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Post Hearing Information Pack of

GenFleet Therapeutics (Shanghai) Inc.
勁方醫藥科技（上海）股份有限公司
(the “Company”)

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

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GenFleet Therapeutics (Shanghai) Inc. 勁方醫藥科技（上海）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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[REDACTED] [REDACTED] and the
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[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

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SUMMARY

This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. You should read this document in its entirety before you decided to [REDACTED] in the [REDACTED]. There are risks associated with any [REDACTED]. Some of the particular risks in [REDACTED] in the [REDACTED] are set out in “Risk Factors” of this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board 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. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours. Our Core Products are the products for the purpose of satisfying the eligibility requirements under Chapter 18A of the Listing Rule and Chapter 2.3 of the Guide for New Listing Applicants, and are in the early stages of clinical development. We may continue to incur substantial costs and expenses in relation to research and development activities for the Core Products, and the Core Products may not be successfully developed or marketed. Your [REDACTED] decision should be made in light of these considerations.

OVERVIEW

Founded in 2017, we are a biopharmaceutical company focused on developing novel treatment options in the fields of oncology, covering different lines of treatments of multiple solid tumors, as well as autoimmune and inflammatory diseases. As of the Latest Practicable Date, we had established a product pipeline consisting of eight product candidates with five under clinical development, including two Core Products — GFH925 and GFH375.

GFH925 (fulzerasib), marketed under the brand name **Dupert®**, an in-house discovered new drug, has been approved for commercialization in China for the treatment of advanced non-small cell lung cancer (“**NSCLC**”), and it was China’s first and globally the third approved selective inhibitor of Kirsten rat sarcoma (“**KRAS**”) G12C. We retain all rights, including conducting R&D, manufacturing and commercialization of GFH925 globally outside of the Greater China, and we have out-licensed all rights related to GFH925 in the Greater China. We are currently conducting Phase II stage of KORCUS trial in the EU for GFH925/cetuximab combination therapy as a first-line treatment of NSCLC. GFH375 is an orally bioavailable small molecule inhibitor of KRAS G12D. We have initiated the Phase II part of a Phase I/II clinical trial in patients with advanced solid tumors harboring the KRAS G12D mutation in China. In addition to our Core Products, we aim to further diversify our pipeline portfolio beyond our RAS matrix, as exemplified by **GFS202A**, an in-house developed bispecific antibody targeting GDF15 and IL-6. Our pipeline also includes GFH312, an in-house developed potent small molecule that targets receptor interacting serine/threonine-protein kinase 1 (“**RIPK1**”) and inhibits its kinase activity. We have obtained NMPA’s approval to conduct a Phase II clinical of GFH312 for the treatment of primary biliary cholangitis (“**PBC**”) in China. Our diversified pipeline portfolio is a natural outcome of our established research and development platforms spanning target discovery, molecular discovery and evaluation, translational science and global clinical development, augmented by our expertise in key chemistry, manufacturing and controls (“**CMC**”) aspects including formulation research and quality analysis.

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

SUMMARY

The following chart summarizes the development status of our drug candidates as of Latest Practicable Date.

Compound	Target	Route of administration	Indication	Pre-Clinical	IND	Phase I	Phase II	Phase III	NDA	Key Regulatory Authority	Expected Upcoming Milestone	Commercial Rights	Partnership
Oncology: RAS-Focused													
★GFH925	KRAS G12C	Oral	advanced stage NSCLC (1 st line, combo) ⁽¹⁾							FDA, EMA ⁽²⁾	2025Q4 Enter Phase III	Global (outside of Greater China)	Innovent 信达生物制药
★GFH375	KRAS G12D	Oral	advanced stage PDAC, NSCLC and CRC ⁽³⁾							NMPA	2025Q4 Enter Pivotal trials	Greater China	VERASTEM 康达生物医药
GFH276	Pan-Ras	Oral	advanced stage Solid tumors							/	2025H2 IND Approval	Global	
GFH784	ADC (new payload)	Injection	advanced stage Solid tumors							/	2026Q1 IND submission	Global	
Oncology: Others													
GFH202A	GDF15 / IL-6	Injection	Cachexia							NMPA	2026H2 Enter Phase II	Global	
GFH009	CDK9	Injection	advanced stage AML ⁽⁴⁾							NMPA	2025H2 Enter Pivotal Trial	Greater China	SELLAS 赛尔生物
GFH018	TGF-βR1	Oral	advanced stage Various solid							NMPA, Taiwan FDA, TGA ⁽⁵⁾	*	Global	
Immunology													
GFH312	RIPK1	Oral	PBC							NMPA	2026H1 Enter Phase II ⁽⁶⁾	Global	
			PAD with PC							TGA, FDA ⁽⁷⁾	*	Global	

