preparation of the investigational new drug application plan and filing to the regulatory, providing regular updates to the customer regarding the Company’s development and the manufacture of licensed compounds and licensed products in the Company’s territory and etc.

The Company considered that the grant the licenses of the drug formula and the clinical trial supporting services are separate performance obligations since they are distinct from each other according to the contract.

The performance obligation of the licensing is satisfied at the point in time when the Company provides the customers with a right to use the formula as it exists at the point in time at which the license is granted, since the Company considered that it would not undertake activities that significantly affect the drug formula and all the licensing contract only provided the customer with a right to use the drug formula.

The performance obligation of providing clinical trials support services is satisfied over the period of development as the customer simultaneously receives and consumes the benefits provided by the Company’s performance as the Company performs. Progress is measured by passage of time with respect to the total estimated time for the development.

The Company is entitled to an upfront payment and various milestone payments during the development stage and sale-based royalties during commercialisation stage. Most of the considerations entitled by the Company are variable considerations and the Company estimates such variable considerations based on the most likely amount. As majority of the considerations are highly susceptible to factors outside the Company’s influence, the variable considerations are constrained until uncertainties associated with the variable considerations are subsequently resolved. At the end of each reporting periods, the Company re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catchup basis, which would affect revenues and earnings in the period of adjustment. Consideration is allocated to the two performance obligations based on the stand-alone selling prices which consider the pricing by competitors for similar products or services as well as the costs and margins.

Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Contract liabilities

A contract liability is recognised when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related goods or services. Contract liabilities are recognised as revenue when the Group performs under the contract (i.e., transfers control of the related goods or services to the customer).

Share-based payments

The Company operates 2017, 2021 and 2023 share incentive plans for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments (“equity-settled transactions”).

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The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using specific models, further details of which are given in note 27 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group’s best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Other employee benefits

Pension scheme

The Company is required to participate in a central pension scheme operated by the local municipal government. The Company is required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

The Group’s subsidiary in the U.S. has a defined contribution plan where participating employees may contribute to the plan 1% to 99% of their eligible annual compensation as defined in the plan, up to the Internal Revenue Service contribution (the “IRS contribution”) limit of USD20,500 for the year ended December 31, 2022 and USD22,500 for the year ended December 31, 2023. Individuals who are age 50 or over at the end of the calendar year can make annual catch-up contributions up to USD6,500 in 2022 and USD7,500 in 2023. The Group’s subsidiary in the U.S. makes a matching contribution of participants’ elective deferral contribution of 6% of eligible participant compensation.

Foreign currencies

The Historical Financial Information is presented in RMB, which is the Company’s functional currency. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognized in the statement of profit or loss.

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Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognized in other comprehensive income or profit or loss is also recognized in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

The functional currencies of the overseas subsidiaries are the United States dollar (“USD”). As at the end of the reporting period, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve, except to the extent that the differences are attributable to non-controlling interests. On disposal of a foreign operation, the cumulative amount in the reserve relating to that particular foreign operation is recognised in the statement of profit or loss.

4. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Historical Financial Information requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Judgements

In the process of applying the Group’s accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the Historical Financial Information:

Research and development costs

All research costs are charged to the statement of profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred. Determining the amounts of development costs to be capitalised requires the use of judgements and estimation. The Group currently expenses all the milestone and upfront payments under the drug license agreements.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each reporting period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Share-based payments

The Company has set up the share incentive plans for the Company’s directors and the Group’s employees.

Estimating the fair value for share-based payment transactions requires the determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires the determination of the most appropriate inputs to the valuation model including volatility and dividend yield and making assumptions about them.

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The assumptions and models used for estimating the fair value for share-based payment transactions are disclosed in note 27 to the Historical Financial Information.

5. OPERATING SEGMENT INFORMATION

Operating segment information

For management purposes, the Group has only one reportable operating segment, which is the development of innovative medicines. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

Geographical information

(a) Revenue from external customers

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Republic of Korea	124	1,174
Chinese Mainland	–	7
	<hr/>	<hr/>
Total Revenue	124	1,181
	<hr/> <hr/>	<hr/> <hr/>

The revenue information above is based on the locations of the customers. The revenue from Republic of Korea is associated with an exclusive license agreement that was executed with one customer in prior fiscal years. The Group has terminated such agreement in 2023. Due to the payments received are non-refundable and the Group has none other obligations, the Group recognizes all contract liabilities as of 31 December 2022 as revenue in 2023.

(b) Non-current assets

Since almost all of the Group’s non-current assets were located in Chinese Mainland, no geographical segment information is presented in accordance with IFRS 8 *Operating Segments*.

Information about the major customers

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Revenue from Customer A	124	1,174
Revenue from Customer B	–	7
	<hr/>	<hr/>
Total Revenue	124	1,181
	<hr/> <hr/>	<hr/> <hr/>

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6. REVENUE

An analysis of revenue is as follows:

	Year ended 31 December 2022 <i>RMB’000</i>	Year ended 31 December 2023 <i>RMB’000</i>
Revenue from contracts with customers	124	1,181

(a) Disaggregated revenue information:

	Year ended 31 December 2022 <i>RMB’000</i>	Year ended 31 December 2023 <i>RMB’000</i>
Revenue from contracts with customers		
Types of goods or services		
Others	–	7
Clinical trials support services	124	1,174
Total	124	1,181
Timing of revenue recognition		
Transferred at a point in time	–	7
Transferred over time	124	1,174
Total	124	1,181

(b) Performance obligations

Information about the Group’s performance obligations is summarized below:

Revenue from the licensing of drug formula

The performance obligation is satisfied at a point in time when the customer obtains the rights to the underlying technology and payment is generally due within 45 days from the date of billing.

Revenue from clinical trials support services

The performance obligation is satisfied over time as services are rendered and payment is generally due within 45 days from the date of billing.

The amounts of transaction price allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at the end of each of the Relevant Periods are as follows:

	31 December 2022 <i>RMB’000</i>	31 December 2023 <i>RMB’000</i>
Amounts expected to be recognised as revenue		
Within one year	196	–
After one year	978	–

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As of the year-end 2022, the remaining performance obligations pertain to clinical trial support services. These services are associated with an exclusive license agreement that was executed with one customer in prior fiscal years. The amounts disclosed above do not include variable consideration which is constrained. In 2023, the Group has terminated this agreement with the customer. Due to the payments received are non-refundable and the Group has none other obligations, the Group recognizes all contract liabilities as of 31 December 2022 as revenue in 2023.

7. OTHER INCOME AND OTHER GAINS

An analysis of other income is as follows:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Other income		
Government grants*	12,714	10,329
Bank interest income	6,015	12,162
Others	4	–
	<u>18,733</u>	<u>22,491</u>
Other gains		
Foreign exchange gains, net	27,715	3,011
Fair value gain on financial assets at fair value through profit or loss	14,302	14,094
	<u>42,017</u>	<u>17,105</u>

* The government grants mainly represent the subsidies received from the local governments for the purpose of compensation of expenses spent on research and clinical trials activities and there are no unfulfilled conditions or contingencies relating to these grants.

8. OTHER EXPENSES

An analysis of other gains and other expenses is as follows:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
<u>Other expenses</u>		
Donations	127	220
Loss on disposal of property, plant and equipment	5	1
Others	25	–
	<u>157</u>	<u>221</u>

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9. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging:

	<i>Notes</i>	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Depreciation of property, plant and equipment	<i>16</i>	6,070	3,655
Depreciation of right-of-use assets	<i>18(a)</i>	2,665	3,487
Amortisation of intangible assets	<i>17</i>	241	262
Lease payments not included in the measurement of lease liabilities	<i>18(c)</i>	206	93
Auditor’s remuneration*		78	79
Fair value gain on financial assets at fair value through profit or loss	<i>8</i>	(14,302)	(14,094)
Professional fees*		25,151	7,821
Employee benefit expense (excluding directors’, supervisors’ and chief executive’s remuneration (<i>note 11</i>)):			
– Salaries, allowances and benefits in kind		47,151	53,154
– Pension scheme contributions (defined contribution scheme)		6,208	7,339
– Share-based payments		6,160	10,904
Foreign exchange gains, net	<i>8</i>	(27,715)	(3,011)
Impairment losses on financial assets		23	8
Government grants	<i>7</i>	(12,714)	(10,329)
Bank interest income	<i>7</i>	(6,015)	(12,162)
Loss on disposal of property, plant and equipment	<i>8</i>	5	1

* Auditor’s remuneration represents auditor’s expense in relation to annual report auditing.

* Professional fees represents fees incurred for business, tax and legal consultation in the ordinary course of business and expenses of legal advisers, reporting accountants and other professional service providers in relation to 2021 HKEx [REDACTED] Application and potential A share [REDACTED].

10. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Interest on lease liabilities	181	248

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11. DIRECTORS’, SUPERVISORS’ AND CHIEF EXECUTIVE’S REMUNERATION

Directors’, supervisors’ and chief executive’s remuneration for the Relevant Periods are as follows:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Fees	662	896
Other emoluments:		
Salaries, bonuses, allowances and benefits in kind	6,256	5,729
Pension scheme contributions	292	1,322
Share-based payments	850	3,880
	<u>8,060</u>	<u>11,827</u>

(a) Independent non-executive directors

Year ended 31 December 2022	Fees RMB’000	Total RMB’000
Independent non-executive directors:		
Li Shupai (a)	337	337
Chui Hoi Yam (b)	47	47
Zheng Zhelan (c)	47	47
	<u>431</u>	<u>431</u>

Year ended 31 December 2023	Fees RMB’000	Total RMB’000
Independent non-executive directors:		
Li Shupai (a)	224	224
Chui Hoi Yam (b)	224	224
Zheng Zhelan (c)	224	224
	<u>672</u>	<u>672</u>

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(b) Executive directors, non-executive directors and supervisors

Year ended 31 December 2022	Fees <i>RMB’000</i>	Salaries, bonuses, allowances and benefits in kind <i>RMB’000</i>	Pension scheme contributions <i>RMB’000</i>	Share-based payments <i>RMB’000</i>	Total <i>RMB’000</i>
Executive directors:					
Frank Wu (d)	–	3,373	163	–	3,536
Wu Di (e)	–	1,853	43	107	2,003
	–	5,226	206	107	5,539
Non-executive director:					
Jia Zhongxin (f)	231	–	–	145	376
Yi Hua (g)	–	–	–	–	–
	231	–	–	145	376
Supervisors:					
Mei Jianghua (h)	–	–	–	–	–
Zhao weili (i)	–	565	43	321	929
Pang Yajing (j)	–	465	43	277	785
	–	1,030	86	598	1,714
	231	6,256	292	850	7,629

Year ended 31 December 2023	Fees <i>RMB’000</i>	Salaries, bonuses, allowances and benefits in kind <i>RMB’000</i>	Pension scheme contributions <i>RMB’000</i>	Share-based payments <i>RMB’000</i>	Total <i>RMB’000</i>
Executive directors:					
Frank Wu (d)	–	2,909	1,184	–	4,093
Wu Di (e)	–	1,769	46	2,595	4,410
	–	4,678	1,230	2,595	8,503
Non-executive director:					
Jia Zhongxin (f)	224	–	–	261	485
Yi Hua (g)	–	–	–	–	–
	224	–	–	261	485
Supervisors:					
Mei Jianghua (h)	–	–	–	–	–
Zhao weili (i)	–	577	46	594	1,217
Pang Yajing (j)	–	474	46	430	950
	–	1,051	92	1,024	2,167
	224	5,729	1,322	3,880	11,155

(a) Li Shupai was appointed as an independent non-executive director of the Company on 17 June 2021.

(b) Chui Hoi Yam was appointed as an independent non-executive director of the Company on 17 October 2022.

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- (c) Zheng Zhelan was appointed as an independent non-executive director of the Company on 17 October 2022.
- (d) Frank Wu was appointed as an executive director of the Company on 10 May 2016. Frank Wu is also the chief executive officer of the Company and his remuneration disclosed above included the services rendered by him as the chief executive.
- (e) Wu Di was appointed as an executive director of the Company on 16 March 2020.
- (f) Jia Zhongxin was appointed as a non-executive director of the Company on 11 September 2018.
- (g) Yi Hua was appointed as a non-executive director of the Company on 16 March 2020.
- (h) Mei Jianghua was appointed as a supervisor of the Company on 16 March 2020.
- (i) Zhao Weili was appointed as a supervisor of the Company on 17 June 2021.
- (j) Pang Yajing was appointed as a supervisor of the Company on 16 July 2021.

Certain directors were granted share-based benefits, in respect of their services to the Group, further details of which are set out in note 27 to the Historical Financial Information.

There was no arrangement under which a director waived or agreed to waive any remuneration during the Relevant Periods.

12. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the years ended 31 December 2022 and 2023 included one and two directors, respectively, details of whose remuneration are included in note 11 to the Historical Financial Information. Details of the remuneration of the remaining highest paid employees who are neither a director nor chief executive of the Company are as follows:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Salaries, allowances, and benefits in kind	6,002	6,448
Pension scheme contributions	2,190	2,654
Share-based payments	4,330	3,807
	<u>12,522</u>	<u>12,909</u>

The number of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands is as follows:

	Year ended 31 December 2022	Year ended 31 December 2023
HK\$2,500,001 to HK\$3,000,000	1	–
HK\$3,000,001 to HK\$3,500,000	1	1
HK\$4,000,001 to HK\$4,500,000	2	–
HK\$4,500,001 to HK\$5,000,000	–	1
HK\$5,000,001 to HK\$5,500,000	–	–
HK\$5,500,001 to HK\$6,000,000	–	–
HK\$6,000,001 to HK\$6,500,000	–	1
	<u>4</u>	<u>3</u>

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13. INCOME TAX EXPENSES

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Chinese Mainland

Under the Law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the estimated tax rate of the Group is 25% during the period presented in the condensed consolidated financial statements. No Chinese Mainland income tax was provided for as the Company is in loss position and has no estimated assessable profits.

Hong Kong

The subsidiary incorporated in Hong Kong is subject to income tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong during the Relevant Periods. No Hong Kong profits tax was provided for as the Group did not generate any assessable profits arising in Hong Kong during the Relevant Periods.

The United States

The subsidiary incorporated in the United States (US) is subject to the federal statutory income tax at the rate of 21% and subject to the corporate income tax of the State of Delaware at the rate of 8.7% on any estimated assessable profits arising in US during the Relevant Periods. No US profits tax was provided for as the Group did not generate any assessable profits arising in US during the Relevant Periods.

A reconciliation of the tax expense applicable to loss before tax at the statutory rate for the country in which the Company and its subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Loss before tax	(251,944)	(343,394)
Tax at the statutory tax rate (25%)	(62,986)	(85,848)
Effect of different tax rates enacted by local authorities	(204)	(620)
Additional deductible allowance for qualified research and development costs	(42,099)	(78,873)
Expenses not deductible for tax	2,012	3,967
Tax losses not recognised	104,827	150,219
Deductible temporary differences not recognised	(1,550)	11,155
	<u> </u>	<u> </u>
Tax at the effective tax rates	<u> </u> –	<u> </u> –

The Group has accumulated tax losses arising in Chinese Mainland of RMB975,483,432.73 and RMB1,513,667,897.86, as at 31 December 2022 and 2023, respectively, that will expire in one to five years for offsetting against future taxable profits of the Group. The Group also has accumulated tax losses arising in Hong Kong and USA of RMB4,343,008.94 and RMB17,558,038.51, as at 31 December 2022 and 2023, respectively, that will be carried forward indefinitely for offsetting against future taxable profits of the companies in which the losses arose. The deferred tax assets and the deferred tax liabilities arising from lease contracts of the same subsidiary have been offset in the statement of financial position for presentation purposes. Except the offset deferred tax assets, the Group has deductible temporary differences for which deferred tax assets are not recognised of RMB14,959,788.40 and RMB59,578,422.13 as at 31 December 2022 and 2023, respectively.

Deferred tax assets have not been recognized in respect of these losses and deductible temporary differences as they have arisen in the Company and its subsidiaries that have been loss-making for some time, and it is not considered probable that taxable profits in foreseeable future will be available against which the tax losses and the deductible temporary differences can be utilized.

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14. DIVIDENDS

No dividends have been paid or declared by the Company during the Relevant Periods.

15. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY

The calculation of the basic loss per share amounts for the years ended 31 December 2022 and 2023, is based on the loss for the years attributable to ordinary equity holders of the Company and the weighted average number of ordinary shares assumed to be in issue after taking into account the retrospective adjustments on the assumption that the Company’s conversion from share premium to share capital had been in effect on 1 January 2022 as disclosed in note 25 to the Historical Financial Information.

The Company had no potentially dilutive ordinary shares in issue during the years ended 31 December 2022 and 2023.

	Year ended 31 December 2022	Year ended 31 December 2023
<u>Loss</u>		
Loss attributable to ordinary owners/ordinary equity holders of the parent, used in the basic and diluted loss per share calculation (RMB’000)	(251,944)	(343,394)
<u>Shares</u>		
Weighted average number of ordinary shares assumed to be in issue during the year used in the basic and diluted loss per share calculation	360,387,427	381,401,928
Loss per share (basic and diluted) (RMB)	(0.70)	(0.90)

The Company had no potentially dilutive ordinary shares in issue during the years ended 31 December 2022 and 2023.

16. PROPERTY, PLANT AND EQUIPMENT

The Group

	Lab equipment RMB’000	Electronic equipment RMB’000	Motor vehicles RMB’000	Leasehold improvement RMB’000	Construction in progress RMB’000	Total RMB’000
At 31 December 2022						
At 1 January 2022:						
Cost	22,267	2,148	1,125	5,635	–	31,175
Accumulated depreciation	(10,722)	(858)	(663)	(3,731)	–	(15,974)
Net carrying amount	11,545	1,290	462	1,904	–	15,201
At 1 January 2022, net of accumulated depreciation	11,545	1,290	462	1,904	–	15,201
Additions	2,539	330	–	34	–	2,903
Disposals	(4)	(1)	–	–	–	(5)
Depreciation provided during the year	(3,754)	(459)	(124)	(1,733)	–	(6,070)

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	Lab equipment <i>RMB'000</i>	Electronic equipment <i>RMB'000</i>	Motor vehicles <i>RMB'000</i>	Leasehold improvement <i>RMB'000</i>	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
At 31 December 2022, net of accumulated depreciation	10,326	1,160	338	205	–	12,029
At 31 December 2022: Cost	24,790	2,465	1,125	5,669	–	34,049
Accumulated depreciation	(14,464)	(1,305)	(787)	(5,464)	–	(22,020)
Net carrying amount	10,326	1,160	338	205	–	12,029
At 31 December 2023						
At 1 January 2023: Cost	24,790	2,465	1,125	5,669	–	34,049
Accumulated depreciation	(14,464)	(1,305)	(787)	(5,464)	–	(22,020)
Net carrying amount	10,326	1,160	338	205	–	12,029
At 1 January 2023, net of accumulated depreciation	10,326	1,160	338	205	–	12,029
Additions	230	127	–	9	2,900	3,266
Disposals	–	(1)	–	–	–	(1)
Depreciation provided during the year	(2,842)	(535)	(100)	(178)	–	(3,655)
At 31 December 2023, Net of accumulated depreciation	7,714	751	238	36	2,900	11,639
At 31 December 2023: Cost	25,020	2,581	1,125	5,677	2,900	37,303
Accumulated depreciation	(17,306)	(1,830)	(887)	(5,641)	–	(25,664)
Net carrying amount	7,714	751	238	36	2,900	11,639

The Company

	Lab equipment <i>RMB'000</i>	Electronic equipment <i>RMB'000</i>	Motor vehicles <i>RMB'000</i>	Leasehold improvement <i>RMB'000</i>	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
At 31 December 2022						
At 1 January 2022: Cost	22,267	2,148	1,125	5,635	–	31,175
Accumulated depreciation	(10,722)	(858)	(663)	(3,731)	–	(15,974)
Net carrying amount	11,545	1,290	462	1,904	–	15,201

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	Lab equipment <i>RMB'000</i>	Electronic equipment <i>RMB'000</i>	Motor vehicles <i>RMB'000</i>	Leasehold improvement <i>RMB'000</i>	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2022, net of accumulated depreciation	11,545	1,290	462	1,904	–	15,201
Additions	2,539	299	–	34	–	2,872
Disposals	(4)	(1)	–	–	–	(5)
Depreciation provided during the year	(3,754)	(458)	(124)	(1,733)	–	(6,069)
At 31 December 2022, net of accumulated depreciation	<u>10,326</u>	<u>1,130</u>	<u>338</u>	<u>205</u>	<u>–</u>	<u>11,999</u>
At 31 December 2022: Cost	24,790	2,434	1,125	5,669	–	34,018
Accumulated depreciation	(14,464)	(1,304)	(787)	(5,464)	–	(22,019)
Net carrying amount	<u>10,326</u>	<u>1,130</u>	<u>338</u>	<u>205</u>	<u>–</u>	<u>11,999</u>
At 31 December 2023						
At 1 January 2023: Cost	24,790	2,434	1,125	5,669	–	34,018
Accumulated depreciation	(14,464)	(1,304)	(787)	(5,464)	–	(22,019)
Net carrying amount	<u>10,326</u>	<u>1,130</u>	<u>338</u>	<u>205</u>	<u>–</u>	<u>11,999</u>
At 1 January 2023, net of accumulated depreciation	10,326	1,130	338	205	–	11,999
Additions	230	127	–	9	2,900	3,266
Disposals	–	(1)	–	–	–	(1)
Depreciation provided during the year	(2,842)	(526)	(100)	(178)	–	(3,646)
At 31 December 2023, net of accumulated depreciation	<u>7,714</u>	<u>730</u>	<u>238</u>	<u>36</u>	<u>2,900</u>	<u>11,618</u>
At 31 December 2023: Cost	25,020	2,550	1,125	5,677	2,900	37,272
Accumulated depreciation	(17,306)	(1,820)	(887)	(5,641)	–	(25,654)
Net carrying amount	<u>7,714</u>	<u>730</u>	<u>238</u>	<u>36</u>	<u>2,900</u>	<u>11,618</u>

As at 31 December 2022 and 2023, there were no pledged property, plant and equipment.