★ = Core Products

NSCLC: non-small cell lung cancer
CRC: colorectal cancer
AML: acute myeloid leukemia

PAD: peripheral artery disease
IC: intermittent claudication
PBC: primary biliary cholangitis

ADC: antibody drug conjugate
PDAC: pancreatic ductal adenocarcinoma

*: Currently assessing the competitive landscape and formulating future clinical development plan.

SUMMARY

Notes:

- (1) Cetuximab used in the clinical trials of GFH925/cetuximab combination was provided by Merck without charge, pursuant to the Merck Agreement. For additional information, please see “Business — Major Collaboration and Licensing Arrangements — Merck Agreement.” The Merck Agreement only provided for supply of cetuximab used in the EU clinical trials. Cetuximab received regulatory approval for the treatment of patients with EGFR-expressing, RAS wild-type metastatic CRC in the U.S. and EU in 2004. Cetuximab received regulatory approval for the treatment of patients with squamous cell cancer of the head and neck in the U.S. in 2006 and EU in 2004.
- (2) Phase Ib and II clinical trials of the GFH925/cetuximab combination were conducted in the EU. We plan to apply for a Phase III clinical trial of the GFH925/cetuximab combination in the United States and had a pre-IND meeting with the FDA in February 2025 regarding our planned IND application. We also plan to submit a clinical trial application for a Phase III clinical trial of the GFH925/cetuximab combination in selected member states within the jurisdiction of the EMA.
- (3) We granted Verastem an option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China within the specified option exercise period. In January 2025, Verastem exercised the option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China.
- (4) We granted SELLAS an exclusive (even to ourselves), sublicensable and royalty-bearing right and license to develop, manufacture and commercialize GFH009 across all therapeutic and diagnostic uses worldwide outside of Greater China.
- (5) The clinical trial of GFH018 was a single trial with a single protocol conducted at different locations.
- (6) We have completed a Phase I clinical trial for GFH312 in healthy participants in China. We submitted an IND application for a Phase II clinical trial of GFH312 for the treatment of PBC to the NMPA in March 2025 and obtained NMPA’s approval in May 2025. We plan to initiate a Phase II clinical trial of GFH312 for the treatment of PBC in the first half of 2026.
- (7) We have completed a Phase I clinical trial for GFH312 in healthy participants in Australia, and we have no plans for subsequent clinical trials in Australia. In July 2022, we submitted an IND application including results of the Phase I clinical trial in Australia to the FDA for a Phase II clinical trial of GFH312 in patients with PAD with IC. The FDA granted our IND application in August 2022, based on the results of the Phase I clinical trial in Australia.

SUMMARY

CORE PRODUCTS

Overview of GFH925

Our Core Product GFH925, also known as fulzerasib and marketed in China under the brand name Dupert[®], is an in-house discovered, small molecule selective inhibitor of the KRAS G12C protein. Having received the NDA approval from the NMPA as a Class 1 new drug in August 2024 for the second or later-line treatment of NSCLC harboring the KRAS G12C mutation, it is China’s first and globally the third approved selective inhibitor of KRAS G12C. GFH925 received the breakthrough therapy designation (“**BTD**”) for advanced NSCLC and was conferred the priority review status by the NMPA, and received marketing approval in merely approximately three years after the NMPA cleared the IND approval in July 2021, underscoring its recognized competitive advantages over existing therapeutic options. GFH925 also received the BTD from the NMPA in May 2023 as a third-line treatment for advanced colorectal cancer (“**CRC**”) harboring the KRAS G12C mutation. We anticipate that GFH925 would qualify for negotiation for inclusion in 2026 National Reimbursement Drug List (“**NRDL**”), because GFH925 is China’s first and globally the third approved selective inhibitor of KRAS G12C and KRAS G12C-mutant NSCLC has substantial patient population in China. With over 15 years of patent term remaining for GFH925 as of the Latest Practicable Date, we anticipate to realize commercial returns from GFH925 to fuel our future growth.