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17. INTANGIBLE ASSETS

The Group and the Company

	Software <i>RMB'000</i>
At 31 December 2022	
At 1 January 2022,	
Cost	1,152
Accumulated amortisation	<u>(130)</u>
Net carrying amount	<u><u>1,022</u></u>
At 1 January 2022, net of accumulated amortisation	1,022
Additions	216
Amortisation provided during the year	<u>(241)</u>
At 31 December 2022, net of accumulated amortisation	<u><u>997</u></u>
At 31 December 2022:	
Cost	1,368
Accumulated amortisation	<u>(371)</u>
Net carrying amount	<u><u>997</u></u>
At 31 December 2023	
At 1 January 2023,	
Cost	1,368
Accumulated amortisation	<u>(371)</u>
Net carrying amount	<u><u>997</u></u>
At 1 January 2023, net of accumulated amortisation	997
Additions	247
Amortisation provided during the year	<u>(262)</u>
At 31 December 2023, net of accumulated amortisation	<u><u>982</u></u>
At 31 December 2023:	
Cost	1,615
Accumulated amortisation	<u>(633)</u>
Net carrying amount	<u><u>982</u></u>

As at 31 December 2022 and 2023, there were no pledged intangible assets.

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18. LEASES

The Group and the Company

Group/Company as a lessee

The Group and the Company has lease contracts for office buildings used in its operations. Leases of office buildings generally have lease terms of 3 years. Generally, the Group and the Company is restricted from assigning and subleasing the leased assets outside the Group and the Company.

(a) *Right-of-use assets*

The carrying amounts of the Group and the Company’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Office buildings <i>RMB’000</i>	Land-use rights <i>RMB’000</i>	Total
At 31 December 2022			
At 1 January 2022	5,134	–	5,134
Depreciation charge	(2,665)	–	(2,665)
	<u>2,469</u>	<u>–</u>	<u>2,469</u>
At 31 December 2022	<u>2,469</u>	<u>–</u>	<u>2,469</u>
At 31 December 2023			
At 1 January 2023	2,469	–	2,469
Additions	5,378	15,622	21,000
Depreciation charge	(3,253)	(234)	(3,487)
	<u>4,594</u>	<u>15,388</u>	<u>19,982</u>
At 31 December 2023	<u>4,594</u>	<u>15,388</u>	<u>19,982</u>

(b) *Lease liabilities*

The carrying amounts of lease liabilities and the movements during the Relevant Periods are as follows:

	31 December 2022 <i>RMB’000</i>	31 December 2023 <i>RMB’000</i>
Carrying amount at 1 January	4,597	2,688
New leases	–	5,378
Accretion of interest recognised during the year	181	248
Payments	(2,090)	(3,507)
	<u>2,688</u>	<u>4,807</u>
Carrying amount at 31 December	<u>2,688</u>	<u>4,807</u>
Analysed into:		
Current portion	2,688	3,457
Non-current portion	–	1,350
	<u>2,688</u>	<u>4,807</u>

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(c) The amounts recognised in the statement of profit or loss in relation to leases are as follows:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Interest on lease liabilities	181	248
Depreciation charge of right-of-use assets	2,665	3,487
Expenses relating to low-value leases	64	73
Expenses relating to short-term leases	142	20
	<u>3,052</u>	<u>3,828</u>
Total amounts recognised in profit or loss	<u><u>3,052</u></u>	<u><u>3,828</u></u>

19. INVESTMENT IN SUBSIDIARIES

The Company

	31 December 2022 RMB’000	31 December 2023 RMB’000
Investment costs	10,682	25,359
	<u>10,682</u>	<u>25,359</u>

The increase in investment in subsidiaries is due to the investment of RMB14,677,000 recognized for the Transthera Sciences (HK) Limited in 2023.

20. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

The Group

	31 December 2022 RMB’000	31 December 2023 RMB’000
Non-current:		
Prepayments for purchase of land use right	7,580	–
Deposits	2,520	2,390
Value-added tax recoverable	1,731	6,496
	<u>11,831</u>	<u>8,886</u>
Total	<u><u>11,831</u></u>	<u><u>8,886</u></u>
Current:		
Accrued interest on short-term bank deposits	604	–
Prepayments	30,862	5,951
Deposits	418	548
Other receivables	468	633
Deferred [REDACTED]	[REDACTED]	[REDACTED]
Allowance for the expected credit losses	(23)	(31)
	<u>35,295</u>	<u>7,271</u>
Total	<u><u>35,295</u></u>	<u><u>7,271</u></u>

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The Company

	31 December 2022 RMB’000	31 December 2023 RMB’000
Non-current:		
Prepayments for purchase of land use right	7,580	–
Deposits	2,520	2,390
Value-added tax recoverable	1,731	6,496
	<u>11,831</u>	<u>8,886</u>
Total	<u>11,831</u>	<u>8,886</u>
Current:		
Accrued interest on short-term bank deposits	604	–
Prepayments	30,862	5,739
Deposits	418	548
Other receivables	468	633
Deferred [REDACTED]	[REDACTED]	[REDACTED]
Allowance for the expected credit losses	(23)	(31)
	<u>35,295</u>	<u>7,059</u>
Total	<u>35,295</u>	<u>7,059</u>

The financial assets included in the above balances relate to receivables for which there was no recent history of material default and past due amounts. The Group and the Company seeks to maintain strict control over its outstanding receivables to minimise credit risk. As at the end of each of the Relevant Periods, the management of the Group and the Company assessed the allowance for the expected credit losses by the expected credit loss model.

The balances are unsecured and interest-free.

21. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

The Group and the Company

	31 December 2022 RMB’000	31 December 2023 RMB’000
Wealth management products	<u>–</u>	<u>341,541</u>

At 31 December 2023, the financial assets at fair value through profit or loss represented wealth management products issued by banks and securities companies, with expected return rates from 2.5% to 3.8% per annum.

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22. CASH AND CASH EQUIVALENTS AND PLEDGED AND SHORT-TERM BANK DEPOSITS

The Group

	31 December 2022	31 December 2023
	<i>RMB’000</i>	<i>RMB’000</i>
Cash at banks	987,413	496,629
Less:		
Pledged deposits	<u>3,479</u>	<u>–</u>
Cash and cash equivalents	<u>983,934</u>	<u>496,629</u>
Short-term bank deposits with maturities of more than three months	<u>139,362</u>	<u>–</u>
	<u><u>1,123,296</u></u>	<u><u>496,629</u></u>
Denominated in:		
RMB	870,283	417,883
USD	252,185	77,622
JPY	<u>828</u>	<u>1,124</u>

The Company

	31 December 2022	31 December 2023
	<i>RMB’000</i>	<i>RMB’000</i>
Cash at banks	978,670	488,714
Less:		
Pledged deposits	<u>3,479</u>	<u>–</u>
Cash and cash equivalents	<u>975,191</u>	<u>488,714</u>
Short-term bank deposits with maturities of more than three months	<u>139,362</u>	<u>–</u>
	<u><u>1,114,553</u></u>	<u><u>488,714</u></u>
Denominated in:		
RMB	870,283	417,883
USD	243,442	69,707
JPY	<u>828</u>	<u>1,124</u>

The RMB is not freely convertible into other currencies, however, under Chinese Mainland’s Foreign Exchange Control Regulations and Administration of Settlement, and Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

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Cash at banks earns interest at floating rates based on daily bank deposit rates. The pledged deposit here represents restricted deposits in margin accounts for the purpose of conducting various foreign currency transactions. The bank balances and pledged deposits are deposited with creditworthy banks with no recent history of default.

The effective interest rates of short-term bank deposits with maturities of more than three months were from 2.36% to 4.90% as at 31 December 2022.

23. TRADE AND OTHER PAYABLES

The Group

	31 December 2022	31 December 2023
	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	72,238	78,578
Government grant*	6,400	6,400
Staff salaries, bonuses and welfare payables	14,686	13,611
Other tax payables	102	85
Other payables	754	431
	<u>94,180</u>	<u>99,105</u>

The Company

	31 December 2022	31 December 2023
	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	72,238	78,578
Government grant*	6,400	6,400
Staff salaries, bonuses and welfare payables	12,072	13,552
Other tax payables	102	85
Other payables	741	138
	<u>91,553</u>	<u>98,753</u>

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

The Group and the Company

	31 December 2022	31 December 2023
	<i>RMB’000</i>	<i>RMB’000</i>
Within one year	<u>72,238</u>	<u>78,578</u>

* Some government grants are received for capital expenditure incurred for the acquisition of lab equipment. When the conditions attached to the government grants are complied, the amounts will be transferred to deferred income and amortised to the statement of profit or loss over the estimated useful lives of the respective assets.

Trade payables are non-interest-bearing and are normally settled within one year.

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Other payables and accruals are unsecured, non-interest-bearing and repayable on demand.

24. CONTRACT LIABILITIES

The Group and the Company

	31 December 2022 RMB’000	31 December 2023 RMB’000
Amounts received in advance for rendering services to customers over time	1,174	–

Analysed into:

	31 December 2022 RMB’000	31 December 2023 RMB’000
Amounts expected to be recognised as revenue		
Within one year	196	–
After one year	978	–

Revenue of RMB124,000 and RMB1,174,000 recognised during the years ended 31 December 2022 and 2023 was included in the contract liabilities at the beginning of the years.

25. SHARE CAPITAL

The Group and the Company

A summary of movements in the Group and the Company’s share capital during the Relevant Periods is as follows:

	Number of ordinary shares	Share capital RMB’000
At 1 January 2022	204,383,017	204,383
Conversion from share premium to share capital (<i>note a</i>)	155,616,983	155,617
Capital contribution from series D+ investors (<i>note b</i>)	19,953,815	19,954
At 31 December 2022 and 1 January 2023	379,953,815	379,954
Capital contribution from series D+ investors (<i>note c</i>)	1,662,818	1,663
At 31 December 2023	381,616,633	381,617

Notes:

- (a) Pursuant to the shareholders’ resolutions dated 17 October 2022, all of the shareholders of the Company approved the conversion of share premium into share capital by way of issuance of additional 0.76 share for every then existing share. An aggregate of 155,616,983 shares were issued and the number of shares of each shareholder increased proportionately. Upon completion, the total share capital of the Company increases to 360,000,000 shares and the shareholding percentage of each shareholder remains unchanged.

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- (b) Pursuant to the share purchase agreement entered into among series D+ investors and all then shareholders, series D+ investors injected RMB240,000,000 into the Company in December 2022, with RMB19,953,815, representing 19,953,815 ordinary shares of the Company, and RMB220,046,185 credited to the Company’s share capital and share premium, respectively.
- (c) Pursuant to the share purchase agreement entered into among series D+ investor and all then shareholders, series D+ investor injected RMB20,000,000 into the Company in February 2023, with RMB1,662,818, representing 1,662,818 ordinary shares of the Company, and RMB18,337,182 credited to the Company’s share capital and share premium, respectively.

26. RESERVES

The Group

The amounts of the Group’s reserves and the movements therein are presented in the consolidated statements of changes in equity on pages I-14 to I-15 of the Historical Financial Information.

(a) Share premium

The share premium of the Group represents the difference between the par value of the shares issued and the consideration received.

(b) Share-based payment reserve

The share-based payment reserve represents the equity-settled equity awards.

(c) Foreign currency translation reserve

The exchange fluctuation reserve comprises all foreign exchange differences arising from the translation of the financial statements of companies in the Group of which the functional currency is not RMB. The reserve is dealt with in accordance with the accounting policy set out in note 3 to the Historical Financial Information.

The Company

The amounts of the Company’s reserves and the movements therein for the Relevant Periods are presented as follows:

Year ended December 31, 2022

	Share premium <i>RMB'000</i>	Other reserves <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2022	1,490,486	(68,840)	(529,303)	892,343
Loss for the year	—	—	(247,601)	(247,601)
Total comprehensive loss for the year	—	—	(247,601)	(247,601)
Capital contribution from series D+ investors	220,046	—	—	220,046
Conversion from share premium to share capital	(155,617)	—	—	(155,617)
Equity-settled share-based transactions	—	7,010	—	7,010
At 31 December 2022	<u>1,554,915</u>	<u>(61,830)</u>	<u>(776,904)</u>	<u>716,181</u>

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Year ended December 31, 2023

	Share premium <i>RMB’000</i>	Other reserves <i>RMB’000</i>	Accumulated losses <i>RMB’000</i>	Total <i>RMB’000</i>
At 1 January 2023	1,554,915	(61,830)	(776,904)	716,181
Loss for the year	—	—	(330,178)	(330,178)
Total comprehensive income for the year	—	—	(330,178)	(330,178)
Capital contribution from series D+ investors	18,337	—	—	18,337
Equity-settled share-based transactions	—	14,784	—	14,784
At 31 December 2023	<u>1,573,252</u>	<u>(47,046)</u>	<u>(1,107,082)</u>	<u>419,124</u>

27. SHARE-BASED PAYMENTS

Share incentive plan

A share incentive plan (the “2017 Share Incentive Plan”) was approved by the shareholders of the Company on 16 March 2017 and became effective on the same day. Options under the 2017 Share Incentive Plan were granted to the employees who contribute to the success of the Company through an incentive platform named Nanjing Yipu Bioscience Technology Partnership (Limited Partnership) (南京益璞生物科技合夥企業(有限合夥)) (“Nanjing Yipu”). Upon vesting, employees will become a limited partner of Nanjing Yipu and indirectly receive economic interest in the corresponding number of underlying shares of the Company held by the Nanjing Yipu.

Subject to the terms and conditions as set out in the 2017 Share Incentive Plan, share options will be vested in the portions of 20%, 20%, 20%, 20% and 20% on the first, second, third, fourth and fifth anniversaries of the grant dates of the options, respectively.

A new share incentive plan, which was approved by the shareholders of the Company on 7 January 2021, became effective on 1 March 2021 (the “2021 Share Incentive Plan”, together with the 2017 Share Incentive Plan, the “Original Share Incentive Plan”). Options under the 2021 Share Incentive Plan were also granted to the employees through the incentive platform of Nanjing Yipu.

Subject to the terms and conditions as set out in the 2021 Share Incentive Plan, share options would be vested in the portions of 30%, 30% and 40% on the third, fourth and fifth anniversaries of the grant dates of the options, respectively.

The following options were outstanding under the Original Share Incentive Plan during the year ended 31 December 2022 and the three-month period ended 31 March 2023 (“Replacement date”):

	Number of options (a)	Weighted average exercise price <i>RMB</i>
At 1 January 2022	3,856,290	5.426
Others during the year (b)	2,936,170	—
At 1 January 2023 and 31 December 2022	6,792,460	3.081
Exercised during the period	1,415,455	1.890
Forfeited during the period	1,004,878	5.216
At 31 March 2023 (c)	<u>4,372,127</u>	<u>2.975</u>

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- (a) The number of options represented in the corresponding number of underlying shares of the Company that employees would indirectly receive the economic interests through Nanjing Yipu
- (b) In October 2022, the shareholders of the Company approved the conversion of share premium into share capital by way of issuance of additional 0.76 share for each existing share. An aggregate of 155,616,983 shares were issued and the number of shares options of each shareholder increased proportionately
- (c) At 31 March 2023 (“Replacement date”), all outstanding options granted under Original Share Incentive Plan were replaced by restricted shares

The exercise period of these options under Original Share Incentive Plan is six years from the grant dates. As of 31 December 2022, the numbers of exercisable options were 1,557,247, and the exercisable period is ranged from July 2018 to May 2027.

In March 2023, a share incentive plan (the “2023 Share Incentive Plan”) was approved by the shareholders of the Company and became effective on 31 March 2023. The 2023 Share Incentive Plan is a replacement of the Original Share Incentive Plan.

Subject to the 2023 Share Incentive Plan, a total of 10,674,066 restricted shares were granted, of which 6,301,939 were newly granted to selected employees and 4,372,127 restricted shares were granted to replace the outstanding share options under the Original Share Incentive Plan. The eligible participants can obtain the whole right of the shares while meeting the vesting condition which requires the employees are in service from the date of grant to the later of (1) five years since the grant date (the “Service Period”) and (2) A lockup period which is determined by the regulations and review policies of securities regulatory of the company’s listing location after successful [REDACTED] of the Company (the “Lock-up Period”). If an eligible participant’s employment terminates during the vesting period, all unvested restricted shares as of the termination date will be forfeited. After taking into consideration of the best estimation of the [REDACTED] date, the management determined the vesting period of those restricted shares would be Service Period.

The fair value of services received in return for a newly restricted share granted is measured by reference to the fair value of the restricted shares less the subscription price, which would be amortized over the Service Period. The fair value of the restricted shares is measured by reference to the Company’s share price for the series D+ investors.

The Company accounted for 4,372,127 restricted shares to replace the outstanding share options under the Original Share Incentive Plan as a modification of the Original Share Incentive Plan. Since such modification increased the fair value of the equity instruments granted to the employees as of 31 March 2023, the Company continued to amortize the share-based expenses before replacement over the vesting period under the Original Share Incentive Plan, and the incremental fair value over the Services Period.

The following restricted shares were outstanding under the 2023 Share Incentive Plan during the year ended 31 December 2023:

	Number of restricted shares	Subscription price per share
At 31 March 2023	10,674,066	1.000
Forfeited during the year	726,445	1.000
At 31 December 2023	9,947,621	1.000

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The following table lists out the key inputs to calculate the fair value of the shares options under the Original Share Incentive Plan as of 31 March 2023:

	31 March 2023 (“Replacement date”)
Risk-free interest rate	2.28%-2.62%
Volatility	44.48%-49.60%
Dividend yield	0%
Equity price*	12.03

* The equity prices of the Company was estimated using the share price in the series D+ Financing.

There are no cash settlement alternatives. The Group accounts for the Schemes as equity-settled plans. The Group recognised share-based payment expenses of RMB7,010,000 and RMB14,785,000 in the statement of profit or loss related to the above share incentive plans (the Original Share Incentive Plan and 2023 Share Incentive Plan) during the years ended 31 December 2022 and 2023.

28. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the year ended 31 December 2023, the Group had non-cash additions to right-of-use assets and lease liabilities of RMB5,378,000 and RMB5,378,0000, respectively, in respect of lease arrangements for office buildings.

During the year ended 31 December 2022, the Group had none non-cash additions to right-of-use assets and lease liabilities.

(b) Changes in liabilities arising from financing activities

	Lease liabilities RMB’000
At 1 January 2022	4,597
Changes from financing cash flows:	
Lease payments	<u>(2,090)</u>
Other change:	
Accretion of interest recognised during the year	<u>181</u>
At 31 December 2022 and 1 January 2023	<u><u>2,688</u></u>
Changes from financing cash flows:	
Lease payments	<u>(3,507)</u>
Other change:	
Accretion of interest recognised during the year	248
New lease	<u>5,378</u>
At 31 December 2023	4,807

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(c) **Total cash outflow for leases**

The total cash outflow for leases included in the consolidated statements of cash flows is as follows:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Within operating activities	206	93
Within financing activities	2,090	3,507
	<u>2,296</u>	<u>3,600</u>

29. COMMITMENTS

The Group had the following capital commitment at the end of each of the Relevant Periods.