Clinical results of GFH925 as a monotherapy have demonstrated promising safety and efficacy profile. For instance, in the single arm registrational Phase II clinical trial that supported the NDA approval, GFH925 was generally well tolerated and demonstrated encouraging antitumor activity in NSCLC patients harboring the KRAS G12C mutation. According to its approved label in China, as of the data cut-off date of December 13, 2023, the confirmed objective response rate (“**ORR**”) was 49.1%, and the disease control rate (“**DCR**”) was 90.5% in 116 patients. The median progression-free survival (“**PFS**”) was 9.7 months, and the median overall survival (“**OS**”) was 13.3 months. The median duration of response (“**DoR**”) was not reached. GFH925 also demonstrated a favorable overall safety profile with absence of Grade 3 or above QT interval prolongation or renal impairment observed in FDA-approved KRAS G12C inhibitors based on reported data, which are critical measurements for cardiac safety and drug clearance. For details, see “Business — Core Product GFH925: A Small Molecule Inhibitor of KRAS G12C — Summary of Clinical Trials.”

We are advancing overseas clinical development of GFH925 to unleash its therapeutic potential, including a Phase Ib/II clinical trial for the first-line treatment of advanced NSCLC as a combination therapy with cetuximab, an antibody drug targeting epidermal growth factor receptor (“**EGFR**”), in countries within the EMA jurisdiction. As EGFR is situated upstream of RAS proteins in the signaling pathway and involved in switching on RAS proteins, we reasoned that the combination therapy may achieve synergistic effects in damping the EGFR-RAS pathway, which is critical for cell growth. We independently developed GFH925/cetuximab combination therapy and its clinical trial design without any involvement or contribution from our partner in China in the study design, protocol development, or trial operations. The combination therapy is among the first of its kind to co-target KRAS G12C and EGFR in terms of the clinical development status. We have been conducting the GFH925/cetuximab combination trial (“**KROCUS Trial**”) independently in Europe and have

SUMMARY

not relied on or used, and does not intend to rely on or use, any data generated from the clinical studies of the same combination therapy in China. Apart from incorporating certain publicly available data or authorized information (authorized for use in a clinical trial application under the Innovent Agreement) on the monotherapies of GFH925 and cetuximab (including the dosage, safety and efficacy data of the Phase I clinical trial of GFH925 in China conducted by Innovent, as well as the chemical nature, approved indication and dosage regime of cetuximab) in our ex-China IND applications — as required under the EMA and FDA regulatory frameworks for combination studies — we have not relied on any research and development activities conducted by Innovent or other third parties. In addition, in advancing the R&D of GFH925 in ex-Greater China regions, we have not relied on or used — and do not intend to rely on or use — any data generated from Innovent’s or other third parties’ clinical studies of the same combination therapy in China.

Interim results from the Phase Ib/II clinical trial in Europe provide preliminary evidence of the synergetic effect of GFH925 and cetuximab, which leads to promising antitumor efficacy compared to GFH925 as a monotherapy or to the current treatment regimens with chemotherapy drugs or PD-(L)1 drugs alone or in combination with chemotherapy. Following completion of the Phase Ib safety confirmation trial and pursuant to the clinical trial protocol, all data review team members, consisting of principal investigators, the CRO medical monitor⁽¹⁾ and we as the clinical trial sponsor, collectively reviewed the clinical data from the Phase Ib trial, and collectively confirmed that the selected dosage of GFH925 is safe, and collectively agreed that the Phase II trial may proceed. The primary endpoints of the Phase Ib were reached and safety confirmation of Phase Ib trial was completed by the data review team, as required by the clinical trial protocol. We anticipate completing the Phase II trial in the fourth quarter of 2025. We plan to leverage the clinical results in Europe to apply for a Phase III clinical trial in the United States and Europe to evaluate the safety and efficacy of the GFH925/cetuximab combination therapy. We had a pre-IND meeting with the FDA in February 2025 regarding our planned IND application for a Phase III clinical trial. Once approved, we plan to initiate the Phase III clinical trial in the fourth quarter of 2025.

NSCLC presents large addressable markets, and we view GFH925 as well-positioned to capture the considerable market opportunities. However, we may face uncertainties in clinical trial development which are subject to a variety of factors, including satisfactory safety and efficacy results from clinical trials, successful enrollment of patients, performance of CROs and other parties involved in clinical trial development and others. For more details, please see “Risk Factors — Risks Relating to the Development, Clinical Trials and Regulatory Approval of Our Pipeline Products — Our business and financial prospects depend substantially on the success of our pipeline products. If we are not able to successfully complete clinical development, obtain regulatory approval and commercialize our pipeline products, including our Core Products, or experience delays in doing so, our business prospects could be adversely affected.”

Note:

- (1) A CRO medical monitor is an expert consultant to clinical trial sponsor and project teams that provides guidance and oversight the essential components of clinical trial planning and execution. Here, the CRO medical monitor is the “Supplier G” referenced and described in “Business — Our Suppliers.”

SUMMARY

Addressable Markets and Competitive Landscape of GFH925

RAS drug market is increasingly competitive with major players actively expanding their RAS matrix. One of the most common mutations in the KRAS gene is G12C, accounting for approximately 15% of all KRAS mutations, and it is also the most prevalent variant of KRAS mutations in NSCLC. The KRAS G12C mutation occurs in approximately 13% of NSCLC and in 3% to 4% of CRC.

GFH925 (fulzerasib) was the first KRAS G12C inhibitor drug that received approval for commercialization in China. Globally, there were four other KRAS G12C inhibitor (adagrasib, sotorasib, garsorasib and glecirasib) drugs that have been approved as of the Latest Practicable Date. Among them, garsorasib, glecirasib and fulzerasib received approval for commercialization in China as of the same date. As of Latest Practicable Date, there were more than 20 KRAS G12C inhibitor candidates being clinically developed globally. With the continuous market penetration of the commercialized KRAS G12C inhibitor drugs and development of new drugs, the global KRAS G12C inhibitor drug market is expected to grow rapidly from US\$489.1 million in 2024 to US\$3,490.7 million in 2033 with a CAGR of 24.4%.

The global incidence of NSCLC increased from 1,937.6 thousand in 2019 to 2,203.5 thousand in 2024, and is expected to further increase to 2,761.6 thousand in 2033. In China, the incidence of NSCLC increased from 830.2 thousand in 2019 to 946.7 thousand in 2024, and is expected to further increase to 1,119.3 thousand in 2033. KRAS G12C mutation alone is present in approximately 13% of all NSCLC cases. The global incidence of CRC increased from 1,849.1 thousand in 2019 to 2,005.2 thousand in 2024, and is expected to further increase to 2,472.6 thousand in 2033. In China, the incidence of CRC increased from 477.1 thousand in 2019 to 542.4 thousand in 2024, and is expected to further increase to 642.0 thousand in 2033. KRAS G12C mutation alone appears in approximately 3-4% of the CRC incidence. For details, see “Business — Core Product GFH925: A Small Molecule Inhibitor of KRAS G12C — Market Opportunity and Competition.”

We are currently focused on the research and development of GFH925 in the Ex-China Territory (i.e. EU and the U.S.) and have not yet formulated a detailed commercialization plan. However, we currently expect GFH925 to be positioned with a competitive pricing strategy in the overseas markets with other approved KRAS G12C inhibitor drugs, leveraging production cost efficiencies anticipated from our second-generation manufacturing process. The pricing of GFH925 outside of Greater China may be affected by differences in national healthcare systems, including pricing mechanisms, insurance reimbursement structures, purchasing power, and R&D expenditures.