	31 December 2022 RMB’000	31 December 2023 RMB’000
Authorised, but not provided for:		
Purchase of land use right	7,580	–
Construction design	2,288	3,617
	<u>9,868</u>	<u>3,617</u>

30. RELATED PARTY TRANSACTIONS

(a) **Name and relationship of related parties**

Name	Relationship
PharmaBlock Sciences (Nanjing), Inc.	Shareholder of the Company

(b) In addition to the transactions detailed elsewhere in the Historical Financial Information, the Group had the following transactions with related parties during the Relevant Periods:

	Year ended 31 December 2022 RMB’000	Year ended 31 December 2023 RMB’000
Purchase of goods and services		
PharmaBlock Sciences (Nanjing), Inc.	49	1,049
	<u>49</u>	<u>1,049</u>

Note: The pricing of goods and services was made according to the published prices and conditions similar to those offered to the major customers of the supplier.

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(c) Outstanding balance with a related party:

	31 December 2022	31 December 2023
	<i>RMB’000</i>	<i>RMB’000</i>
Trade payable:		
Due to a shareholder:		
PharmaBlock Sciences (Nanjing), Inc.	–	38
	<u> </u>	<u> </u>

(d) Compensation of key management personnel of the Group:

	Year ended 31 December 2022	Year ended 31 December 2023
	<i>RMB’000</i>	<i>RMB’000</i>
Short term employee benefits	15,346	12,562
Post-employment benefits	2,525	2,839
Share-based payments	5,794	6,516
	<u> </u>	<u> </u>
	<u>23,665</u>	<u>21,917</u>

Further details of directors’, supervisors’ and the chief executive’s emoluments are included in note 11 to the Historical Financial Information.

31. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

As at 31 December 2022

Financial assets

	Financial assets at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayment, other receivables and other assets	3,987
Short-term bank deposits	139,362
Pledged deposits	3,479
Cash and cash equivalents	983,934
	<u> </u>
	<u>1,130,762</u>

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Financial liabilities

	Financial liabilities at amortised cost <i>RMB’000</i>
Trade payables	72,238
Financial liabilities included in other payables and accruals	754
Lease liabilities	2,688
	<hr/>
	75,680
	<hr/> <hr/>

As at 31 December 2023

Financial assets

	Financial assets at fair value through profit or loss (mandatorily classified) <i>RMB’000</i>	Financial assets at amortised cost <i>RMB’000</i>	Total <i>RMB’000</i>
Financial assets included in prepayment, other receivables and other assets	–	3,540	3,540
Financial assets at fair value through profit or loss	341,541	–	341,541
Cash and cash equivalents	–	496,629	496,629
	<hr/>	<hr/>	<hr/>
	341,541	500,169	841,710
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

Financial liabilities

	Financial liabilities at amortised cost <i>RMB’000</i>
Trade payables	78,578
Financial liabilities included in other payables and accruals	431
Lease liabilities	4,807
	<hr/>
	83,816
	<hr/> <hr/>

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ACCOUNTANTS’ REPORT

32. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Fair values

Management has assessed that the fair values of financial assets included in prepayments, other receivables and other assets, pledged deposits, cash and cash equivalents, trade payables and financial liabilities included in other payables and accruals approximate to their carrying amounts largely due to the short term maturities of these instruments. The wealth management products which are classified as financial assets at fair value through profit or loss are valued by discounted cash flows using market rates that reflect the risk of the wealth management products. The fair values of the other non-current financial liabilities and non-current financial assets have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities, which approximate to their carrying amounts.

The Group’s finance department is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At the end of each of the Relevant Periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The directors of the Company review the results of the fair value measurement of financial instruments periodically for financial reporting.

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Assets measured at fair value:

As at 31 December 2023

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1) RMB’000	Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Wealth management products	–	341,541	–	341,541

The Group did not have any financial assets measured at fair value as at 31 December 2022 and did not have any financial liabilities measured at fair value as at the end of each of the Relevant Periods.

During the Relevant Periods, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

33. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments comprise cash and bank balances and financial assets at fair value through profit or loss. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as other receivables and trade and other payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors of the Company reviews and agrees policies for managing each of these risks and they are summarised below.

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from currencies other than the units’ functional currencies.

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The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in foreign currency exchange rates, with all other variables held constant, of the Group’s loss before tax and the Group’s equity.

	Decrease/ (increase) in rate of foreign currency %	Decrease/ (increase) in loss before tax RMB’000	Increase/ (decrease) in equity RMB’000
31 December 2022			
If RMB weakens against USD	5	10,522	10,522
If RMB strengthens against USD	(5)	(10,522)	(10,522)
If RMB weakens against JPY	5	27	27
If RMB strengthens against JPY	(5)	(27)	(27)
If RMB weakens against HKD	5	(43)	(43)
If RMB strengthens against HKD	(5)	43	43
If RMB weakens against EUR	5	(977)	(977)
If RMB strengthens against EUR	(5)	977	977
31 December 2023			
If RMB weakens against USD	5	693	693
If RMB strengthens against USD	(5)	(693)	(693)
If RMB weakens against JPY	5	56	56
If RMB strengthens against JPY	(5)	(56)	(56)
If RMB weakens against EUR	5	(11)	(11)
If RMB strengthens against EUR	(5)	11	11

Credit risk

The Group trades only with recognised and creditworthy third parties. It is the Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and the Group’s exposure to bad debts is not significant.

Maximum exposure and year-end staging

The table below shows the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification at the end of each of the Relevant Periods. The amounts presented are gross carrying amounts for financial assets.

As at 31 December 2022

	12-month ECLs Stage 1 RMB’000
Financial assets included in prepayments, other receivables and other assets	4,010
Pledged deposits	3,479
Short-term bank deposits	139,362
Cash and cash equivalents	983,934
	<hr/>
	1,130,785
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As at 31 December 2023

	12-month ECLs Stage 1 RMB’000
Financial assets included in prepayments, other receivables and other assets	3,571
Cash and cash equivalents	496,629
	<u>500,200</u>

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

	At 31 December 2022				
	On demand	Less than 6 months	6 to less than 12 months	1 to 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	72,238	–	–	–	72,238
Financial liabilities included in other payables and accruals	754	–	–	–	754
Lease liabilities	838	962	962	–	2,762
	<u>73,830</u>	<u>962</u>	<u>962</u>	<u>–</u>	<u>75,754</u>

	At 31 December 2023				
	On demand	Less than 6 months	6 to less than 12 months	1 to 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	78,578	–	–	–	78,578
Financial liabilities included in other payables and accruals	431	–	–	–	431
Lease liabilities	1,697	957	941	1,393	4,988
	<u>80,706</u>	<u>957</u>	<u>941</u>	<u>1,393</u>	<u>83,997</u>

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise owners’ value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to owners, return capital to owners or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Relevant Periods.

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The Group monitors capital using a debt-to-asset ratio which is total liabilities divided by total assets. The debt-to-asset ratios as at the end of each of the Relevant Periods were as follows:

	As at 31 December 2022 RMB’000	As at 31 December 2023 RMB’000
Total liabilities	98,042	103,912
Total assets	1,189,641	887,090
Debt-to-asset ratio	8.24%	11.71%

34. EVENT AFTER THE RELEVANT PERIODS

No significant subsequent events have occurred to the Company or to the Group after 31 December 2023 and up to the date of this report.

35. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or any of its subsidiaries in respect of any period subsequent to 31 December 2023.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

TAXATION OF SECURITY HOLDERS

The taxation of income and capital gains of holders of H Shares is subject to the laws and practices of the PRC and of jurisdictions in which holders of H Shares are residents or otherwise subject to tax. The following summary of certain relevant taxation provisions is based on current effective laws and practices, and no predictions are made about changes or adjustments to relevant laws or policies, and no comments or suggestions will be made accordingly. The discussion has no intention to cover all possible tax consequences resulting from the investment in H Shares, nor does it take the specific circumstances of any particular investor into account, some of which may be subject to special regulations. Accordingly, you should consult your own tax advisor regarding the tax consequences of an investment in H Shares. The discussion is based upon laws and relevant interpretations in effect as of the date of this document, which is subject to change or adjustment and may have retrospective effect.

No issues of PRC or Hong Kong taxation other than income tax, capital appreciation and profit tax, business tax/appreciation tax, stamp duty and estate duty are addressed in this discussion. Prospective investors are urged to consult their financial advisors regarding the PRC, Hong Kong and other tax consequences of owning and disposing of H Shares.

The PRC Taxation

Taxation on Dividends

Individual Investors

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》), which was most recently amended on August 31, 2018 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was most recently amended on December 18, 2018 (hereinafter collectively referred to as the "IIT Law"), dividends distributed by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless specifically exempted by the tax authority of the State Council or reduced by relevant tax treaty. Pursuant to the Notice on Certain Policy Issues concerning Individual Income Tax (《關於個人所得稅若干政策問題的通知》) issued by the Ministry of Finance and the State Administration of Taxation on May 13, 1994 and implemented on the same day, the dividends and bonuses received by foreign individuals from foreign-invested enterprises are temporarily exempted from individual income tax.

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TAXATION AND FOREIGN EXCHANGE

Enterprise Investors

In accordance with the Corporate Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) issued by NPC on March 16, 2007 and latest amended on December 29, 2018 and the Implementation Provisions of the Corporate Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) issued by the State Council on December 6, 2007, came into effect on January 1, 2008 and amended on April 23, 2019 (hereinafter collectively referred to as the "CIT Law"), the rate of enterprise income tax shall be 25%. A non-resident enterprise is generally subject to a 10% corporate income tax on PRC-sourced income (including dividends received from a PRC resident enterprise), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise.

The Circular of the State Administration of Tax on Issues Relating to the Withholding and Remitting of Corporate Income Tax by PRC Resident Enterprises on Dividends Distributed to Overseas Non-Resident Enterprise Shareholders of H Shares (《國家稅務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》), which was issued and implemented by the State Administration of Taxation (hereinafter referred to as SAT) on November 6, 2008, further clarified that a PRC-resident enterprise shall withhold and remit corporate income tax at a unified rate of 10% on the dividends of 2008 and onwards that it distributes to overseas non-resident enterprise shareholders of H Shares.

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (hereinafter referred to as the "the Arrangement"), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company unless a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《<內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排>第五議定書》), which came into effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Arrangement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》).

Tax Treaties

Non-resident investors residing in jurisdictions which have entered into treaties or adjustments for the avoidance of double taxation with the PRC might be entitled to a reduction of the Chinese corporate income tax imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties or Arrangements with a number of countries and regions including Hong Kong Special Administrative Region, Macau Special Administrative Region, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the U.S. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant taxation treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the corporate income tax in excess of the agreed tax rate, and the refund application is subject to approval by the Chinese tax authorities.

Taxation on Share Transfer

VAT and Local Additional Tax

Pursuant to the Notice on Fully Implementing the Pilot Reform for the Transition from Business Tax to Value-added Tax (《關於全面推開營業稅改徵增值稅試點的通知》) (hereinafter referred to as “Circular 36”), which was implemented on May 1, 2016 and abrogated in part on July 1, 2017, January 1, 2018 and April 1, 2019, entities and individuals engaged in the services sale in the PRC are subject to VAT and “engaged in the services sale in the PRC” means that the seller or buyer of the taxable services is located in the PRC. Circular 36 also provides that transfer of financial products, including transfer of the ownership of marketable securities, shall be subject to VAT at 6% on the taxable revenue (which is the balance of sales price upon deduction of purchase price), for a general or a foreign VAT taxpayer. However, individuals who transfer financial products are exempt from VAT, which is also provided in the Notice of Ministry of Finance and State Administration of Taxation on Several Tax Exemption Policies for Business Tax on Sale and Purchase of Financial Commodities by Individuals (《財政部、國家稅務總局關於個人金融商品買賣等營業稅若干免稅政策的通知》) effective on January 1, 2009. According to these regulations, if the holder is a non-resident individual, the PRC VAT is exempted from the sale or disposal of H shares; if the holder is a non-resident enterprise and the H-share buyer is an individual or entity located outside China, the holder is not necessarily required to pay the PRC VAT, but if the H-share buyer is an individual or entity located in China, the holder may be required to pay the PRC VAT. However, it is still uncertain whether the non-Chinese resident enterprises are required to pay the PRC VAT for the disposal of H shares in practice.

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At the same time, VAT payers are also required to pay urban maintenance and construction tax, education surtax and local education surcharge (hereinafter collectively referred to as "Local Additional Tax"), which shall be usually subject to 12% of the value-added tax, and consumption tax actually paid (if any).

Income tax

Individual Investors

According to the IIT Law, gains on the transfer of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%. Pursuant to the Circular on Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) issued by the State Administration of Tax on March 20, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. The State Administration of Taxation has not expressly stated whether it will continue to exempt tax on income of individuals from transfer of the shares of listed enterprises in the latest amended Individual Income Tax Law.

However, on December 31, 2009, the Ministry of Finance, SAT and China Securities Regulatory Commission jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》), which came into effect on December 31, 2009, which states that individuals' income from the transfer of listed shares obtained from the public offering of listed companies and transfer market on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant restricted shares as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) jointly issued and implemented by the abovementioned departments on November 10, 2010. As of the Latest Practicable Date, no aforesaid provisions have expressly provided that individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges.

Enterprise Investors

In accordance with the CIT Law, a non-resident enterprise is generally subject to corporate income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

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Stamp Duty

Pursuant to the Stamp Duty Law of the People's Republic of China (《中華人民共和國印花稅法》) promulgated on June 10, 2021 and came into effect on July 1, 2022, PRC stamp duty only applies to specific taxable document executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

As of the Latest Practicable Date, no estate duty has been levied in the PRC under the PRC laws.

HONG KONG TAXATION

Taxation on Dividends

No tax is payable by any person or corporation under the laws of Hong Kong in respect of dividends paid by our Company.

Profits Tax

Hong Kong profits tax will not be payable by any Shareholders (other than Shareholders carrying on a trade, profession or business in Hong Kong and holding the Shares for trading purposes) on any capital gains made on the sale or other disposal of the Shares. Shareholders should take advice from their own professional advisers as to their particular tax position.

Stamp Duty

Hong Kong stamp duty will be charged on the sale and purchase of Shares at the current rate of 0.2% of the consideration for, or (if greater) the value of, the Shares being sold or purchased, whether or not the sale or purchase is on or off the Hong Kong Stock Exchange. The Shareholder selling the Shares and the purchaser will each be liable for one-half of the amount of Hong Kong stamp duty payable upon such transfer. In addition, a fixed duty of HK\$5 is currently payable on any instrument of transfer of Shares.

Estate Duty

The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong, pursuant to which no Hong Kong estate duty is payable and no estate duty clearance papers are needed for an application of a grant of representation in respect of holders of H Shares whose deaths occur on or after February 11, 2006.

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Enterprise Income Tax

According to the EIT Law, enterprises and other income-generating organizations (hereinafter referred to as "enterprises") within the PRC are taxpayers of enterprise income tax and shall pay enterprise income tax in accordance with the provisions of the EIT Law. The tax rate for enterprise income tax is 25%. According to the Administrative Measures for Determination of High and New Tech Enterprises (《高新技術企業認定管理辦法》) promulgated by the Ministry of Science and Technology, the MOF and the SAT on April 14, 2008, amended on January 29, 2016, and becoming effective on January 1, 2016, enterprises recognized as high and new technology enterprises can apply for a 15% preferential enterprise income tax rate in accordance with the relevant provisions of the EIT Law.

Value-added Tax

According to the Provisional Regulations of the People's Republic of China on Value-added Tax (《中華人民共和國增值稅暫行條例》) promulgated by the State Council on December 13, 1993, becoming effective on January 1, 1994, and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the People's Republic of China on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》) promulgated by the MOF on December 25, 1993 and becoming effective on the same day, and amended on December 15, 2008 and October 28, 2011, entities and individuals engaging in sale of goods or provision of processing services, repair and replacement services, and import of goods within the PRC are taxpayers of value-added tax and shall pay value-added tax in accordance with laws and regulations. The rate of value-added tax for sale of goods is 17% unless otherwise specified, such as the rate of value-added tax for sale of transportation is 11%. With the value-added tax reforms in the PRC, the rate of value-added tax has been changed several times. The MOF and the SAT issued the Notice of the MOF and the SAT on Adjusting Value-added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the value-added tax rates of 17% and 11% applicable to any taxpayer's taxable sale or import of goods to 16% and 10%, respectively. Such adjustment became effective on May 1, 2018. Subsequently, the MOF, the SAT and the General Administration of Customs jointly issued the Announcement of the MOF and the SAT on Relevant Policies for Deepening the Value-added Tax Reform (《財政部、國家稅務總局關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make further adjustments, which came into effect on April 1, 2019. The value-added tax rate of 16% applicable to the taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

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TAXATION OF OUR COMPANY IN HONG KONG

Taxation on Dividends

According to the current practice of the Hong Kong Inland Revenue Department, no tax is payable in Hong Kong in respect of dividends paid by us.

Capital Gains and Profit Tax

No tax is imposed in Hong Kong in respect of capital gains from the sales of H Shares. However, trading gains from the sale of the H Shares by persons carrying on a trade, profession or business in Hong Kong, where such gains are derived from or arise in Hong Kong from such trade, profession or business will be subject to Hong Kong profits tax, which is currently imposed at the maximum rate of 16.5% on corporations and at the maximum rate of 15% on unincorporated businesses. Certain categories of taxpayers (for example, financial institutions, insurance companies and securities dealers) are likely to be regarded as deriving trading gains rather than capital gains unless these taxpayers can prove that the investment securities are held for long-term investment purposes. Trading gains from sales of H Shares effected on the Stock Exchange will be considered to be derived from or arise in Hong Kong. Liability for Hong Kong profits tax would thus arise in respect of trading gains from sales of H Shares effected on the Stock Exchange realized by persons carrying on a business of trading or dealing in securities in Hong Kong.

Stamp Duty

At present, every purchase and sale of Hong Kong securities, including H Shares, is subject to Hong Kong stamp duty at the ad valorem rate of 0.1% on the higher of the consideration for or the market value of the H Shares, and shall be payable by the purchaser and seller (in other words, a total of 0.2% is currently payable on a typical sale and purchase transaction involving H Shares). In addition, a fixed duty of HK\$5.00 is currently payable on any instrument of transfer of H Shares. Where one of the parties is a resident outside Hong Kong and does not pay the ad valorem duty due by it, the duty not paid will be assessed on the instrument of transfer (if any) and will be payable by the transferee. If no stamp duty is paid on or before the due date, a penalty of up to ten times the duty payable may be imposed.

Estate Duty

The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong, pursuant to which no Hong Kong estate duty is payable and no estate duty clearance papers are needed for an application of a grant of representation in respect of holders of H Shares whose deaths occur on or after February 11, 2006.

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FOREIGN EXCHANGE

The lawful currency of the PRC is Renminbi, which is currently subject to foreign exchange control and cannot be freely converted into foreign currency. The State Administration of Foreign Exchange (hereinafter referred to as "SAFE"), with the authorization of the People's Bank of China (hereinafter referred to as "PBOC"), is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

The Regulations on Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) (the "Foreign Exchange Control Regulations"), which was issued by the State Council on January 29, 1996, implemented on April 1, 1996 and latest amended on August 5, 2008, classifies all international payments and transfers into current items and capital items. Current items are subject to the reasonable examination of the veracity of transaction documents and the consistency of the transaction documents and the foreign exchange receipts and payments by financial institutions engaging in conversion and sale of foreign currencies and supervision and inspection by the foreign exchange control authorities. For capital items, overseas organizations and overseas individuals making direct investments in China shall, upon approval by the relevant authorities in charge, process registration formalities with the foreign exchange control authorities. Foreign exchange income received overseas can be repatriated or deposited overseas, and foreign exchange and foreign exchange settlement funds under the capital account are required to be used only for purposes as approved by the competent authorities and foreign exchange administrative authorities. In the event that international revenues and expenditure occur or may occur a material imbalance, or the national economy encounters or may encounter a severe crisis, the State may adopt necessary safeguard and control measures on international revenues and expenditure.

The Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》), which was promulgated by the PBOC on June 20, 1996 and implemented on July 1, 1996, removes other restrictions on convertibility of foreign exchange under current items, while imposing existing restrictions on foreign exchange transactions under capital account items.

According to the Announcement on Improving the Reform of the Renminbi Exchange Rate Formation Mechanism (《關於完善人民幣匯率形成機制改革的公告》), which was issued by the PBOC and implemented on July 21, 2005, the PRC has started to implement a managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand and adjusted with reference to a basket of currencies since July 21, 2005. Therefore, the Renminbi exchange rate was no longer pegged to the U.S. dollar. PBOC would publish the closing price of the exchange rate of the Renminbi against trading currencies such as the U.S. dollar in the interbank foreign exchange market after the closing of the market on each working day, as the central parity of the currency against Renminbi transactions on the following working day.

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According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign investment enterprises) which need foreign exchange for current item transactions may, without the approval of the foreign exchange administrative authorities, effect payment through foreign exchange accounts opened at the designated foreign exchange bank, on the strength of valid transaction receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange (such as our Company) may, on the strength of resolutions of the board of directors or the shareholders' meeting on the distribution of profits, effect payment from foreign exchange accounts at the designated foreign exchange bank, or effect exchange and payment at the designated foreign exchange bank.

According to the Decisions on Matters including Canceling and Adjusting a Batch of Administrative Approval Items (《國務院關於取消和調整一批行政審批項目等事項的決定》) which was promulgated by the State Council on October 23, 2014, it decided to cancel the approval requirement of the SAFE and its branches for the remittance and settlement of the proceeds raised from the overseas listing of the foreign shares into RMB domestic accounts.

According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE and implemented on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of state administration of foreign exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), which was issued by the SAFE on February 13, 2015, came into effect on June 1, 2015 and partially repealed on December 30, 2019, the confirmation of foreign exchange registration under domestic direct investment and the confirmation of foreign exchange registration under overseas direct investment shall be directly examined and handled by banks. SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks.

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionizing and Regulating Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) which was promulgated by the SAFE and implemented on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative

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percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjust of the SAFE in due time in accordance with international revenue and expenditure situations.

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This Appendix summarizes certain aspects of PRC laws and regulations which are relevant to the Company’s operations and business. Laws and regulations relating to taxation in the PRC are discussed separately in “Appendix III – Taxation and Foreign Exchange” to this document. This Appendix also contains a summary of certain material differences between laws and regulatory provisions of Hong Kong and the PRC Company Law. The principal objective of this summary is to provide potential investors with an overview of the principal laws and regulatory provisions applicable to the Company. This summary is not intended to include all the information which is important to the potential investors. For a discussion of laws and regulations which are relevant to the Company’s business, see “Regulatory Overview” in this document.

THE PRC LEGAL SYSTEM

The PRC legal system is based on the PRC Constitution (《中華人民共和國憲法》) (hereinafter referred to as the “Constitution (《憲法》)”) and is made up of written laws, administrative regulations, local regulations, separate regulations, rules and regulations of departments of the State Council, rules and regulations of local governments, autonomous regulations, separate regulations of autonomous regions, special administrative region law and international treaties and other regulatory documents signed by the PRC government. Court decisions do not constitute binding precedents, although they are used for the purposes of judicial reference and guidance.

According to the Constitution and the Legislation Law of the People’s Republic of China (《中華人民共和國立法法》) (the “Legislation Law (《立法法》)”), which was amended by the National People’s Congress (the “NPC”) on March 13, 2023 and became effective on March 15, 2023, the NPC and the NPC Standing Committee are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing criminal and civil matters, state organs and other matters. The SCNPC is empowered to formulate and amend laws other than those required to be enacted by the NPC and to supplement and amend any parts of laws enacted by the NPC during the adjournment of the NPC, provided such supplements and amendments are not in conflict with the basic principles of such laws. The NPC is empowered to authorize the SCNPC to formulate relevant laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws. The people’s congresses of provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people’s congresses of cities divided into districts and their standing committees may formulate local regulations on matters such as urban and rural construction and management, ecological civilization construction, historical and cultural protection and grassroots governance based on the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of the Constitution, laws, administrative regulations and local

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regulations of such provinces or autonomous regions. Where laws have other stipulations on matters of local regulations formulated by cities divided into districts, such stipulations shall prevail. The local regulations of cities divided into districts shall be submitted to the standing committees of the people's congresses of provinces and autonomous regions for approval before implementation. The standing committees of the people's congresses of provinces or autonomous regions shall examine the legality of local regulations submitted for approval, and such approval should be granted within four months if they are deemed to be not in conflict with the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. People's congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in the light of the political, economic and cultural characteristics of the nationality (nationalities) in the areas concerned. The ministries, commissions, PBOC, NAO of the State Council and institutions with administrative functions directly under the State Council and institutions required by laws may formulate rules and regulations within the jurisdiction of their respective departments based on the laws and the administrative regulations, decisions and rulings of the State Council.

The Constitution has supreme legal authority and no laws, administrative regulations, local regulations, autonomous regulations or separate regulations or rules may contravene the Constitution. The authority of laws is greater than that of administrative regulations, local regulations and rules. The authority of administrative regulations is greater than that of local regulations and rules. The authority of the rules enacted by the people's governments of the provinces and autonomous regions is greater than that of the rules enacted by the people's governments of the cities divided into districts within their respective administrative regions.

The NPC has the power to alter or annul any inappropriate laws enacted by the SCNPC, and to annul any autonomous regulations and separate regulations which have been approved by the SCNPC but which contravene the Constitution and the Legislation Law; the SCNPC has the power to annul administrative regulations that contravene the Constitution and laws, to annul local regulations that contravene the Constitution, laws and administrative regulations, and to annul autonomous regulations and separate regulations which have been approved by the standing committees of the people's congresses of the relevant provinces, autonomous regions or municipalities directly under the Central Government, but which contravene the Constitution and the Legislation Law; The State Council has the power to alter or annul any inappropriate ministerial rules and rules of local governments; The people's congresses of provinces, autonomous regions and municipalities directly under the Central Government have the power to alter or annul any inappropriate local regulations enacted or approved by their respective standing committees; The standing committees of the local people's congresses have the power to annul inappropriate rules enacted by the people's governments at the corresponding level; The people's governments of provinces and autonomous regions have the power to alter or annul any inappropriate rules enacted by the people's governments at a lower level.

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According to the Constitution and the Legislation Law, the power to interpret laws is vested in the SCNPC. According to the Decision of the SCNPC Regarding the Strengthening of Interpretation of Laws (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed by the SCNPC and effective on June 10, 1981, the Supreme People’s Court shall give interpretation on questions involving the specific application of laws and decrees in court trials. The Supreme People’s Procuratorate shall interpret all issues involving the specific application of laws and decrees in the procuratorial work. Interpretation of questions involving the specific application of laws and decrees in areas unrelated to judicial and procuratorial work shall be provided by the State Council and competent authorities. Where the scope of local regulations needs to be further defined or additional stipulations need to be made, the standing committees of the people’s congresses of provinces, autonomous regions and municipalities directly under the Central Government which have enacted these regulations shall provide the interpretations or make the stipulations. Interpretation of questions involving the specific application of local regulations shall be provided by the competent departments of the people’s governments of provinces, autonomous regions and municipalities.

PRC JUDICIAL SYSTEM

According to the Constitution and the Law of the PRC of Organization of the People’s Courts (《中華人民共和國人民法院組織法》) amended by the SCNPC on October 26, 2018 and becoming effective on January 1, 2019, the PRC People’s Court is made up of the Supreme People’s Court, the local people’s courts, and other special people’s courts. The local people’s courts are divided into three levels, namely the basic people’s courts, the intermediate people’s courts and the higher people’s courts. The basic people’s courts may set up certain people’s tribunals based on the status of the region, population and cases. The Supreme People’s Court shall be the highest judicial organ of the state. The Supreme People’s Court shall supervise the administration of justice by the local people’s courts at all levels and by the special people’s courts. The people’s courts at a higher level shall supervise the judicial work of the people’s courts at lower levels.

According to The Constitution and d the Law of Organization of the People’s Procuratorate of the PRC “《中華人民共和國人民檢察院組織法》” revised by SCNPC on October 26, 2018 and taking effect on January 1, 2019, the People’s Procuratorate is the law supervision organ of the state. The Supreme People’s Procuratorate shall be the highest procuratorial organ. The Supreme People’s Procuratorate shall direct the work of the local people’s procuratorates at all levels and of the special people’s procuratorates; the people’s procuratorates at higher levels shall direct the work of those at lower levels.

The people’s courts employ a two-tier appellate system, i.e., judgments or rulings of the second instance at the people’s courts are final. A party may appeal against the judgment or ruling of the first instance of a local people’s courts. The people’s procuratorate may present a protest to the people’s courts at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people’s procuratorate within the stipulated period, the judgments or rulings of the people’s

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courts are final. Judgments or rulings of the second instance of the intermediate people’s courts, the higher people’s courts and the Supreme People’s Court and those of the first instance of the Supreme People’s Court are final. However, if the Supreme People’s Court or the people’s courts at the next higher level finds any definite errors in a legally effective final judgment or ruling of the people’s court at a lower level, or if the chief judge of a people’s court at any level finds any definite errors in a legally effective final judgment or ruling of such court, the case can be retried according to judicial supervision procedures.

The PRC Civil Procedure Law (《中華人民共和國民事訴訟法》) (the “PRC Civil Procedure Law (《中國民事訴訟法》)”) adopted by the SCNPC on September 1, 2023 and became effective on January 1, 2024 sets forth the requirements for instituting a civil action, the jurisdiction of the people’s courts, the procedures to be followed for conducting a civil action and the procedures for enforcement of a civil judgment or order. All parties to a civil action conducted within the PRC must comply with the PRC Civil Procedure Law. Civil cases are generally heard by the courts where the defendants are located. The court of jurisdiction in a civil action may be chosen by express agreement between the parties, provided that the court is located at a place that has direct connection with the dispute, such as the plaintiff’s or the defendant’s place of domicile, the place where the contract is performed or signed or the object of the action is located. However, the choice of the court cannot be in conflict with the regulations of different jurisdictions and exclusive jurisdictions in any case.

A foreign individual, a person without nationality, a foreign-invested enterprise or a foreign organization must have the same litigation rights and obligations as a PRC citizen, legal person or other organizations when initiating or defending any proceedings at a people’s court. If a foreign court limits the litigation rights of PRC citizens and enterprises, the PRC court may apply the same limitations to the citizens and enterprises of such foreign country. A foreign individual, a person without nationality, a foreign-invested enterprise or a foreign organization must engage a PRC lawyer if such person needs to engage a lawyer in initiating or defending any proceedings at a people’s court. Under an international treaty or the principle of reciprocity signed or acceded to by the PRC, the people’s court and foreign courts may require each other to act on their behalf to serve documents, conduct investigations, collect evidence and take other actions on behalf of each other. If the request by a foreign court would result in the violation of the PRC’s sovereignty, security or public interest, the people’s court shall decline the request.

All parties must comply with legally effective civil judgments and rulings. If any party to a civil action refuses to comply with a judgment or order made by a people’s court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people’s court for enforcement within two years. Suspension or disruption of the time limit for applying for such enforcement shall comply with the provisions of the applicable law concerning the suspension or disruption of the time-barring of actions.

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When a party applies to a people’s court for enforcing an effective judgment or ruling by a people’s court against a party who is not located within the territory of the PRC or whose property is not within the PRC, the party may apply to a foreign court with proper jurisdiction for recognition and enforcement of the judgment or ruling. A foreign judgment or ruling may also be recognized and enforced by the people’s court according to the PRC enforcement procedures if the PRC has entered into, or acceded to, an international treaty with the relevant foreign country, which provides for such recognition and enforcement, or if the judgment or ruling satisfies the court’s examination according to the principle of reciprocity, unless the people’s court finds that the recognition or enforcement of such judgment or ruling will result in a violation of the basic legal principles of the PRC, its sovereignty or security, or for reasons of social and public interests.

The PRC Company Law, Trial Measures for Administration and Guidelines for the Articles of Association

A joint stock limited company incorporated in the PRC seeking a list on The Stock Exchange of Hong Kong Limited (the “Stock Exchange”) is mainly subject to the following laws and regulations of the PRC:

The PRC Company Law (《中華人民共和國公司法》) (hereinafter referred to as the “Company Law (《公司法》)”) was adopted by the Fifth Standing Committee Meeting of the Eighth NPC on December, 29 1993 and came into effect on July 1, 1994, and was amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018 with last amendment made on December 29, 2023, and will be effective on July 1, 2024.

The Trial Measures for Administration promulgated by the CSRC on February 17, 2023 and effective on March 31, 2023, are applicable to the overseas securities offering and listing by domestic enterprises.

The Guidelines for the Articles of Association of Listed Companies (“Guidelines for the Articles of Association”) issued by the CSRC on December 16, 1997, which was last amended on December 15, 2023 and became effective on the same date, provides guidance on the articles of association. Accordingly, the contents of the Guidelines are set out in the Company’s Articles of Association, and the summary of which is set out in the section headed “Appendix V – Summary of the Articles of Association” of this document.

Set out below is a summary of the major provisions of the Company Law, Trial Measures for Administration and Guidelines for the Articles of Association which are applicable to the Company.

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General Provisions

“A joint stock limited company” means is a corporate legal person incorporated under the Company Law, whose registered capital is divided into shares of equal par value. The liability of its shareholders is limited to the extent of the shares held by them and the liability of a company is limited to the full value of all the property owned by it.

A company must conduct its business in accordance with laws as well as public and commercial ethics. A company may invest in other limited liability companies. The liabilities of the company to such invested companies are limited to the amount invested. Unless otherwise provided by laws, a company cannot be the capital contributor who has the joint liabilities associated with the debts of the invested enterprises.

Incorporation

A joint stock limited company may be incorporated by promotion or subscription. A joint stock limited company may be incorporated by a minimum of two but not more than 200 promoters, and at least half of the promoters must have residence within the PRC.

The promoters shall convene an inaugural meeting of the company within 30 days after the share capital has been paid-up, and shall notified all subscribers the date of the meeting or make an announcement in this regard 15 days before the meeting. The inaugural meeting may be held only the presence of promoters and subscribers holding more than 50% of the total number of shares. Powers to be exercised at the inaugural meeting include but not limited to the adoption of articles of association and the election of members of the board of directors and the supervisory committee of a company. The aforesaid matters shall be resolved by more than 50% of the votes to be casted by subscribers presented at the meeting.

Within 30 days after the conclusion of the inaugural meeting, the board of directors shall apply to the registration authority for registration of the incorporation of the joint stock limited company. A company is formally established and has the status of a legal person after the business license has been issued by the relevant registration authority. A joint stock limited company established by the subscription method shall obtain the approval for listing from the securities regulatory authority of the State Council and submit the approval to the company registration authority.

A joint stock limited company’s promoters shall be liable for: (1) the payment of debts and expenses incurred in the incorporation process jointly and severally if a company cannot be incorporated; (2) the refund of subscription monies paid by the subscribers, together with interest, at bank rates of deposit for the same period jointly and severally if a company cannot be incorporated; and (3) the compensation of any damages suffered by a company as a result of the default of the promoters in the course of its establishment.

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Registered Capital

Under the Company Law, shareholders may make capital contributions in cash, or with non-monetary property that may be valued in money and legally transferred, such as contribution in kind or with an intellectual property rights or land use rights.

The Trial Measures for Administration stipulates that fund raising and dividend distributions of a domestic enterprise may be made in foreign currencies or RMB. According to the Trial Measures for Administration, shareholders holding domestic unlisted shares of a domestic enterprise directly listed overseas and are applying for the conversion of the domestic unlisted shares held by them into overseas listed shares and to be listed for trading at overseas stock exchanges, shall comply with the relevant requirements of the CSRC, and file with the CSRC through a domestic enterprise. The term "domestic unlisted shares" mentioned in the previous paragraph refers to shares that have been issued by domestic enterprises but are not listed or traded on any domestic stock exchange. Domestic unlisted shares should be registered and held centrally at domestic securities registration and clearing institutions. The registration and settlement arrangements for overseas listed shares shall be subject to the regulations of the overseas listing jurisdiction.

Under the Company Law, when a company issues shares in registered form, it shall maintain a register of shareholders, stating the following matters: (1) the name and domicile of a shareholder; (2) the number of shares held by each shareholder; (3) the serial number of the shares held by each shareholder; and (4) the date on which each shareholder acquired the shares.

Increase in Share Capital

Under the Company Law, in the case of a joint stock limited company issuing new shares, resolutions shall be passed at the shareholders' general meeting in respect of the class and number of new shares, the issue price of the new shares, the commencement and end dates for the issuance of new shares and the class and number of the new shares proposed to be issued to existing shareholders. When a company launches a list of new shares under the permission of the securities regulatory authority of the State Council, it must publish a document for the new shares and financial and accounting reports, and prepare the share subscription form. After payment in full for the new shares issued, a company must change its registration with a company registration authority and make an announcement accordingly.

Reduction of Share Capital

A company may reduce its registered capital in accordance with the following procedures prescribed by the Company Law:

- (1) To prepare a balance sheet and a property list.

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- (2) A company makes a resolution at shareholders' general meeting to reduce its registered capital.
- (3) A company shall inform its creditors within 10 days and publish an announcement in newspapers within 30 days after the approval of resolution of reducing registered capital.
- (4) The creditors shall have the right to require a company to repay its debts or provide corresponding guarantees within 30 days after receiving the notice or within 45 days after the announcement if the creditors have not received the notice.
- (5) When a company reduces its registered capital, it shall register the change with a company registration authority in accordance with the law.

Share Buy-Back

Under the Company Law, a company shall not purchase its own shares. Except for any following circumstances:

- (1) reducing the registered capital;
- (2) merging with other company that holds the shares of the Company;
- (3) using the shares for employee stocks plan or equity incentives;
- (4) with respect to shareholders voting against any resolution adopted at the shareholders' general meeting on the merger or division of our Company, the right to demand our Company to acquire the shares held by them;
- (5) using the shares for the conversion of convertible corporate bonds issued by the listed company;
- (6) as required for maintenance of the corporate value and shareholders' rights and interests of a listed company.

The purchase of shares of a company for reasons specified in the case of (1) to (2) above shall be subject to the resolution of the general meeting; the purchase of shares of a company for reasons specified in the case of (3), (5) and (6) above shall be subject to the resolution of the Board meeting attended by more than two-thirds of the directors in accordance with the provisions of the Articles of Association or the authorization from the general meeting.

Following the purchase of a company's shares by a company in accordance with the above provisions, such shares shall be canceled within 10 days from the date of buy-back in the case of item (1) above; such shares shall be transferred or canceled within six months in the case of items (2) and (4) above; the total numbers of share of our Company held by a company shall not exceed 10% of the total issued shares of a company, and shall be transferred or canceled within three years in the case of items (3), (5) and (6) above.

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Transfer of Shares

Shares held by a shareholder may be transferred according to the law. Under the Company Law, a shareholder should effect a transfer of his shares on securities established exchange according to the law or by any other means as required by the State Council. Registered shares may be transferred by endorsement of shareholders or by other means stipulated by laws or administrative regulations. After the transfer, a company shall record the name and address of the transferee in the register of shareholders. No changes of registration in the share register provided in the foregoing requirement shall be effected during a period of 20 days prior to the convening of shareholder's general meeting or 5 days prior to the record date for a company's distribution of dividends. However, if any law provides otherwise for the registration of changes in the register of members of a listed company, such provisions shall prevail. The transfer of bearer share certificates shall become effective upon delivery of such share certificates to the transferee by the shareholder.

Under the Company Law, shares in the Company held by promoters shall not be transferred within one year after the date of establishment of a company. Shares issued by a company prior to the listed of shares shall not be transferred within one year from the date on which the shares of accompany are listing on a securities exchange. Directors, supervisors and senior management of a company shall declare to a company their shareholdings in a company and any changes of such shareholdings, and the shares transferred each year during their term of office shall not exceed 25% of the total shares they hold in a company. Shares of a company held by its directors, supervisors and senior management shall not be transferred within one year from the date of a company's listed on a securities exchange, nor within six months after their resignation from their positions with a company.

Shareholders

Under the Company Law and the Guidelines for the Articles of Association, the rights of a shareholder of ordinary shares of a company include:

- (1) to receive dividends and other forms of distributions in proportion to their shareholdings;
- (2) to request, convene, preside over, attend or appoint a proxy to participate in the shareholders' general meeting in accordance with the law, and exercise the corresponding voting rights;
- (3) to supervise and manage a company's business, and to present proposals or to raise inquiries;
- (4) to transfer, grant or pledge shares held by them in accordance with laws, administrative regulations and the provisions of the Articles of Association;
- (5) to inspect the Articles of Association, register of members, stubs of corporate bonds, minutes of general meetings, resolutions of the Board, resolutions of the supervisory committee, financial and accounting reports;

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- (6) in the event of the winding-up or liquidation of a company, to participate in the distribution of remaining property of a company in proportion to the number of shares held;
- (7) to require the company to purchase its shares in the event that a shareholder disagrees with the resolution on merger or division of the company approved at a general meeting;
- (8) other rights as stipulated by laws, administrative regulations, departmental rules and the Articles of Association.