SUMMARY

KRAS G12C Inhibitor Drugs Approved Globally

Brand Name	Generic Name	Company	Indication	Treatment Line	Nature of Drug Program	First Approval Time	Route of Administration	Efficacy	Safety	Treatment schedules	Annual Cost ⁽¹⁾ (thousand USD)	Annual Sales (2023)	Reimbursement coverage
捷伯特	Fulzerasib	Innovent/GenFleet	KRAS G12C mutated advanced NSCLC adult patients	2L+	Mono	2024/08/21 (NMPA)	oral	ORR 49.1% DCR 90.5% mPFS 9.7 months OS 13.3 months	SAE 14.0%, TRAEs led to dose reduction 18.3%, drug interruption 32.6%, permanent discontinuation 2.7%	600 mg, BID	31.0	–	No
安方寧	Garosorasib	Chia Tai Tianqing/Inventisbio	KRAS G12C mutated advanced NSCLC adult patients	2L+	Mono	2024/11/08 (NMPA)	oral	ORR 52.0% DCR 88.6% mPFS 9.1 months OS 14.1 months	TRAEs 95.9% TRAEs led to dose reduction 30.1%, drug interruption 41.5%, permanent discontinuation 0%	600 mg, BID	35.0	–	No
艾瑞凱	Glecirasib	Jacobio/Allist	KRAS G12C mutated advanced NSCLC adult patients	2L+	Mono	2025/5/20 (NMPA)	oral	ORR 49.6% DCR 86.3% mPFS 8.2 months OS 13.6 months	TRAEs 97.5% TRAEs led to dose reduction 37.8%, drug interruption 18.5%, permanent discontinuation 5%	800 mg, QD	NA	–	No
Krazati	Adagrasib	BMS	KRAS G12C mutated locally advanced or metastatic NSCLC adult patients	2L+	Mono	2022/12/12 (FDA) 2024/01/05 (EMA)	oral	ORR 42.9% mPFS 6.5 months OS 12.6 months	TRAEs led to dose reduction 28%, drug interruption 77%, permanent discontinuation 13%	600 mg, BID	280.0	126 million USD	
			KRAS G12C mutated metastatic CRC	2L	Combo with cetuximab	2024/06/21 (FDA)		ORR 34% DCR 85.1% mPFS 6.9 months mOS 15.9 months	TRAEs led to dose reduction 35%, drug interruption 62%, permanent discontinuation 2 patients (about 0.02%)				
Lumakras	Sotorasib	Amgen	KRAS G12C mutated locally advanced or metastatic NSCLC adult patients	2L+	Mono	2021/05/28 (FDA) 2022/01/06 (EMA) 2022/01/20 (PMDA)	oral	ORR 37.1% DCR 80.6% mPFS 6.3 months mOS 12.5 months	SAE 14.0%, TRAEs led to dose reduction 5%, drug interruption 34%, permanent discontinuation 9%	960 mg, QD	266.9	350 million USD	
			KRAS G12C mutated metastatic CRC	2L	combo with panitumumab	2025/11/17 (FDA)		ORR 26% mPFS 5.6 months mOS Not Reached	TRAE 45.3%				

Notes:

- (1) The significant differences of annual costs of approved KRAS G12C inhibitor drugs in China and U.S. are due to the differences in healthcare systems between the two countries, including pricing mechanism, insurance payment system, spending power and R&D costs.
- (2) The basis for calculating the annual cost of each drug is: (i) daily dosage based on the recommended dosage in the package insert; (ii) unit price per day based on publicly available drug price; and (iii) treatment duration based on clinical PFS data. The calculation is fair without bias.

While the first commercially-available KRAS G12C inhibitors have shown promising efficacy results, drug resistance and certain side effects including gastrointestinal toxicity have been observed in their clinical applications. GFH925, as a KRAS G12C inhibitor, is not designed or expected to eliminate drug resistance or certain side effects, such as gastrointestinal toxicity, associated with other approved KRAS G12C inhibitor drugs. For details, see “Industry Overview — Overview of RAS Drug Market — Overview of KRAS G12C Drugs.”

Our clinical development of GFH925 has been focused on the GFH925/cetuximab combination therapy as a first-line treatment for patients with advanced NSCLC with KRAS G12C mutations.

SUMMARY

Overview of GFH375

GFH375 is an orally bioavailable small molecule inhibitor of KRAS G12D. KRAS G12D is the most prevalent oncogenic KRAS variant that lacks approved treatment options. It is found in various cancer types, including approximately 35% of pancreatic cancer, 12% of CRC and 4% of NSCLC.

We have overcome the technical challenges to discover GFH375, a small molecule inhibitor that targets KRAS G12D in both “on” and “off” states with a strong, low nanomolar-level binding affinity, as demonstrated in our preclinical studies. GFH375 has also demonstrated preclinical antitumor activity in controlling tumor growth in different animal models. Furthermore, GFH375 differentiates itself from many other product candidates currently under development for KRAS G12D in terms of route of administration. Formulated as a once-daily, orally available treatment instead of requiring infusions, we believe GFH375 could potentially ease repeated drug administration, improve patient compliance, and therefore potentially increase the overall efficacy of the treatment regimen. Notably, multiple cases of antitumor activities have been observed at starting doses.