The obligations of a shareholder of ordinary shares of a company include:

- (1) to comply with the Articles of Association;
- (2) to pay subscription money according to the number of shares subscribed and the method of subscription;
- (3) not to abuse their shareholders' rights to damage the interests of a company or other shareholders; not to abuse the independent legal person status of a company and the limited liability of shareholders to damage the interests of the creditors of a company;
- (4) other obligations conferred by laws, administrative regulations and the Articles of Association.

Shareholder's General Meetings

Under the Company Law, the shareholders' general meeting of a joint stock limited company is made up of all shareholders. The shareholders' general meeting is the organ of authority of a company, which exercises the following functions and powers:

- (1) to decide on a company's business policies and investment plans;
- (2) to elect and replace directors and supervisors who are not representatives of the employees and to decide on matters relating to the remuneration of directors and supervisors;
- (3) to examine and approve reports of the board of directors;
- (4) to examine and approve reports of the supervisory committee or supervisors;
- (5) to examine and approve a company's annual financial budget and final accounts;
- (6) to examine and approve a company's profit distribution plans and loss recovery plans;

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- (7) to resolve on the increase or reduction of a company's registered capital;
- (8) to resolve on the issuance of corporate bonds;
- (9) to resolve on the merger, division, dissolution, liquidation or change of corporate form of a company;
- (10) to amend the a company's Articles of Association;
- (11) other functions and powers specified in provision of the Articles of Association.

Under the Company Law, annual shareholders' general meetings are required to be held once every year. An extraordinary shareholders' general meeting is required to be held within two months after the occurrence of any of the following circumstances:

- (1) the number of directors is less than the number stipulated in the Company Law or less than two-thirds of the number specified in the Articles of Association;
- (2) when the unrecovered losses of a company amount to one-third of the total paid-up share capital;
- (3) shareholders individually or jointly holding 10% or more of the company's shares request;
- (4) when deemed necessary by the Board;
- (5) the Supervisory Committee proposes to convene the meeting;
- (6) other circumstances as stipulated in the Articles of Association.

Shareholders' general meetings shall be convened by the board of directors, and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or not performing his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or not performing his duties, a director nominated by more than half of directors shall preside over the meeting.

Where the board of directors is incapable of performing or is not performing its duties to convene the general meeting, the supervisory board shall convene and preside over shareholders' general meeting in a timely manner. If the supervisory board fails to convene and preside over shareholders' general meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may unilaterally convene and preside over shareholders' general meeting.

Notice of general meeting shall state the time and venue of and matters to be considered at the meeting and shall be given to all shareholders 20 days before the meeting. A notice of extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting.

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Under the Company Law, a shareholder may entrust a proxy to attend a shareholders' general meeting. The proxy shall present a written power of attorney issued by the shareholder to a company and shall exercise his voting rights within the scope of authorization. There is no specific provision in the Company Law regarding the number of shareholders constituting a quorum in a shareholders' general meeting.

Under the Company Law, shareholders present at a shareholders' general meeting have one vote for each share they hold, save that shares held by a company are not entitled to any voting rights.

The cumulative voting system may be adopted for the election of directors and supervisors at the shareholders' general meeting in accordance with the provisions of the Articles of Association or the resolutions of the shareholders' general meeting. Under the accumulative voting system, each share shall have the same number of voting rights as the number of directors or supervisors to be elected at the shareholders' general meeting, and shareholders may consolidate their voting rights when casting a vote.

Under the Company Law, the passing of any resolution requires affirmative votes of shareholders representing more than half of the voting rights represented by the shareholders who attend the shareholders' general meeting. Matters relating to merger, division or dissolution of a company, increase or reduction of registered capital, change of corporate form or amendments to the articles of association must be approved by more than two-thirds of the voting rights held by the shareholders present at the meeting.

Directors

Under the Company Law, a joint stock limited company shall have a board of directors, which shall consist of five to nineteen members. The term of office of a director shall be stipulated in the Articles of Association, but each term of office shall not exceed three years. Directors may serve consecutive terms if re-elected.

Meetings of the board of directors shall be convened at least twice a year. All directors and supervisors shall be noticed 10 days before the meeting for every meeting. The Board exercises the following functions and powers:

- (1) to convene shareholder's general meetings and report its work to the shareholder's general meetings;
- (2) to implement the resolutions of the shareholder's general meeting;
- (3) to decide on a company's business plans and investment plans;
- (4) to formulate a company's annual financial budget and final accounts;
- (5) to formulate a company's profit distribution plan and loss recovery plan;

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- (6) to formulate proposals for the increase or reduction of a company's registered capital and the issue of corporate bonds;
- (7) to formulate plans for cake, division, dissolution or change of corporate form of a company;
- (8) to decide on the internal management structure of a company;
- (9) to decide on the appointment or dismissal of the manager of a company and their remuneration;
- (10) to decide on the appointment or dismissal of the deputy manager and financial officer of a company based on the nomination of the manager and as well as remuneration;
- (11) to formulate a company's basic management system;
- (12) other functions and powers specified in the Articles of Association.

Under the Company Law, a person may not serve as a director of a company if he is:

- (1) a person without capacity or with restricted capacity;
- (2) a person who has been sentenced to criminal punishment due to corruption, bribery, infringement of property, misappropriation of property or destruction of the socialist market economic order, where less than five years have elapsed since the date of completion of the sentence; or a person who has been deprived of his political rights due to a crime, where less than five years have elapsed since the date of completion of the sentence;
- (3) a person who was a director, factory manager or manager of a company or enterprise which has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the insolvency and liquidation of such company or enterprise;
- (4) persons who were legal representatives of a company or enterprise which had its business license revoked due to violation of the law and had been closed down by order, and who were personally liable, where less than three years have elapsed since the date of the revocation of the business license of the company or enterprise; and
- (5) persons who have a relatively large amount of debts due and outstanding.

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The board of directors shall have one chairman, who shall be elected by more than half of all the directors. The chairman shall exercise the following functions and powers (including but not limited to):

- (1) to preside over shareholders' general meetings and convene and preside over board meetings;
- (2) to cause and check the implementation of the resolutions of the Board;
- (3) to exercise other powers conferred by the Board.

Supervisors

Under the Company Law, a joint stock limited company shall have a supervisory committee composed of not less than three members. The supervisory committee shall comprise shareholder representatives and an appropriate proportion of the company's staff representatives, of which the proportion of staff representatives shall not be less than one-third and the specific proportion shall be stipulated in the Articles of Association. Employee representatives of the supervisory committee shall be democratically elected by the company's employees at the employee representative assembly, employee general meeting or otherwise. Directors or senior management may not act concurrently as supervisors.

The Supervisory Committee exercises the following powers:

- (1) to examine the company's financial affairs;
- (2) to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, administrative regulations, the Articles of Association or resolutions of shareholders' general meetings;
- (3) to demand rectification by a director or senior management when the acts of such persons are harmful to the company's interest;
- (4) to propose the convening of extraordinary general meetings, and to convene and preside over shareholders' general meetings when the Board fails to perform the duty of convening and presiding over shareholders' general meetings under the Company Law;
- (5) to submit proposals to the shareholders' general meeting;
- (6) to initiate legal proceedings against directors and senior management in accordance with the Company Law;

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- (7) other functions and powers specified in the Articles of Association.

Managers and Senior Management

Under the Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. The manager is accountable to the board of directors and may exercise the following powers:

- (1) to be in charge of the production, operation and management of the company and to organize the implementation of the resolutions of the board of directors;
- (2) to organize the implementation of the company's annual business plans and investment plans;
- (3) to formulate plans for the establishment of the company's internal management structure;
- (4) to draft the company's basic management system;
- (5) to formulate the basic rules and regulations of the company;
- (6) to propose the appointment or dismissal of the company's deputy manager and financial controller;
- (7) to appoint or dismiss management personnel other than those required to be appointed or dismissed by the board of directors; and
- (8) to exercise other powers conferred by the Articles of Association and the Board.

According to the Company Law, senior management shall refer to the manager, deputy manager(s), financial controller, secretary of the board of directors and other personnel as stipulated in the Articles of Association of the company.

Finance and Accounting

Under the Company Law, a company shall establish its financial and accounting systems according to laws, administrative regulations and the regulations of the financial department of the State Council. At the end of each fiscal year, the Company shall prepare a financial and accounting reports which shall be audited by an accounting firm in accordance with the law. The financial and accounting reports shall be prepared in accordance with the laws, administrative regulations and the regulations of the financial department of the State Council.

A joint stock limited company shall make its financial and accounting reports available at the company for inspection by the shareholders 20 days before the convening of an annual general meeting of shareholders. A joint stock limited company issuing its shares in public must publish its financial and accounting reports.

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When distributing each year's after-tax profits, the company shall set aside 10% of its profits into its statutory reserve fund. The company can no longer withdraw statutory reserve fund if it has accumulated to more than 50% of the registered capital. If the statutory reserve fund of the company is insufficient to make up for the losses of the previous years, the current year profits shall be used to make up for the losses before making allocations to the statutory reserve in accordance with the preceding paragraph. After the company has made an allocation to the statutory reserve fund from its after-tax profit, it may also make an allocation to the discretionary reserve fund from its after-tax profit upon a resolution of the general meeting or the shareholders' general meeting.

A joint stock limited company may distribute profits in proportion to the number of shares held by its shareholders, except for profit distributions that are not in proportion to the number of shares held in accordance with the provisions of the Articles of Association of the joint stock limited company.

The premium over the nominal value of the shares of a joint stock limited company from the issue of shares and other incomes required by the financial department of the State Council to be treated as the capital reserve fund shall be accounted for as the capital reserve fund of the company.

The reserve fund of the company shall be used to make up losses of the company, expand the production and operation of the company or increase the capital of the company. However, the capital reserve shall not be used to make up the company's losses. When the statutory reserve fund is converted into capital, the balance of the statutory reserve shall not be less than 25% of the registered capital before such conversion.

The company shall not keep accounts other than those provided by law.

Appointment and Dismissal of Accounting Firms

Pursuant to the Company Law, the engagement or dismissal of an accounting firm responsible for the company's auditing shall be determined by a shareholders' general meeting or the board of directors in accordance with the articles of association. The accounting firm should be allowed to make representations when the general meeting or the board of directors conduct a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal or withholding or falsification of information.

Profit Distribution

Under the Company Law, a company shall not distribute profits before losses are covered and the statutory reserve fund is drawn.

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Dissolution and Liquidation

According to the Company Law, a company shall be dissolved for the following reasons:

- (1) the term of business stipulated in the Articles of Association has expired or other events of dissolution specified in the Articles of Association have occurred;
- (2) the general meeting or the shareholders' general meeting resolves to dissolve the company;
- (3) dissolution is necessary due to a merger or division of the company;
- (4) the business license is revoked, or the business license is ordered to be closed or revoked in accordance with laws;
- (5) where the company encounters serious difficulties in its operation and management and its continuance shall cause a significant loss in the interest of shareholders, and where this cannot be resolved through other means, shareholders who hold more than 10% of the total shareholders' voting rights of the company may present a petition to a people's court for the dissolution of the company with the support of the judgment.

Where the company is dissolved in accordance with sub-paragraph (1) above, it may carry on its existence by amending its articles of association, which must be approved by more than two-thirds of the voting rights held by the shareholders present at the shareholders' general meeting. Where the Company is dissolved pursuant to sub-paragraphs (1), (2), (4) or (5) above, a liquidation committee shall be established and the liquidation shall commence within 15 days after the occurrence of an event of dissolution. The liquidation committee of a joint stock limited company shall be composed of directors or the personnel determined by a shareholders' general meeting. If a liquidation committee is not established within the stipulated period to conduct liquidation, the creditors may apply to the people's court to appoint relevant personnel to form a liquidation committee to conduct liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The liquidation committee shall exercise the following functions and powers during the liquidation period:

- (1) to liquidate the company's property and respectively prepare balance sheet and list of property;
- (2) to notify creditors by notice or public announcement;
- (3) to deal with the outstanding business of the company involved in the liquidation;

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- (4) to pay all outstanding taxes and taxes arising in the course of liquidation;
- (5) to liquidate claims and debts;
- (6) to deal with the remaining property of the company after paying off debts;
- (7) to participate in civil litigations on behalf of the company.

The remaining property of the company after the payment of liquidation expenses, employees' wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to their shareholdings.

During the liquidation period, the company shall continue to exist but shall not carry out any business activities unrelated to the liquidation. The company's assets shall not be distributed to the shareholders before the liquidation in accordance with the preceding paragraph.

If the liquidation committee, having thoroughly examined the company's assets and having prepared a balance sheet and an inventory of assets, discovers that the company's assets are insufficient to pay its debts in full, it shall apply to the people's court for a declaration of insolvency. After the people's court has declared the company bankrupt, the liquidation committee shall hand over the affairs of the liquidation to the people's court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report to be submitted to the shareholders' general meeting or the people's court for confirmation, and submit to the company registration authority to apply for cancelation of the company's registration and to announce the termination of the company.

Members of the liquidation committee are required to discharge their duties honestly and in compliance with laws. Members of the liquidation committee shall be prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's properties. A member of the liquidation committee is liable to indemnify the company and its creditors in respect of any loss arising from his willful or material default.

Overseas listing

According to the Trial Measures for Administration, a PRC domestic company seeking an overseas listing shall submit an application to the CSRC in accordance with the administrative filing procedures as required by the Trial Measures for Administration.

Securities Laws and Regulations

In October 1992, the State Council established the Securities Committee and the CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities-related institutions in the PRC and administering the CSRC. The CSRC is the regulatory arm of the Securities Committee and is

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responsible for the drafting of regulatory provisions of securities markets, supervising securities companies, regulating listing of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking research and analysis. On March 29, 1998, the State Council consolidated the above two departments and reformed the CSRC.

The Provisional Regulations Concerning the Issue and Trading of Shares (《股票發行與交易管理暫行條例》) promulgated by the State Council and effective on April 22, 1993 provide the application and approval procedures for listing of shares, trading in shares, the acquisition of listed companies, the deposit, settlement and transfer of listed shares, the disclosure of information with respect to a listed company, investigation and penalties and dispute arbitration.

The Regulations of the State Council Concerning the Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內上市外資股的規定》), which were promulgated by the State Council and came into effect on December 25, 1995, mainly provide for the issue, subscription, trading and payment of dividends of domestic listed foreign shares and disclosure of information of joint stock limited companies with domestic listed foreign shares.

The Securities Law of the People’s Republic of China (《中華人民共和國證券法》) (hereinafter referred to as the “PRC Securities Law”), which was amended by the Standing Committee of the NPC on December 28, 2019 and came into effect on March 1, 2020, provides a series of provisions regulating, among other things, the issue and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council’s securities regulatory authorities in the PRC, and comprehensively regulates activities in the PRC securities market. The PRC Securities Law provides that a domestic enterprise must comply with the relevant provisions of the State Council in issuing securities directly or indirectly outside the PRC or listing and trading its securities outside the PRC. Currently, the issue and trading of foreign issued shares are mainly governed by the rules and regulations promulgated by the State Council and the CSRC.

The Guidelines for the Application for “Full Circulation” of Domestic Unlisted Shares of H Share Companies (《H股公司境內未上市股份申請“全流通”業務指引》) issued by the CSRC on November 14, 2019 and revised on August 10, 2023 regulates the list and circulation (hereinafter referred to as “Full Circulation”) of listed domestic shares of domestic stock companies (hereinafter referred to as “H share companies”) listed on the Hong Kong Stock Exchange (including unlisted domestic shares held by domestic shareholders prior to overseas listing, listed domestic shares issued in China upon overseas listing and listed shares held by overseas shareholders). Shareholders of domestic unlisted shares have the flexibility to jointly decide the amount and proportion of shares that will be included in the circulation application. This decision should be reached through mutual consultation, ensuring compliance with relevant laws, regulations and policies governing state-owned asset administration, foreign investment and industry regulation. Meanwhile, H share companies corresponding to these shares may be authorized to file for “full circulation” with the CSRC. An unlisted domestic joint stock company may file with the CSRC for “full circulation” at the time of its initial public offering and listing overseas.

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Arbitration and Enforcement of Arbitral Awards

Under the Arbitration Law of the People’s Republic of China (《中華人民共和國仲裁法》) (hereinafter referred to as “Arbitration Law”) amended by the Standing Committee of the NPC on September 1, 2017 and effective on January 1, 2018, the Arbitration Law is applicable to economic disputes involving foreign parties, and all parties have entered into a written agreement to refer the matter to an arbitration committee constituted in accordance with the Arbitration Law. An arbitration committee may, before the promulgation by the PRC Arbitration Association of arbitration regulations, formulate interim arbitration rules in accordance with relevant regulations under the Arbitration Law and the PRC Civil Procedure Law (《中國民事訴訟法》). Where both parties have agreed to settle disputes by means of arbitration, the people’s court will refuse to take legal action brought by a party in the people’s court.

Under the Arbitration Law, an arbitral award is final and binding on the parties. If a party fails to comply with an award, the other party to the award may apply to the people’s court for enforcement according to the PRC Civil Procedure Law. A people’s court may refuse to enforce an arbitral award made by an arbitration commission if there is any procedural irregularity (including irregularity in the composition of the arbitration committee or the making of an award on matters beyond the scope of the arbitration agreement or the jurisdiction of the arbitration commission). A party seeking to enforce an arbitral award of foreign arbitration commission against a party who or whose property is not within the PRC shall apply to a foreign court with jurisdiction over the case for recognition and enforcement. Similarly, an arbitral award made by a foreign arbitration body may be recognized and enforced by the people’s court in accordance with the principles of reciprocity or any international treaty concluded or acceded to by the PRC.

According to the Arrangement of the Supreme People’s Court on Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (《最高人民法院關於內地與香港特別行政區相互執行仲裁裁決的安排》) promulgated by the Supreme People’s Court on January 24, 2000 and became effective on February 1, 2000, and the Supplementary Arrangement of the Supreme People’s Court on Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (《最高人民法院關於內地與香港特別行政區相互執行仲裁裁決的補充安排》) promulgated by the Supreme People’s Court and became effective on November 26, 2020, awards made by PRC arbitral authorities can be enforced in Hong Kong, and Hong Kong arbitration awards are also enforceable in the PRC.

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Summary of Material Differences between Hong Kong and the PRC Company Law

The Hong Kong law applicable to a company incorporated in Hong Kong is based on the Hong Kong Companies Ordinance and is supplemented by common law and the rules of equity that apply to Hong Kong. As a joint stock limited company established in the PRC that is seeking an list of shares on the Stock Exchange, we are subject to the Company Law and all other rules and regulations promulgated pursuant to the Company Law.

Set out below is a summary of certain material differences between Hong Kong Company Law applicable to a company incorporated in Hong Kong and the Company Law applicable to a joint stock limited company incorporated and existing under the Company Law. This summary is, however, not intended to be an exhaustive comparison.

Corporate Existence

Under the Hong Kong Companies Ordinance, a company with share capital must be incorporated by the Registrar of Companies in Hong Kong, which will grant a registration certificate to the company upon its incorporation, and the company will acquire an independent corporate existence. A company may be incorporated as a public company or a private company.

Under the Company Law, a joint stock limited company may be incorporated by promotion or public subscription. The minimum registered capital of a joint stock limited company is not required, unless otherwise provided by laws, administrative regulations and the decisions of the State Council, for the paid-up registered capital and the minimum registered capital of a joint stock limited company.

The Hong Kong Company Law does not prescribe any minimum registered capital requirements for a Hong Kong company.

Share Capital

Under Hong Kong law, the concept of the nominal value of a share capital in a Hong Kong company has been abolished, and the companies have greater flexibility to alter its share capital by: (1) increasing its share capital; (2) capitalizing its profits; (3) allotting and issuing bonus shares with or without increasing its share capital; (4) increasing or decreasing the number of shares; and (5) canceling its shares. Hence, the directors of a Hong Kong company may, with the prior approval of the shareholders, if required, cause the company to issue new shares. The Company Law does not provide for authorized share capital.

Under the PRC Securities Law, an application for listing shall comply with the listing rules of the stock exchange. Hong Kong law does not prescribe any minimum capital requirements for companies incorporated in Hong Kong.

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Under the Company Law, shareholders may provide capital contribution in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws and administrative regulations). For non-monetary assets to be used as capital contributions, appraisals and assets verification must be carried out to ensure no overvaluation or under-valuation of the assets. There is no such restriction on a Hong Kong company under Hong Kong law.

Restrictions on Shareholding and Transfer of Shares

Under PRC law, the Domestic Shares, which are denominated and subscribed for in Renminbi, can only be subscribed for and traded by PRC investors, designated qualified overseas institutional investors or qualified overseas strategic investors. Overseas listed shares, which are denominated in Renminbi and subscribed for in a foreign currency, may only be subscribed for, and traded by, investors from countries and regions outside the PRC or other qualified PRC institutional investors. If the H Shares are eligible securities under the Southbound Trading Link, they are also available for subscription and trading by domestic investors in the PRC pursuant to the rules and restrictions of Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect.

Under the Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in a joint stock limited company held by its directors, supervisors and senior management transferred each year during their term of office shall not exceed 25% of the total shares they held in the company, and the shares they held in the company cannot be transferred within one year from the listing of the shares, and also cannot be transferred within half a year after the said personnel has left office. There are no such restrictions on shareholdings and transfers of shares under Hong Kong law.

Financial Assistance for Acquisition of Shares

Although the Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of an acquisition of its own or its holding company's shares, the Guidelines for the Articles of Association contain certain restrictions on a company and its subsidiaries on providing such financial assistance similar to those under Hong Kong Company Law.

Notice of Shareholders' General Meeting

Under the Company Law, notice of a shareholders' general meeting must be given not less than 20 days before the meeting, while notice of an extraordinary general meeting must be given not less than 15 days before the meeting. If a company has bearer shares, a public announcement of a shareholders' general meeting must be made at least 30 days prior to the meeting.

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For a limited company incorporated in Hong Kong, the minimum period of notice of a shareholders' general meeting is 14 days. In addition, where a meeting involves consideration of a resolution requiring special notice, the company must also give its shareholders notice of the resolution 14 days before the meeting. The notice period for an annual general meeting is 21 days.

Quorum for Shareholders' General Meetings

The Company Law does not specify any quorum requirement for a shareholders' general meeting. Under Hong Kong law, the quorum for a shareholders' general meeting is two members unless the articles of association of the company otherwise provide. For a single member company, one member is a quorum.

Voting at Shareholders' General Meetings

Under the Company Law, the passing of any resolution requires more than half of the votes held by the shareholders present in person or by proxy. Amendments to the articles of association, change of corporate form, increase or decrease of registered capital and merger, division or dissolution must be approved by shareholders or proxies representing more than two-thirds of the voting rights being present in shareholders' general meeting.

Under Hong Kong law, (1) an ordinary resolution is passed by a simple majority of votes cast by members present in person or by proxy at a shareholders' general meeting and (2) a special resolution is passed by a majority of not less than three-fourths of votes cast by members present in person or by proxy at a shareholders' general meeting.

Variation of Class Rights

The Company Law has no special provision relating to variation of class rights. However, the Company Law states that the State Council can promulgate regulations relating to other kinds of shares.

Under the Hong Kong Companies Ordinance, no rights attached to any class of shares can be varied except (1) with the approval of a special resolution of the holders of the relevant class at a separate meeting; (2) with the consent in writing of the holders of at least three-fourths of the total voting rights of holders of shares in the class in question; (3) by agreement of all the members of a Hong Kong company or (4) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

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Directors, Senior Management and Supervisors

The Company Law, unlike Hong Kong Companies Ordinance, does not contain any requirements relating to the declaration of directors’ interests in material contracts, restrictions on directors’ authority in making major dispositions, restrictions on companies providing certain benefits to directors and guarantees in respect of directors’ liability and prohibitions against compensation for loss of office without shareholders’ approval.

Supervisory Committee

Under the Company Law, a joint stock limited company’s directors and senior management are subject to the supervision of a supervisory committee. There is no mandatory requirement for the establishment of a supervisory committee for a company incorporated in Hong Kong.

Derivative Action by Minority Shareholders

Under Hong Kong law, a shareholder may, with the leave of the court, bring a derivative action on behalf of a company against our directors for any misconduct.

Under the Company Law, if the directors and senior management of a joint stock limited company violate laws, administrative regulations or its articles of association, resulting in losses to the company, shareholders individually or jointly holding over 1% of the shares in the company for more than 180 consecutive days may request in writing the supervisory committee to initiate proceedings in the people’s court. If the supervisors violate the relevant provisions of the Company Law, the above shareholders may request in writing the board of directors to initiate litigation at the people’s court. Upon receipt of such written request from the shareholders, if the supervisory committee or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days upon receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company’s interests, have the right to initiate proceedings directly to the people’s court in their own name.

Protection of Minorities

Under Hong Kong law, a shareholder who complains that the affairs of a company incorporated in Hong Kong are conducted in a manner unfairly prejudicial to his interests may petition to court to either wind up the company or make an appropriate order regulating the affairs of the company. In addition, on the application of a specified number of members, the Financial Secretary of Hong Kong may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated in Hong Kong.

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The Company Law provides that any shareholders holding 10% or more of the voting rights of all issued shares of a company may request a People’s Court to dissolve the company to the extent that the operation or management of the company experiences any serious difficulties and the company continues to suffer serious losses and no other alternatives can resolve.

Financial Disclosure

Under the Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its shareholders’ general meeting. In addition, a joint stock limited company of which the listed Shares are offered must publish its financial report. The Hong Kong Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial report, auditors’ report and directors’ report, which are to be presented before the company in its annual general meeting, not less than 21 days before such meeting.

Under the Company Law, a company shall at the end of each accounting year prepare a financial report which shall be audited by the accounting firm in accordance with the laws.

Information on Directors and Shareholders

The Company Law gives shareholders the right to inspect the articles of association, minutes of the shareholders’ general meetings and financial and accounting reports. Under the articles of association, shareholders have the right to inspect and copy (at reasonable fee) certain information on shareholders and on directors similar to that available to shareholders of Hong Kong companies under the Hong Kong Companies Ordinance.

Receiving Agents

Under the Company Law and Hong Kong law, dividends once declared are debts payable to shareholders. Under Hong Kong law, the limitation period for an action to demand repayment of a debt is six years, whereas the PRC Civil Code (《中華人民共和國民法典》) provides that the limitation period for an action to be taken is three years.

Corporate Reorganization

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to the Hong Kong Companies Ordinance or a compromise or arrangement between the company and its creditors or between the company and its members, which requires the sanction of the court. In addition, subject to shareholders’ approval, a wholly owned subsidiary within the Group may also be horizontally or vertically consolidated under the Hong Kong Companies Ordinance.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Under the Company Law, the merger, demerger, dissolution or change to the forms of a joint stock limited company has to be approved by shareholders in shareholders’ general meeting.

Statutory Deductions

Under the Company Law, a company shall draw 10% of the profits as its statutory reserve fund before it distributes any profits after taxation. When the aggregate amount of the company’s statutory reserve fund reaches 50% of the company’s registered capital, the company may no longer make allocations from the statutory reserve fund. After a company has made an allocation to its statutory reserve fund from its after-tax profit, it may make an allocation to its discretionary reserve fund from its after-tax profit upon a resolution approved at the shareholders’ general meeting. There are no such requirements under Hong Kong law.

Dispute Arbitration

Under Hong Kong law, disputes between shareholders and a company or its directors, managers or other senior management may be resolved through the courts.

Remedies of Company

Under the Company Law, if a director, supervisor or senior management in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or senior management should be responsible to the company for such damages.

The Hong Kong Listing Rules require listing companies’ articles of association to provide for remedies of the company (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

Dividend

The company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder.

Under Hong Kong law, the limitation period for an action to recover a debt (including the recovery of dividends) is six years, whereas under PRC laws, the relevant limitation period is three years. The company shall not exercise its powers to forfeit any unclaimed dividend after the expiry of the applicable limitation period.

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL AND
REGULATORY PROVISIONS**

Fiduciary Duties

In Hong Kong, directors owe a fiduciary duty to the company, including a duty not to conflict with the company's interests. In addition, the Hong Kong Companies Ordinance has taken into account the statutory duty of care of directors.

Under the Company Law, directors, supervisors, managers and other senior management personnel of a company have the duty of loyalty and diligence to the company. Such persons shall abide by the articles of association of the company, perform their duties faithfully, safeguard the interests of the company, and shall not use their position and authority in the company for their personal gain.

Closure of Register of Members

The Hong Kong Companies Ordinance requires that the register of shareholders of a company must not generally be closed for the registration of transfers of shares for more than 30 days (extendable to 60 days in certain circumstances) in a year, whereas, as required by the Company Law, share transfers shall not be registered within 20 days before the date of a shareholders' general meeting or within five days before the base date set for the purpose of distribution of dividends.

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

SHARES

Issuance of shares

The shares of the Company shall take the form of share certificates.

The Company shall issue shares in an open, fair and just manner, and each share of the same class shall rank *pari passu* with each other.

Shares of the same class in the same issue shall be listed under the same conditions and at the same price; any entity or individual shall pay the same price for each share subscribed.

Overseas listed shares of the Company listed on the Hong Kong Stock Exchange are referred to as “H shares”. Shares issued by the Company but not listed on domestic and foreign stock exchanges are referred to as non-listed shares. Upon filing with a competent authority of the State Council, the non-listed shares of the Company may convert into overseas listed shares and list and trade on an overseas stock exchange, and such listing and trading shall comply with the supervision procedures, regulations and requirements of the overseas stock exchange. The conversion of non-listed shares into overseas listed shares for the listing and trading on an overseas stock exchange does not require the convening of a Shareholders’ General Meeting for voting.

Increase/Decrease and Repurchase of Shares

Capital Increase

The Company may, based on its operation and development needs and in accordance with laws, administrative regulations and respective resolutions of Shareholders’ General Meetings, increase its registered capital in the following ways:

- (1) public offer of shares;
- (2) non-public offer of shares;
- (3) issue of bonus shares to its existing shareholders;
- (4) conversion of capital reserve into share capital;
- (5) other means approved by laws and regulations, the CSRC and the Hong Kong Stock Exchange.

Capital Reduction

According to the Articles of Association, the Company may reduce its registered capital. The Company shall reduce its registered capital in accordance with the Company Law, the Hong Kong Listing Rules, other relevant regulations and the procedures stipulated in the Articles of Association.

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

When the Company intends to reduce its registered capital, it must prepare a balance sheet and an inventory of assets. The Company shall notify its creditors within 10 days and publish an announcement in newspapers within 30 days after the resolution approving the reduction has been made. The creditors shall have the right to require the Company to repay its debts within 30 days after receiving the notice, or provide corresponding repayment guarantees within 45 days after the announcement if the creditors have not received the notice.

The Company's registered capital after reduction shall not be less than the statutory minimum amount.

Share Repurchase

The Company may not purchase its shares, except under any of the following circumstances:

- (1) reduction of its registered capital;
- (2) merging with another company that holds shares in the Company;
- (3) using the shares for employee stock ownership plan or equity incentives;
- (4) purchasing shares held by shareholders (upon their request) who vote against any resolution proposed in any Shareholders' General Meeting on the merger or division of the Company;
- (5) using the shares for conversion of corporate bonds issued by the listed company that are convertible into shares;
- (6) it is necessary for the listed company to safeguard its corporate value and shareholders' interests;
- (7) other circumstances permitted by laws, administrative regulations, departmental rules, regulatory rules of the place where the Company's shares are listed, etc.

The Company may purchase its shares through public and centralized trading, or through other methods permitted by laws, administrative regulations and the CSRC, and the purchase shall comply with applicable laws, administrative regulations, departmental rules and securities regulatory rules of the place where the Company's shares are listed.

Where the Company purchase its shares due to the circumstances specified in (3), (5) and (6) above, the purchase shall comply with the Hong Kong Listing Rules and the requirements of the Hong Kong Stock Exchange and other securities regulatory rules of the place where the Company's shares are listed and carry out in a centralized trading manner.

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

Where the Company purchases its own shares due to the circumstances set out in items (1) and (2) above, it shall be subject to the resolution of the Shareholders’ General Meeting; where the Company acquires its own shares under the circumstances set out in items (3), (5) and (6) above, it shall be subject to the resolution of the Board meeting attended by more than two-thirds of the Directors. If the securities regulatory rules of the place where the Company’s shares are listed require otherwise, they shall prevail on the premise that they do not violate the Company Law, the Securities Law, the Trial Measures for Administration (《管理試行辦法》) and the Guidelines for the Articles of Association of Listed Companies(《上市公司章程指引》).

After the Company has bought back its own shares, such shares shall be cancelled within 10 days from the date of buy-back in the case of item (1), which is solely for the purpose reduction of its registered capital; such shares shall be transferred or cancelled within 6 months in the case of items (2) and (4); such shares shall not exceed 10% of the total issued shares of the Company in the case of items (3), (5) and (6), and shall be transferred or cancelled within 3 years.

Transfer of Shares

Shares of the Company held by the promoters shall not be transferred within one year from the date of establishment of the Company. The shares issued by the Company prior to the public offer of shares shall not be transferred within 1 year from the date of listing of the Company’s shares on the stock exchange.

Directors, Supervisors and Senior Management of the Company shall report to the Company their shareholdings in the Company and changes thereof and shall not transfer more than 25% of the total number of shares of the Company held by them each year during their term of office. The shares held by the Company shall not be transferred within 1 year from the date of listing of the Company’s shares. The aforementioned personnel shall not transfer the shares of the Company held by them within half a year after they leave the Company.

SHAREHOLDERS AND SHAREHOLDERS’ GENERAL MEETINGS

Share Register

The Company shall maintain a register of shareholders in accordance with the Companies Law, the Hong Kong Listing Rules and other relevant requirements and the Articles of Association. The register of shareholders shall be sufficient evidence of the shareholders’ shareholdings in the Company. Shareholders have the rights and obligations according to the class of shares they hold; shareholders holding the same class of shares shall enjoy the same rights and assume the same obligations.

When the Company intends to convene a Shareholders’ General Meeting, distribute dividends, enter into liquidation and engage in other activities that involve determination of shareholdings, the Board or the convener of Shareholders’ General Meeting shall determine the Record Date, and the shareholders included in the register of shareholders at the close of business on Record Date shall be the entitled shareholders.

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

Rights and Obligations of Shareholders

Shareholders of the Company shall enjoy the following rights:

- (1) to receive dividends and other distributions in proportion to the number of shares held;
- (2) to request convening, host and preside over, attend or appoint a proxy to attend Shareholders' General Meetings, speak at Shareholders' General Meetings and to exercise the corresponding voting rights in accordance with the laws;
- (3) to supervise the Company's operations, and to put forward proposals or raise inquiries;
- (4) the right to transfer, give or pledge shares held by them in accordance with laws administrative regulations and the Articles of Association;
- (5) to check the Articles of Association, register of shareholders, stubs of corporate bonds, minutes of Shareholders' General Meetings, resolutions of Board meetings, resolutions of meetings of the Supervisory Committee and financial and accounting reports;
- (6) in the event of the termination or liquidation of the Company, to participate in the distribution of remaining assets of the Company in accordance with the number of shares held;
- (7) to request the Company to purchase the shares held by shareholders who vote against any resolution proposed in any Shareholders' General Meeting on the merger or division of the Company;
- (8) other rights conferred by laws, administrative regulations, departmental rules or the Articles of Association.

Shareholders of the Company shall assume the following obligations:

- (1) to abide by laws, administrative regulations and the Articles of Association;
- (2) to pay subscription monies according to the number of shares subscribed and the method of subscription;
- (3) not to withdraw their shares unless required by laws and administrative regulations;

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

- (4) not to abuse their shareholders' rights to damage the interests of the Company or other shareholders; not to abuse the independent legal person status of the Company and the limited liability of shareholders to damage the interests of the creditors of the Company;
- (5) other obligations under laws, administrative regulations and the Articles of Association.

Where a shareholder of the Company abuses his/her shareholder's rights and causes losses to the Company or other shareholders, he/she shall be liable for compensation in accordance with the law; where a shareholder of the Company abuses the independent legal person status of the Company and the limited liability of shareholders to evade repayment of debts and seriously damage the interests of the creditors of the Company, he/she shall be jointly and severally liable for the debts of the Company.

Restrictions on Controlling Shareholders' Rights

The controlling shareholder and actual controller of the Company may not take advantage of their connected relationships to harm the interests of the Company, and they shall be held liable for damages if, as a result of violating a regulation, they cause the Company to sustain a loss.

The controlling shareholder and the actual controller of the Company bear a fiduciary duty toward the Company and public shareholders. The controlling shareholder shall exercise its rights as an investor in strict accordance with the laws. He or she may not use such means as profit distribution, asset restructuring, investment in a third party, appropriation of funds, loan security, etc. or use its controlling position to harm the lawful rights and interests of the Company and the public shareholders.

General Rules for Shareholders' General Meetings

The Shareholders' General Meeting shall be the organ of authority of the Company and shall exercise the following functions and powers in accordance with laws:

- (1) to election and replace directors and supervisors not held by employee representatives, and to determine the remuneration of directors and supervisors;
- (2) to consider and approve the report of the Board;
- (3) to consider and approve the report of the Board of Supervisory Committee;
- (4) to consider and approve the Company's annual financial budget plan and final accounts plan;

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

- (5) to consider and approve the Company's profit distribution plan and loss recovery plan;
- (6) to pass resolutions concerning the increase or reduction of the Company's registered capital;
- (7) to pass resolutions on the issuance of corporate bonds;
- (8) to pass resolutions on the merger, division, dissolution, liquidation or change in corporate form of the Company;
- (9) to amend these Articles of Association;
- (10) to pass resolutions on the engagement, dismissal or non-renewal of the engagement of accounting firms by the Company;
- (11) to consider and approve the guarantee matters subject to the approval of a Shareholders' General Meeting as stipulated in the Articles of Association;
- (12) to consider matters relating to the purchase or disposal of material assets by the Company within one year in an amount representing more than 30% of the Company's latest audited total assets;
- (13) to consider and approve the changes in the use of proceeds;
- (14) to review equity incentive plans and employee shareholding plans;
- (15) to consider other matters that shall be decided by Shareholders' General Meetings as provided in laws, administrative regulations, departmental rules, the listing rules of the place where the Company's shares are listed or the Articles of Association.

The Shareholders' General Meetings are divided into annual Shareholders' General Meetings and extraordinary Shareholders' General Meetings. The annual Shareholders' General Meeting shall be held once every year within 6 months after the end of the previous accounting year.

Under any of the following circumstances, the Company shall convene an Extraordinary Shareholders' General Meeting within 2 months from the date of occurrence:

- (1) the number of Directors is less than the number stipulated in the Company Law or less than 2/3 of the number specified in the Articles of Association;
- (2) when the unrecovered losses of the Company amount to 1/3 of the total amount of its paid-up share capital;

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

- (3) when request by the shareholders individually or jointly holding more than 10% of the Company's shares;
- (4) when deemed necessary by the Board;
- (5) as proposed by the Supervisory Committee;
- (6) other circumstances stipulated by laws, administrative regulations, departmental rules or the Articles of Association.

Convening of Shareholders' General Meetings

Shareholders' General Meetings shall be convened by the Board in accordance with laws.

The independent non-executive Directors have the right to propose to the Board to convene Extraordinary Shareholders' General Meetings. For the proposal of the independent non-executive Directors to convene an Extraordinary Shareholders' General Meeting, the Board shall, in accordance with the provisions of laws, administrative regulations and the Articles of Association, provide written feedback on whether or not to convene the Extraordinary Shareholders' General Meeting within 10 days after receiving the proposal. If the Board agrees to convene the Extraordinary Shareholders' General Meeting, a notice of convening the Shareholders' general meeting shall be issued within 5 days after the resolution of the Board is made. If the Board does not agree to convene the Shareholders' general meeting, it will explain the reasons and make an announcement.

The Supervisory Committee shall have the right to propose to the Board to convene an Extraordinary Shareholders' General Meeting, and shall propose to the Board in writing. The Board shall, in accordance with the laws, administrative regulations and the Articles of Association, provide written feedback on whether or not to convene the Extraordinary Shareholders' General Meeting within 10 days after receiving the proposal.

If the Board agrees to convene the Extraordinary Shareholders' General Meeting, a notice of convening the Extraordinary Shareholders' General Meeting shall be issued within 5 days after the resolution of the Board is made. Changes to the original proposals as set out in the notice must have the consent of the Supervisory Committee.

If the Board does not agree to convene the Extraordinary Shareholders' General Meeting, or fails to give feedback within 10 days after receipt of the proposal, it will be deemed that the Board is unable to perform or fails to perform its duty to convene a Shareholders' General Meeting, and the Supervisory Committee may convene and preside over the meeting on its own.