We are conducting a Phase I/II clinical trial of GFH375 in China to evaluate its safety and efficacy in treating advanced solid tumors with the KRAS G12D mutation and a Phase II clinical trial of GFH375 in China to evaluate its safety and efficacy in treating PDAC with the KRAS G12D mutation. As of the Latest Practicable Date, the Phase I clinical data demonstrated good oral bioavailability and anti-tumor activities of GFH375, with potentially encouraging efficacy in treating multiple tumor types including PDAC and NSCLC. As of the data cutoff date of March 31, 2025, among the 62 patients enrolled, there were no DLTs observed across all dose levels (100-900 mg QD and 300 mg BID), and the TRAEs were mostly Grade 1/2. No TRAE-related deaths were reported. As of the data cutoff date of May 16, 2025, among the 52 patients across all dose levels and indications who received at least one post-treatment tumor assessment (efficacy evaluable): the overall ORR was 38% and DCR was 90%; 38 patients exhibited reduction in target lesion, and 20 patients achieved partial response. According to Frost & Sullivan, GFH375 was one of the most advanced orally bioavailable KRAS G12D inhibitors in the world in terms of development status as of the Latest Practicable Date.

We have granted to our partner Verastem an exclusive license to develop and commercialize GFH375 in territories outside of Greater China. Verastem initiated a Phase I/IIa clinical trial of GFH375 in patients with advanced solid tumors harboring the KRAS G12D mutation in the U.S. in June 2025.

SUMMARY

Addressable Markets and Competitive Landscape of GFH375

The KRAS G12D mutation accounts for approximately 29% of all KRAS mutations, making it the most prevalent variant in human cancers. The KRAS G12D mutation is particularly frequent in pancreatic cancer (approximately 35%), CRC (approximately 12%) and NSCLC (approximately 4%). Compared to the KRAS G12C mutation, the KRAS G12D mutation causes more disruption of intrinsic GTPase activity, resulting in a higher proportion of active GTP-bound KRAS in tumor cells.

As of the Latest Practicable Date, there was no approved KRAS G12D inhibitor drug globally. GFH375 is one of the most advanced orally bioavailable inhibitors of KRAS G12D in terms of development status as of the same date. There were 16 KRAS G12D inhibitor candidates being clinically developed globally as of Latest Practicable Date. For details of the targeted markets of GFH375, see “Industry Overview — Overview of RAS Drug Market — Overview of KRAS G12D Drugs.”

Our clinical development of GFH375 has been focused on GFH375 as a second or later line treatment for patients with PDAC, NSCLC or CRC with KRAS G12D mutations.

RAS MATRIX PIPELINE PRODUCTS

- **GFH276** is a pan-RAS (on) molecular glue. We believe that pan-RAS approaches are differentiated from pan-KRAS approaches that aim to address multiple KRAS mutations at the same time. GFH276 demonstrated potential anti-proliferative activity in cell lines that harbor various mutations in the RAS family members or in cell lines with KRAS G12C that are conferred resistance to sotorasib and adagrasib. We believe GFH276 may exhibit a potentially lower efficacious dose and better tolerability in humans, which underscores the competitiveness of GFH276 as a pan-RAS inhibitor and its potential to benefit the patient population in need. Additionally, available clinical results suggest that some pan-RAS inhibitors may be associated with adverse effects that are related to their comprehensive blockage of RAS proteins. Therefore, pan-RAS inhibitor drug candidates with improved safety profiles may have enhanced therapeutic potentials. For details, see “Industry Overview — Overview of RAS Drug Market — Overview of Pan-RAS Drugs” and “Business — Our RAS Matrix Pipeline Products — GFH276: A Pan-RAS Molecular Glue.”
- **GFS784** is a new molecular modality leveraging synergistic effect of large and small molecules, which we call functional antibody synergistic conjugate (“**FAScon**”), featuring a combination of antibody and small molecule drug targeting separate components of the same signaling pathway. GFS784 is our leading FAScon candidate, consisting of an antibody that blocks EGFR, an upstream cell surface receptor of RAS signal pathway, and a small molecule pan-RAS inhibitor. We believe this design has the potential to deliver promising clinical benefits. For details, see “Business — Our RAS Matrix Pipeline Products — GFS784: EGFR-Pan-RAS Functional Antibody Synergetic Conjugate.”