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

The shareholders individually or collectively holding more than 10% of the Company's shares have the right to propose to the Board to convene an Extraordinary Shareholders' General Meeting, and shall propose to the Board in writing. The Board shall, in accordance with the provisions of laws, administrative regulations, departmental rules and the Articles of Association, provide written feedback on whether or not to convene the Extraordinary Shareholders' General Meeting within 10 days after receiving the written request.

If Board agrees to convene the Extraordinary Shareholders' General Meeting, a notice of convening the Extraordinary Shareholders' General Meeting shall be issued within 5 days after the resolution of the Board is made. Changes to the original proposals as set out in the notice must have the consent of such shareholders. Where laws, administrative regulations and departmental rules provide otherwise, such provisions shall prevail.

If the Board does not agree to convene the Extraordinary Shareholders' General Meeting, or fails to give feedback within 10 days after receiving the request, such shareholders individually or collectively holding more than 10% of the shares of the Company shall have the right to make the same request to the Supervisory Committee in writing.

If the Supervisory Committee agrees to convene the Extraordinary Shareholders' General Meeting, it shall issue a notice of convening the Shareholders' General Meeting within 5 days upon receipt of the request. Changes to the original proposals as set out in the notice must have the consent of the such shareholders.

If the Supervisory Committee fails to issue a notice of the Shareholders' General Meeting within the prescribed time limit, it shall be deemed that the Supervisory Committee does not convene and preside over the Shareholders' General Meeting. After passing 90 consecutive days, such shareholders individually or collectively holding more than 10% of the shares of the Company may convene and preside over the meeting on their own.

Proposals at Shareholders' General Meetings

Any Shareholders' General Meeting or meeting of the Board, Supervisory Committee convened by the Company and shareholders who individually or collectively hold more than 3% of the Company's shares shall have the right to make proposals to the Company.

Shareholders who individually or collectively hold more than 3% of the shares of the Company may submit an interim proposal in writing to the convener 10 days before the holding of a Shareholders' General Meeting. The convener shall issue a supplemental notice of the Shareholders' General Meeting within 2 days after receiving the interim proposal in order to publicize it.

Except for the circumstances stipulated in the preceding paragraph and laws, administrative regulations and the listing rules of the place where the Company's shares are listed, the meeting convener shall not modify the proposals specified in the notice of a Shareholders' General Meeting or add new proposals after the notice has been issued.

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

Proposals not set out in the notice of a Shareholders' General Meeting or not complying with the Articles of Association shall not be voted on or resolved at any Shareholders' General Meeting.

Notice of Shareholders' General Meeting

The convener shall notify the shareholders by way of announcement at least 21 days prior to an annual Shareholders' General Meeting, and shall notify the shareholders by way of announcement at least 15 days prior to the date of an Extraordinary Shareholders' General Meeting. In both time frames the day on which the respective meeting is convened is excluded.

Convening of Shareholders' General Meetings

All the shareholders listed in the register of shareholders on the Record Date or their agents shall be entitled to attend Shareholders' General Meetings, and exercise their voting rights in accordance with relevant laws, regulations, the Hong Kong Listing Rules and the Articles of Association. Shareholders may attend Shareholders' General Meetings in person or appoint a proxy to attend and vote on his/her behalf.

An individual shareholder who attends a meeting in person shall produce his or her own identity card or other valid document or proof evidencing his or her identity and his or her share account card. If he or she appoints a proxy to attend the meeting on his or her behalf, such proxy shall produce his or her own valid proof of identity and the instrument of appointment from the shareholder.

Shareholders that are legal persons shall be represented at a meeting by their legal representative or a proxy appointed by their legal representative. If the legal representative attends the meeting, he or she shall produce his or her own identity card and valid proof of his or her legal representative status. If a proxy has been appointed to attend the meeting, such proxy shall produce his or her own identity card and documents proving that he/she is appointed by the shareholder who is a legal person (except that the shareholder is a recognised clearing house as defined in the relevant ordinances in force from time to time under the laws of Hong Kong or the securities regulatory rules of the place where the Company's shares are listed or its nominee).

Where the shareholder is a recognised clearing house, the recognised clearing house may authorise such person or persons as it thinks fit to act as its representative or representatives at any shareholders' general meeting or at any meeting of any class of shareholders or at any meeting of creditors; provided that, if more than one person is so authorised, the authorisation shall specify the number and class of shares in respect of which each such person is so authorized and shall be signed by an authorised officer of the recognised clearing house. A person so authorised may attend a meeting on behalf of the recognised clearing house (without

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

production of a share certificate, notarised authorisation and/or further evidence that he is duly authorised) and exercise the same rights as if he were an individual shareholder of the Company (and enjoy the same statutory rights as other shareholders, including the right to speak and to vote).

The power of attorney shall state whether the proxy(ies) can vote according to his or her own will if the shareholder does not give specific instructions.

The instrument appointing a voting proxy shall be placed at the domicile of the Company or at such other place as specified in the notice of meeting at least 24 hours prior to the meeting at which the proxy is authorized to vote or 24 hours prior to the specified time of the voting. If the power of attorney is signed by a person authorized by the principal, the power of attorney or other authorization documents shall be notarized. The notarized power of attorney or other authorization documents shall, together with the instrument appointing the voting proxy, be deposited at the Company's domicile or at such other place as specified in the notice of the meeting.

If the principal is a legal person, its legal representative or such person as is authorized by resolution of its Board of Directors or other governing body to act as its representative may attend at the Shareholders' General Meeting of the Company. A partnership shareholder shall attend the shareholders' general meetings of the Company by its managing partner or the appointed representative of the managing partner or the person authorized by the resolution of the partners' meeting or other decision-making body.

Resolutions of Shareholders' General Meetings

Resolutions of the Shareholders' General Meeting shall be divided into ordinary resolutions and special resolutions. To adopt an ordinary resolution, votes representing more than one-half of the voting rights represented by the shareholders (including proxies) present at the meeting must be exercised in favor of the resolution in order for it to be passed. To adopt a special resolution, votes representing more than two-thirds of the voting rights represented by the shareholders (including proxies) present at the meeting must be exercised in favor of the resolution in order for it to be passed.

The following shall be resolved by an ordinary resolution at a Shareholders' General Meeting:

- (1) work reports of the Board and the Supervisory Committee;
- (2) profit distribution plans and loss recovery plans formulated by the Board;
- (3) appointment and removal of the members of the Board and the members of the Supervisory Committee with shareholder representatives, and determination of their remuneration and method of payment;

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- (4) annual financial budgets and final accounts of the Company;
- (5) annual report of the Company;
- (6) the appointment or removal or no longer renews the appointment of an accounting firm;
- (7) other matters other than those required by the laws, administrative regulations, or the Articles of Association to be adopted by special resolutions.

The following shall be resolved by a special resolution at a Shareholders' General Meeting:

- (1) the increase in or decrease of the Company's registered capital;
- (2) the division, spin-off, merger, dissolution, liquidation and change in the corporate form of the Company;
- (3) the amendment of the Articles of Association;
- (4) the purchase or sale by the Company within one year of (a) material asset(s) or amount of guarantees exceeding 30% of the audited total assets of the Company at latest period;
- (5) any other matters required by the laws, administrative regulations or the Articles of Association, and matters considered by the Shareholders' General Meeting, by way of an ordinary resolution, to be of a nature which may have a material impact on the Company and should be adopted by a special resolution.

DIRECTORS AND BOARD OF DIRECTORS

Directors

Directors shall be elected or replaced at Shareholders' General Meetings and may be removed from office by Shareholders' General Meetings before the expiration of his term of office. Directors are appointed for a term of three years, subject to re-election upon expiry of the term, unless otherwise provided by relevant laws, regulations and the listing rules of the place where the Company's shares are listed.

The term of office of a director shall be calculated from the date when he takes office, until expiration of the term of office of the Board of the session. In case of failure to timely elect a director upon expiration of the director's term of office, the existing directors shall continue to perform their duties in accordance with laws, administrative regulations, departmental rules, the listing rules of the place where the Company's shares are listed and the Articles of Association until the new directors assume their office.

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Directors may be held concurrently by the president or other senior management member, but the total number of directors who concurrently hold the positions of president or other senior management member shall not exceed one-half of the total number of directors of the Company.

The Board

The Company has a Board of Directors, which is accountable to the Shareholders' General Meeting. The Board consists of 5 to 13 Directors.

The Board exercises the following powers:

- (1) to convene Shareholders' General Meetings and report its work to the Shareholders' General Meetings;
- (2) to implement the resolutions of the Shareholders' General Meeting;
- (3) to decide on the Company's business plans and investment plans;
- (4) to formulate the Company's annual financial budget and final accounts;
- (5) to formulate the Company's profit distribution plan and loss recovery plan;
- (6) to formulate the proposals for increase or reduction of the Company's registered capital and the issue and listing of bonds or other securities of the Company;
- (7) to formulate plans for material acquisitions, purchase of the Company's shares, merger, division, dissolution and change of corporate form of the Company;
- (8) to decide on such matters as the Company's external investment, acquisition or disposal of assets, pledge of assets, external guarantees, entrusted assets management, connected transactions, external donations, etc., to the extent authorized by the Articles of Association and the Shareholders' General Meeting;
- (9) to determine the establishment of the Company's internal management structure;
- (10) to engage or dismiss the Company's president and secretary to the Board and other senior management member, and deciding on matters relating to their remuneration, rewards and punishments; to engage or dismiss such senior management members as deputy president, financial officer and etc., as proposed by the president, and deciding on matters relating to their remuneration, rewards and punishments;
- (11) to formulate the Company's basic management system;
- (12) to formulate proposals for any amendment to the Articles of Association;

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- (13) to manage the information disclosure of the Company;
- (14) to propose to the Shareholders' General Meeting the appointment or replacement of an accounting firm that provides audit service to the Company;
- (15) to listen to the work reports of the Company's president and inspect his or her work;
- (16) to exercise other functions and powers conferred by laws, administrative regulations, departmental rules or the Articles of Association.

The chairman of the Board of Directors exercises the following powers:

- (1) to preside over Shareholders' General Meetings and convene and preside over meetings of the Board;
- (2) to supervise and inspect the implementation of resolutions of the Board;
- (3) to sign the important documents of the Board;
- (4) other powers authorized by the Board.

Board meetings comprise regular meetings and ad hoc meetings. Regular meetings shall be held at least four times each year (at approximately quarterly interval).

Under any of the following circumstances, the chairman of the Board shall convene and preside over an extraordinary meeting of the Board within ten days after receipt of the proposal:

- (1) proposed by shareholders representing more than one tenth of the voting rights;
- (2) jointly proposed by more than one-third of the Directors;
- (3) proposed by the Supervisory Committee;
- (4) proposed by the chairman;
- (5) proposed by more than half of the independent non-executive Directors;
- (6) other circumstance as specified by the Articles of Association.

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Senior Management

The Company shall have one president, several vice president and other senior management personnel, one chief financial officer, one secretary to the Board, who shall be appointed or dismissed by the Board.

The president shall be accountable to the Board and exercise the following functions and powers:

- (1) to be in charge of the production, operation and management of the Company, to organize the implementation of the resolutions of the Board and to report to the Board;
- (2) to organize the implementation of the Company's annual business plans and investment plans;
- (3) to formulate the Company's internal management structure;
- (4) to draft the Company's basic management system;
- (5) to formulate the specific rules and regulations of the Company;
- (6) to propose the Board to appoint or dismiss of the vice president, chief financial officer of the Company;
- (7) to appoint or dismiss management personnel other than those required to be appointed or dismissed by the Board;
- (8) other powers conferred by the Articles of Association or the Board.

Supervisors and the Supervisory Committee

The Company shall have the Supervisory Committee. The Supervisory Committee consists of three Supervisors, including 2 shareholder representative Supervisors and 1 employee representative Supervisor. Among them, employee representative Supervisors shall be elected democratically through the employee representatives' meeting, employee meeting or otherwise.

The Supervisory Committee exercise the following powers:

- (1) to review and audit the share issuance documents and the Company's regular reports prepared by the Board and propose written review and audit opinions. Supervisors shall sign the written confirmation opinions;
- (2) to examine the Company's financial affairs;

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- (3) to supervise the Directors and Senior Management in their performance of their duties and to propose the removal of Directors and Senior Management who have violated laws, administrative regulations, the Articles of Association or resolutions of Shareholders' General Meetings;
- (4) to demand rectification by a Director or Senior Management when the acts of such persons are harmful to the Company's interest;
- (5) to propose the convening of extraordinary general meetings and to convene and preside over Shareholders' General Meetings when the Board fails to perform the duty of convening and presiding over Shareholders' General Meetings under the Company Law;
- (6) to submit proposals to the Shareholders' General Meeting;
- (7) to initiate legal proceedings against Directors and Senior Management in accordance with the Company Law;
- (8) to conduct investigations whenever unusual conditions of operation of the Company arise and if necessary, to engage professional institutions such as firms of accountants and lawyers to assist in the investigations. Any reasonable costs arising therefore shall be borne by the Company;
- (9) other functions and powers granted by the Shareholders' General Meeting.

Financial and Accounting System

The Company shall establish its financial and accounting system in accordance with the laws, administrative regulations as well as the regulations formulated by the relevant departments of the State.

The Company shall submit and disclose documents such as annual report and interim report in accordance with the requirements of the securities regulatory rules of the place where the Company's shares are listed.

The above annual report, interim report and other documents shall be prepared in accordance with the relevant laws, administrative regulations and the requirements of the stock exchange.

The Company shall not keep accounts other than those provided by law. The assets of the Company shall not be deposited in any account opened in the name of any individual.

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Profit Distribution

The Company formulates profit distribution policies in accordance with the law and strictly complies with the requirements of laws, regulations and the relevant provisions of the stock exchange where the Company's shares are listed.

Accounting Firm

The Company shall employ an independent accounting firm that complies with relevant national regulations to audit the financial statements, verify the net assets, carry out other relevant consultations, etc. The term of employment of an accounting firm employed by the Company shall be between the end of the annual general meeting of the Company and the end of the next annual general meeting, which shall be further extended.

The Company shall provide the engaged accounting firm with truthful and complete accounting vouchers, account books, financial reports and other accounting data, and shall not refuse to do so or conceal any of them or make any false statement.

Notice

Notices of the Company may be given in the following ways:

- (1) by hand;
- (2) by facsimile, electronic mail or post;
- (3) by means of instant messaging software such as phone calls and WeChat.
- (4) by way of an announcement;
- (5) such ways as the Company and the notified party agreed in advance or any other way which is recognized by the notified party upon receipt of the notice; and
- (6) other ways which are recognized by the securities regulatory authority of the place where the shares of the Company are listed or stipulated in the Articles of Association.

Merger and Division of the Company

In the event of a merger of the Company, the parties to the merger shall enter into a merger agreement and prepare a balance sheet and an inventory of assets. The Company shall notify its creditors within ten (10) days from the date on which the Company's merger resolution is passed, and shall publish an announcement in a newspaper within thirty (30) days. Creditors are entitled to, within thirty (30) days upon receipt of the notification, or for creditors who have not received such notification, within forty-five days after the date of announcement,

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

request the Company to make repayments or provide relevant guarantees in respect of its indebtedness. Upon the completion of a merger, the respective accounts payable and receivable will be inherited by the continuing company, or the newly formed company after the merger.

As for the division of a company, the properties thereof shall be divided accordingly. In the event of a division, balance sheets and checklists of properties shall be prepared. The Company shall notify its creditors within ten (10) days from the date on which the Company's division resolution is passed, and shall publish an announcement in a newspaper within thirty (30) days.

Dissolution and Liquidation of the Company

The Company shall be dissolved upon the following reasons:

- (1) the term of business stipulated in the Articles of Association has expired or other events of dissolution specified in the Articles of Association have occurred;
- (2) the Shareholders' General Meeting resolves to dissolve the Company;
- (3) dissolution is necessary due to a merger or division of the Company;
- (4) the business license is revoked, or the business is ordered to close down or is revoked;
- (5) where the Company encounters serious difficulties in its operation and management and its continuance shall cause a significant loss to the interest of shareholders, and where this cannot be resolved through other means, shareholders who hold more than 10% of the total shareholders' voting rights of the Company may present a petition to the People's Court for the dissolution of the Company, the People's Court dissolves in accordance with the law.

In the event of (1) above, the Company may carry on its existence by amending its Articles of Association.

Amendment of the Articles of Association in accordance with the above paragraph shall be passed by no less than two-thirds of the voting rights held by the shareholders present at the general meeting.

Where the Company is dissolved under the provisions of (1), (2), (4), (5) above, a liquidation committee shall be established and the liquidation shall commence within 15 days after the occurrence of an event of dissolution. The liquidation committee shall be composed of the persons determined by the Directors or the Shareholders' General Meeting. If a liquidation committee is not established within the stipulated period to conduct liquidation, the creditors may apply to the People's Court to appoint relevant personnel to form a liquidation committee to conduct liquidation.

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

The liquidation committee shall exercise the following functions and powers during the liquidation period:

- (1) to sort out the Company's assets and prepare a balance sheet and an inventory of assets respectively;
- (2) to notify the creditors and make announcements;
- (3) to deal with and settle the outstanding business of the Company;
- (4) to pay all outstanding taxes and taxes arising in the course of liquidation;
- (5) to settle claims and debts;
- (6) to deal with the surplus assets of the Company after its debts have been paid off;
- (7) to participation in civil lawsuits on behalf of the Company.

The liquidation committee shall notify creditors within ten days after its establishment and shall make announcements in newspapers within 60 days. A creditor shall lodge his/her claim with the liquidation committee within 30 days after receiving the notice or within 45 days after the date of announcement if he/she did not receive the notice.

When declaring their claims, the creditors shall explain the matters related to their claims and provide supporting materials. The liquidation committee shall register the creditor's rights.

During the period of declaration of claims, the liquidation committee shall not settle any debts to creditors.

Upon liquidation of the Company's properties and the preparation of the balance sheet and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit it to the Shareholders' General Meeting or the People's Court for confirmation.

The remaining assets of the Company after payment of liquidation expenses, wages, social insurance expenses and statutory compensation of employees, outstanding taxes and the Company's debts shall be distributed to shareholders in proportion to their shareholdings.

During the liquidation period, the Company shall continue to exist but shall not carry out any business activities unrelated to the liquidation. The assets of the Company shall not be distributed to the shareholders before the settlements are made in accordance with the preceding provisions.

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

The liquidation committee, having thoroughly examined the Company's assets and having prepared a balance sheet and an inventory of assets, discovers that the Company's assets are insufficient to pay its debts in full, it shall apply to the People's Court for a declaration of insolvency in accordance with law.

After the People's Court has declared the Company bankrupt, the liquidation committee shall hand over the affairs of the liquidation to the People's Court.

Following the completion of liquidation of the Company, the liquidation committee shall prepare a liquidation report, which is submitted to the shareholders' general meeting or to the People's Court for confirmation, and shall report to the company registration authorities for confirmation for application for cancelling the registration of the Company and a public announcement shall be made for the termination of the Company.

Amendments to the Articles of Association

Under any one of the following circumstances, the Company shall amend the Articles of Association:

- (1) after amendment has been made to the Company Law or relevant laws, administrative regulations and the listing rules of the place where the company's shares are listed, the contents of the Articles of Association are in conflict with the amended laws, administrative regulations and the listing rules of the place where the company's shares are listed;
- (2) the changes that the Company have undergone are inconsistent with the records made in the Articles of Association;
- (3) the shareholders' general meeting has resolved to amend the Articles of Association.

Dispute Resolution

The Company shall comply with the following rules for dispute resolution:

- (1) Whenever any disputes or claims arise between holders of the overseas listed shares and the Company, holders of the overseas listed shares and the Company's Directors, Supervisors, president or other Senior Management, or holders of the overseas listed shares and holders of domestic shares, based on the Articles of Association or any rights or obligations conferred or imposed by the Company Law or any other relevant laws and administrative regulations concerning the affairs of the Company, such disputes or claims shall be referred by the relevant parties to arbitration.

Where a dispute or claim of rights referred to in the preceding paragraph is referred to arbitration, the entire claim or dispute must be referred to arbitration, and all persons who have a cause of action based on the same facts giving rise to the dispute

APPENDIX V SUMMARY OF THE ARTICLES OF ASSOCIATION

or claim or whose participation is necessary for the resolution of such dispute or claim, shall abide by the arbitration provided that such person is the Company or the Company's shareholder, Director, Supervisor, president or other Senior Management.

Disputes in relation to the definition of shareholders and disputes in relation to the register of shareholders need not be resolved by arbitration.

- (2) A claimant may elect arbitration at either the China International Economic and Trade Arbitration Commission in accordance with its arbitration rules or the Hong Kong International Arbitration Centre in accordance with its securities arbitration rules. Once a claimant refers a dispute or claim to arbitration, the other party must submit to the arbitral body elected by the claimant.

If a claimant elects arbitration at Hong Kong International Arbitration Centre, any party to the dispute or claim may apply for a hearing to take place in Shenzhen in accordance with the Securities Arbitration Rules of the Hong Kong International Arbitration Centre.

- (3) If any disputes or claims of rights are settled by way of arbitration in accordance with item (1), the laws of the People's Republic of China (excluding Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan Region) shall apply, save as otherwise provided in laws and administrative regulations.
- (4) The award of an arbitration body shall be final and conclusive and binding on all parties.
- (5) In the process of arbitration, the Articles of Association shall continue to be performed except for the disputes between the parties that are under arbitration.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

FURTHER INFORMATION ABOUT OUR COMPANY

1. Incorporation of Our Company

Our Company was established as a limited liability company in the PRC on April 15, 2014 and was converted into a joint stock company with limited liability on July 2, 2021 under the laws of the PRC. Accordingly, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. The relevant PRC laws and regulatory provisions and a summary of our Articles of Association are set out in Appendices IV and V to this document, respectively. As of the Latest Practicable Date, the registered share capital of our Company was RMB381,616,633.

Our Company has established a place of business in Hong Kong at Room 2609, China Resources Building, 26 Harbour Road, Wanchai, Hong Kong and has registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on March 15, 2024. Ms. Wong Tik, the joint company secretary of our Company, has been appointed as our authorized representative for the acceptance of service of process in Hong Kong whose correspondence address is the same as our place of business in Hong Kong.

2. Changes in Share Capital of Our Company

On April 15, 2014, our Company was established as a limited liability company with a registered capital of RMB10,000,000. On July 2, 2021, our Company was converted into a joint stock company with limited liability and renamed as TransThera Sciences (Nanjing), Inc. (藥捷安康(南京)科技股份有限公司). The following sets out changes in the share capital of our Company within the two years immediately preceding the date of this document.

On December 22, 2022, the registered capital of our Company increased from RMB360,000,000 to RMB378,290,997 with the additional registered capital of RMB18,290,997, comprising 18,290,997 Shares, subscribed by certain Pre-[REDACTED] investors as part of the Series D+ Financing.

On December 29, 2022, the registered capital of our Company increased from RMB378,290,997 to RMB379,953,815 with the additional registered capital of RMB1,662,818, comprising 1,662,818 Shares, subscribed by Jiangbei Assets Management as part of the Series D+ Financing.

On February 17, 2023, the registered capital of our Company increased from RMB379,953,815 to RMB381,616,633 with the additional registered capital of RMB1,662,818, comprising 1,662,818 Shares, subscribed by BOC Capital as part of the Series D+ Financing.

For further details, please see the section headed “History, Development and Corporate Structure” in this document. Save as aforesaid, as of the Latest Practicable Date, there has been no alteration in our share capital within two years immediately preceding the date of this document.

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3. Resolutions of the Shareholders

Pursuant to a general meeting of our Shareholders held on March 18, 2024, the following resolutions, among others, were passed by our Shareholders:

- (a) the issue by our Company of H Shares of nominal value of RMB1.00 each and such H Shares be [REDACTED] on the Hong Kong Stock Exchange be issued;
- (b) the number of H Shares to be issued shall not be more than [REDACTED]% of the total issued share capital of our Company as enlarged by the [REDACTED], and the grant to the [REDACTED] of the [REDACTED] of not more than [REDACTED]% of the number of H Shares issued pursuant to the [REDACTED];
- (c) subject to the completion of the [REDACTED], the adoption of the Articles of Association which shall become effective on the [REDACTED], and the authorization to the Board to amend the Articles of Association in accordance with the requirements of the relevant laws and regulations and the Listing Rules; and
- (d) authorization of our Board to handle all relevant matters relating to, among other things, the [REDACTED] and [REDACTED] of the H Shares.

APPENDIX VI STATUTORY AND GENERAL INFORMATION

FURTHER INFORMATION ABOUT THE BUSINESS OF OUR COMPANY

1. Summary of Material Contract

We have entered into the following contract (not being a contract entered into in the ordinary course of business) within the two years immediately preceding the date of this document that are or may be material:

- (a) the [REDACTED].

2. Intellectual Property Rights

Trademarks

As of the Latest Practicable Date, we have registered the following trademarks in the PRC, which we considered to be material to our business:

No.	Owner	Registration No.	Place of Registration	Trademark	Class	Validity Period
1	Company	305721255	Hong Kong		5 and 42	August 18, 2021 to August 17, 2031
2	Company	36816737	PRC		42	October 28, 2019 to October 27, 2029
3	Company	36815434	PRC		5	November 14, 2019 to November 13, 2029
4	Company	36805393	PRC		5	October 28, 2019 to October 27, 2029
5	Company	36799579	PRC		5	October 28, 2019 to October 27, 2029
6	Company	36799021	PRC		42	October 28, 2019 to October 27, 2029
7	Company	36796238	PRC		42	November 07, 2019 to November 06, 2029
8	Company	60589186	PRC		35	July 7, 2022 to July 6, 2032

APPENDIX VI STATUTORY AND GENERAL INFORMATION

No.	Owner	Registration No.	Place of Registration	Trademark	Class	Validity Period
9	Company	60576059	PRC		35	July 7, 2022 to July 6, 2032
10	Company	64467950	PRC		10	November 7, 2022 to November 6, 2032
11	Company	64461480	PRC		44	January 14, 2023 to January 13, 2033

Patents

Please see the paragraph headed “Business – Intellectual Property” in this document for patents registered as of the Latest Practicable Date, which we considered to be material to our business.

Domain Names

As of the Latest Practicable Date, we have registered the following domain names which we consider to be material to our business:

No.	Owner	Domain Name	Registration Date
1.	Company	transtherabio.com	August 4, 2016
2.	Company	transthera.com.cn	September 12, 2018
3.	Company	transthera.net	September 12, 2018
4.	Company	transthera.org	September 12, 2018
5.	Company	transtherabio.org	September 12, 2018
6.	Company	transtherasciences.com	July 19, 2021
7.	Company	transtherasciences.cn	July 19, 2021
8.	Company	transtherasciences.com.cn	July 19, 2021

FURTHER INFORMATION ABOUT OUR DIRECTORS, SUPERVISORS AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of Interests

Save as disclosed below, immediately following completion of the [REDACTED] (without taking into account the H Shares which may be [REDACTED] and [REDACTED] pursuant to the exercise of the [REDACTED]), so far as our Directors are aware, none of our Directors, Supervisors and chief executive has any interest or short positions in our Shares, underlying Shares or debentures of our Company or any associated corporations (within the

APPENDIX VI STATUTORY AND GENERAL INFORMATION

meaning of Part XV of the SFO) which will have to be notified to our Company and the Hong Kong Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they are taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to our Company and the Hong Kong Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers contained in the Listing Rules.

Name	Position	Nature of Interest	Number and class of Shares held	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED] (%)	Approximate percentage of shareholding in the total share capital of our Company after the [REDACTED] (%)
Dr. Wu ⁽¹⁾	Executive Director	Beneficial owner	[REDACTED] (H Shares)	[REDACTED]	[REDACTED]
		Interest in controlled corporations	[REDACTED] (H Shares)	[REDACTED]	
			[REDACTED] (Unlisted Shares)	[REDACTED]	

Note:

- (1) Dr. Wu is the general partner of Nanjing Yipu and Nanjing Jiminrui and is responsible for the management of Nanjing Yipu and Nanjing Jiminrui. As such, Dr. Wu is deemed to be interested in the [REDACTED] Shares held by Nanjing Yipu and [REDACTED] Shares held by Nanjing Jiminrui under the SFO.

2. Substantial Shareholders

For the information on the persons who will, immediately following the completion of the [REDACTED], have interests or short positions in our Shares or underlying Shares which would be required to be disclosed to our Company and the Hong Kong Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, please see the section headed “Substantial Shareholders” in this Document.

Save as set out above, our Directors are not aware of any other person (other than our Directors, Supervisors or chief executive) will, immediately following completion of the [REDACTED], directly or indirectly, be interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Company.

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STATUTORY AND GENERAL INFORMATION

3. Service Contracts

Each of our Directors and Supervisors has entered into a service contract with our Company. The principal particulars of these service contracts comprise (a) a term of three years commencing from the date of appointment; and (b) termination provisions in accordance with their respective terms. Our Directors may be re-appointed subject to Shareholders’ approval.

Save as disclosed above, none of our Directors and Supervisors has or is proposed to have entered into any service contract with our Company (excluding contracts expiring or determinable by our Company within one year without payment of compensation other than statutory compensation).

4. Remuneration of Directors and Supervisors

Save as disclosed in the section headed “Directors, Supervisors and Senior Management” and “Appendix I – Accountants’ Report – II Notes to The Historical Financial Information – 11. Directors’, Supervisors’ and Chief Executive’s Emoluments” for the financial years ended December 31, 2022 and 2023, none of our Directors or Supervisors received other remunerations of benefits in kind from us.

5. Employee Incentive Schemes

The following is a summary of the principal terms of the Employee Incentive Schemes approved and adopted by our Shareholders’ meeting on March 16, 2017 (“**2017 Scheme**”), January 7, 2021 (“**2021 Scheme**”) and February 28, 2023 (“**2023 Scheme**”), respectively and as amend from time to time (collectively, the “**Schemes**”). The terms of the Schemes are not subject to the provisions of Chapter 17 of the Listing Rules as the Schemes does not involve the grant of options by our Company after the [REDACTED]. Given the underlying Shares under the Employee Incentive Schemes had already been issued, there will not be any dilution effect to the issued Shares upon the vesting of the awards under the Employee Incentive Schemes.

As of the Latest Practicable Date, the Company had established three Employee Incentive Platforms, namely Nanjing Yipu, Nanjing Yicheng and TT Therapeutics. Nanjing Yipu holds 54,726,152 Shares directly. Each of Nanjing Yicheng and TT Therapeutics was a limited partner of Nanjing Yipu with approximately 26.37% and 22.16% partnership interest, respectively. For the details of the Employee Incentive Platforms, please see “History, Development and Corporate Structure – Employee Incentive Schemes” in this document.

Objectives

The purpose of the Schemes is to build an incentive mechanism for the employees of our Company, raising the competitiveness of our Company in the labour market. The Schemes also serve the purpose of attracting, stabilizing and recruiting future senior management and professionals.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

Eligibility

Pursuant to the scheme documents (the “**Scheme Documents**”) and the award offers (the “**Award Offers**”), participants of the Schemes include our Directors, Company’s core employees, senior management members and employees who had great contribution to the development of our Company. The Scheme Documents provided that the following employees may not be selected as participants to the Schemes (as applicable):

- Employees who have caused the material losses of our Company due to the willful intent or significant negligence;
- Employees who have convicted of crime;
- Employees who have caused the material losses of our Company due to the violation of the laws and regulations, the Articles of Association of our Company, the Company’s management policies;
- Employees who have misappropriated, stole and revealed our Company’s technology and secrets or commit damage to our Company’s interest or reputation; and
- Employees who are otherwise not eligible according to the discretionary decision by the Board.

Grant of Awards

The general partner of each of Nanjing Yipu and Nanjing Yicheng is Dr. Wu and Dr. Wu is the sole member of TT Therapeutics. Thus, in effect, all management powers and voting rights of the Employee Incentive Platforms reside with Dr. Wu.

All selected participants do not have any voting rights in our Company. The selected participants will be granted awards in the form of economic interest in the Employee Incentive Platforms conditional upon certain vesting conditions as specified in Scheme Documents and the Award Offers and upon vesting, such selected participants will become a limited partner of Nanjing Yipu or Nanjing Yicheng or a shareholder of TT Therapeutics. Upon becoming the limited partner or shareholder (as applicable) of Employee Incentive Platforms, the selected participants indirectly receive economic interest in the corresponding number of underlying Shares held by Nanjing Yipu.

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STATUTORY AND GENERAL INFORMATION

Administration of the Schemes

The 2017 Scheme and 2021 Scheme are subject to the approval of the Shareholders' meeting and administration of the Board or its relevant committee.

The 2023 Scheme is subject to the approval of the Shareholders' meeting and administration of the Board and Dr. Wu.

Restriction on Disposals

Pursuant to the terms of the Scheme Documents, the selected participants under 2017 Scheme and 2021 Scheme may not dispose of, transfer or pledge his or her interest in the limited partnership and shall be entitled to receive distribution upon Nanjing Yipu disposes its equity interests in our Company.

Pursuant to the terms of the Scheme Documents, the selected participants under 2023 Scheme shall be subject to a lock-up period of three years and will be unlocked in tranches with 30% being unlocked from the first anniversary of the [REDACTED] Date (or 36 months after the grant date, whichever is the later), 30% being unlocked from the second anniversary of the [REDACTED] Date (or 36 months after the grant date, whichever is the later), and 40% being unlocked from the third anniversary of the [REDACTED] Date (or 60 months after the grant date, whichever is the later).

6. Disclaimers

Save as disclosed in this document:

- (a) save as disclosed in this document, none of our Directors, Supervisors or any of the parties listed in "Qualifications of Experts" of this Appendix is:
 - (i) interested in our promotion, or in any assets which have been, within two years immediately preceding the date of this document, acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to any member of our Company; or
 - (ii) materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to our business;

APPENDIX VI STATUTORY AND GENERAL INFORMATION

- (b) save in connection with the [REDACTED] and the [REDACTED], none of the parties listed in "Qualification of Experts" of this Appendix:
 - (i) is interested legally or beneficially in any shares our Company; or
 - (ii) has any right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for any securities our Company;
- (c) none of our Directors or Supervisors is a director or employee of a company that has an interest in the share capital of our Company which, once the H Shares are [REDACTED] on the Hong Kong Stock Exchange, would have to be disclosed pursuant to Divisions 2 and 3 of Part XV of the SFO; and
- (d) so far as is known to our Directors, none of our Directors or Supervisors or their respective close associates (as defined under the Listing Rules) or Shareholders who owns more than 5% of the issued shares of our Company has any interests in the five largest customers or the five largest suppliers of our Company.

OTHER INFORMATION

1. Estate duty

Our Directors have been advised that no material liability for estate duty is likely to impose on our Company under the laws of the PRC.

2. Litigation

As of the Latest Practicable Date, we were not involved in any litigation, arbitration or claim of material importance, and, so far as we are aware, no litigation, arbitration or claim of material importance is pending or threatened against us, which would have a material adverse effect on our financial condition or results of operations, taken as a whole.

3. Joint Sponsors

The Joint Sponsors have made an application on behalf of our Company to the Hong Kong Stock Exchange for the [REDACTED] of, and permission to [REDACTED] in, our H Shares. All necessary arrangements have been made to enable the securities to be admitted into CCASS.

The Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of Listing Rules.

Each of the Joint Sponsors will receive a fee of US\$300,000 to act as a sponsor to our Company in connection with the [REDACTED].

4. Preliminary expenses

As of the Latest Practicable Date, our Company has not incurred material preliminary expenses.

APPENDIX VI STATUTORY AND GENERAL INFORMATION

5. Qualifications of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given opinions and/or advice in this document are as follows:

Name	Qualifications
CITIC Securities (Hong Kong) Limited	Licensed corporation to conduct Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities under the SFO
Huatai Financial Holdings (Hong Kong) Limited	Licensed corporation under the SFO to conduct type 1 (dealing in securities), type 2 (dealing in futures contracts), type 4 (advising on securities), type 6 (advising on corporate finance), type 7 (providing automated trading services) and type 9 (asset management) regulated activities
Ernst & Young	Certified public accountants
Jia Yuan Law Offices	PRC Legal Adviser
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Independent industry consultant

6. Consents

Each of the experts as referred to in the paragraph headed “5. Qualifications of Experts” of this Appendix has given and has not withdrawn its respective written consents to the issue of this document with the inclusion of certificates, letters, opinions or reports and the references to its name included herein in the form and context in which it respectively included.

7. Taxation of Holders of H Shares

(1) *Hong Kong*

The sale, purchase and transfer of H Shares are subject to Hong Kong stamp duty. The current rate charged on each of the purchaser and seller is 0.1% of the consideration or, if higher, the fair value of the H Shares being sold or transferred. For further details in relation to taxation, please see “Appendix III – Taxation and Foreign Exchange” to this document.

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(2) Consultation with professional advisers

Potential [REDACTED] in the [REDACTED] are urged to consult their professional tax advisers if they are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposing of or dealing in our H Shares (or exercising rights attached to them). None of our Company, our Directors, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], or any other person or party involved in the [REDACTED] accept responsibility for any tax effects on, or liabilities of, any person, resulting from the subscription, purchase, holding or disposal of, dealing in or the exercise of any rights in relation to our H Shares.

8. No Material Adverse Change

Our Directors confirm that, as of the date of this document, there has been no material adverse change in the financial or trading position of our Company since December 31, 2023 (being the date to which the latest audited consolidated financial statements of our Company were prepared).

9. Promoters

The promoters of our Company are all then 21 shareholders of our Company as of June 17, 2021 before our conversion into a joint stock company with limited liability. Save as disclosed in this document, within the two years preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to any promoter in connection with the [REDACTED] and the related transactions described in this document.

10. Restrictions on Repurchase

For details, please see "Appendix IV – Summary of Principal Legal and Regulatory Provisions" and "Appendix V – Summary of the Articles of Association" to this document.

11. Binding Effect

This document shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

12. Bilingual Document

The English and Chinese language versions of this document are being published separately, in reliance upon the exemption provided under section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

13. Miscellaneous

Save as otherwise disclosed in this document:

- (a) within the two years preceding the date of this document, (i) our Company has not issued nor agreed to issue any share or loan capital fully or partly paid either for cash or for a consideration other than cash; and (ii) no commission, discount, brokerage or other special term has been granted in connection with the issue or sale of any shares of our Company;
- (b) no Share or loan capital of our Company, if any, is under option or is agreed conditionally or unconditionally to be put under option;
- (c) our Company has not issued nor agreed to issue any founder shares, management shares or deferred shares;
- (d) our Company has no outstanding convertible debt securities or debentures;
- (e) there is no arrangement under which future dividends are waived or agreed to be waived;
- (f) there has been no interruption in our business which may have or have had a significant effect on the financial position in the last 12 months;
- (g) our Company is not presently listed on any stock exchange or traded on any trading system; and
- (h) our Company is a joint stock limited company and is subject to the PRC Company Law.

APPENDIX VII

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND AVAILABLE ON DISPLAY

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to a copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (i) a copy of each of the material contracts referred to in the paragraph headed “Appendix VI – Statutory and General Information – Further Information about the Business of our Company – 1. Summary of Material Contracts” in this document; and
- (ii) the written consents referred to in the paragraph headed “Appendix VI – Statutory and General Information – Other Information – 6. Consents” in this document.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the website of the Hong Kong Stock Exchange at www.hkexnews.hk and our website at www.transthera.com during a period of 14 days from the date of this document:

- (a) the Articles of Association;
- (b) the accountants’ report prepared by Ernst & Young, the text of which is set out in Appendix I to this document;
- (c) the audited consolidated financial statements of our Company for the years ended December 31, 2022 and 2023;
- (d) the report prepared by Ernst & Young on the unaudited [REDACTED] financial information of our Company, the text of which is set out in Appendix II to this document;
- (e) the industry report issued by Frost & Sullivan (Beijing) Co., Shanghai Branch Co. referred to in the section headed “Industry Overview” in this document;
- (f) the PRC legal opinions issued by Jia Yuan Law Offices, our legal advisors as to PRC law, in respect of, among other things, the general matters of our Company under the PRC laws;
- (g) the material contract referred to in the paragraph headed “Appendix VI – Statutory and General Information – Further Information about the Business of our Company – 1. Summary of Material Contract” in this document;

APPENDIX VII

**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND AVAILABLE ON DISPLAY**

- (h) the service contracts referred to in the paragraph headed “Appendix VI – Statutory and General Information – Further Information about Our Directors, Supervisors and Substantial Shareholders – 3. Service Contracts” in this document;
- (i) the written consents referred to in the paragraph headed “Appendix VI – Statutory and General Information – Other Information – 6. Consents” in this document; and
- (j) the PRC Company Law, the PRC Securities Law and the Oversea Listing Trial Measures together with unofficial English translations thereof.