SUMMARY

SELECTED OTHER PIPELINE PRODUCTS

- **GFH312** is an in-house developed inhibitor of the kinase RIPK1. RIPK1 is a master regulator of the cellular decision between pro-survival signaling and death in response to inflammatory and pro-death stimuli. The unique hydrophobic pocket in the allosteric regulatory domain of RIPK1 has enabled the development of highly selective small molecules of its kinase activity. As RIPK1 plays an important role in driving cell death and inflammation, RIPK1 inhibitors potentially possess broad therapeutic applications for the treatment of a wide range of human diseases, such as autoimmune diseases, inflammatory disorders and neurodegenerative conditions.

The prevalence of PBC reached 1.2 million globally and 291.1 thousand in China in 2024, according to Frost & Sullivan. The global PBC drug market grew from US\$1,004 million in 2019 to US\$1,147.3 million in 2024, and is expected to further grow to US\$1,542.2 million in 2033. China’s PBC drug market grew from US\$235.0 million in 2019 to US\$232.4 million in 2024, and is expected to further grow to US\$284.0 million in 2033. We believe that GFH312 possesses the therapeutic potential to alleviate the root cause of PBC. For details of the targeted markets of GFH312, see “Industry Overview — Overview Of Ripk1 Drug Market.”

We completed a Phase I clinical trial for GFH312 in healthy participants in Australia and China, respectively, achieving the predefined safety and pharmacokinetic objectives. After reviewing results from the Australian Phase I clinical trial, the FDA has granted us approval to commence a Phase II clinical trial of GFH312 for PAD with IC. We are also planning to investigate GFH312 for the treatment of PBC in China. We submitted an IND application for a Phase II clinical trial of GFH312 for the treatment of PBC to the NMPA in March 2025 and obtained NMPA’s approval in May 2025. We plan to initiate a Phase II clinical trial of GFH312 for the treatment of PBC in the first half of 2026.

- **GFS202A** is a novel bispecific antibody targeting both GDF15 and IL-6, two important cytokines that play crucial roles in inflammatory processes, metabolic regulation, cancer progression and cachexia. Cachexia is a common, life-threatening wasting condition that can significantly impact quality of life in affected patients with cancer or other types of chronic diseases. As of the Latest Practicable Date, there had been no FDA- or NMPA-approved drug specifically for the treatment of cachexia, according to Frost & Sullivan. As overexpression of GDF15 and IL-6 is associated with cachexia development and poor survival, we believe a dual neutralization of GDF15 and IL-6 may potentially achieve a better activity compared to targeting GDF15 alone. For details, see “Business — Other Pipeline Products — GFS202A: A Novel Bispecific Antibody Targeting GDF15 and IL-6 as a Potential Treatment of Cachexia.”
- **GFH009** is a selective small molecule compound that targets CDK9 and inhibits the activity of the CDK9/cyclin T1 complex. CDK9, a serine/threonine kinase, plays crucial roles in tumor growth. GFH009 is designed as a potential treatment for multiple types of hematological malignancies. It received from the FDA the orphan drug designation

SUMMARY

(“**ODD**”) and the fast track designation (“**FTD**”) in October 2023 and January 2024, respectively, for the treatment of acute myeloid leukemia (“**AML**”). We also forged collaborations with SELLAS, which has significant expertise in hematological malignancies and solid tumors, on GFH009.

- **GFH018** is a small-molecule inhibitor of TGF- β R1. Elevated expression of TGF- β signaling genes is linked to various solid tumors. Results from a Phase I clinical trial in patients with advanced solid tumors in Mainland China demonstrated potentially favorable safety and preliminary efficacy profiles of GFH018.

STRENGTHS

We believe the following strengths differentiate us from our competitors:

- Comprehensive innovative drug portfolio addressing RAS
- Core Product GFH925, the first approved selective inhibitor of KRAS G12C in China with a favorable safety and efficacy profile and considerable market potential
- Core Product GFH375, an orally bioavailable small molecule inhibitor of KRAS G12D with the potential to target both active and inactive forms of KRAS
- Key Product GFH312, a small molecule inhibitor of RIPK1 that possesses broad therapeutic applications for the treatment of autoimmune diseases, inflammatory disorders and neurodegenerative conditions
- A powerhouse with a suite of integrated research and development platforms, and CMC expertise to accelerate drug development and facilitate cost control
- Seasoned discovery and development leadership team with successful first-to-market drug experiences

STRATEGIES

We plan to pursue the following significant opportunities and execute our key strategies accordingly:

- Advance our Core Products through global clinical development
- Advance and replenish our other innovative product pipeline with a focus on the comprehensive RAS pathway product matrix
- Execute global strategy through broad and diverse collaborations in commercialization arrangements, business development and pipeline development

SUMMARY

RESEARCH AND DEVELOPMENT

As of the Latest Practicable Date, 48 members of our R&D team had obtained advanced degrees, including 13 members with doctorate degrees and 35 members with master’s degrees. Our R&D team has strong expertise, deep understanding and broad development experience, and is led by a team of world-class scientists with years of drug development experience. Our core R&D personnel consists of six members covering the fields of chemistry, biology, pharmacology and medicine. All of our core R&D personnel have been working in the pharmaceutical industry for over 15 years. Our drug discovery team members also have expertise in the fields of chemistry, biology, pharmacology and medicine, which support our product development. For details, see “Business — Research and Development — R&D team.”

We aspire to leverage our industry experience and established R&D capabilities to develop new and effective treatment options in the fields of oncology, autoimmune and inflammatory diseases. During our endeavor, we have established and leveraged a proven, integrated research and development platform spanning target discovery, molecular discovery and evaluation, translational science and clinical development. Our technological capabilities include discovery of original molecular structures and new molecular entities, investigation of molecular process routes and quality standards, as well as exploration of clinical drug combination development paths. Combining these internally accumulated capabilities and external resources of our collaborators and service providers, we have rendered our pipeline products among the frontrunners in both China and the global market.

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 business focus, capabilities and overall market recognition.

For the years ended December 31, 2023 and 2024 and the four months ended April 30, 2024 and 2025, we recorded R&D expenses of RMB312.7 million, RMB332.1 million and RMB142.3 million and RMB69.8 million, respectively, representing 86.2%, 85.1%, 91.1% and 74.7% of our total operating expenses (defined as the sum of R&D expenses and administrative expenses) in the corresponding periods, respectively. We anticipate to continue to significantly invest in our R&D efforts, since we plan to expand the indications and continue the clinical development of our Core Products, advance more pipeline candidates along clinical trials and conduct additional preclinical studies.

For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, we recorded major items of research and development costs attributable to our Core Products, namely GFH925 and GFH375, of RMB121.1 million, RMB143.3 million and RMB78.1 million, and RMB27.2 million, respectively, representing 38.7%, 43.1%, 54.9% and 39.0% of our total research and development costs in the corresponding periods, respectively. For details, see “Financial Information — Research and Development Costs.”

SUMMARY

CHEMISTRY, MANUFACTURING & CONTROLS

As of the Latest Practicable Date, our CMC team consisted of 15 professionals with extensive experience in process development, production and quality management from well-known biopharmaceutical and pharmaceutical companies. Our CMC team members have on average approximately 11 years’ experience. Our CMC team specialized in preclinical and clinical support throughout the drug development process. The CMC function in our Company 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 quality meets regulatory requirements.

We have established CMC capabilities that covers key aspects from the design of synthetic routes for preclinical candidates to process development and quality control in clinical development. We have in-depth expertise in areas including small molecule production process development, dosage form selection, formulation determination, formulation process development, drug quality control strategies, development and validation of quality control methodologies, non-GMP kilogram-scale pilot production, and NDA-stage process validation.

Our CMC functions facilitate a smooth drug development and enables cost control. In particular, we develop suitable process and ensure quality control according to applicable drug registration regulations at early stages of product development. This strategy enables us to avoid detours in subsequent development stage resulted from CMC issues that could have been addressed earlier in the process, therefore may improve the overall efficiency of our research and development efforts. In addition, our CMC process development capabilities allow us to device efficient synthetic routes and establish measures to ensure consistent and reliable production, thereby contribute to cost control and efficient use of resources. We are able to significantly lower the manufacturing cost of GFH925 by optimizing the process route, and we believe our CMC expertise also facilitated GFH925 to receive marketing approval in China in merely approximately three years after it obtained IND approval. We are also actively developing the second-generation manufacturing process for GFH925, taking full responsibility for the entire process, including vendor selection. We have engaged two vendors to collaborate on this initiative. We anticipate that the second-generation manufacturing process will significantly enhance the cost-efficiency of drug production. We believe that possessing core competency in CMC expertise will enable us to ensure the safety and quality of the drug supply while positioning us to independently pursue ex-China regulatory approvals and capitalize on potential commercial opportunities for GFH925 once the necessary regulatory milestones are obtained.

As of the Latest Practicable Date, we did not have in-house manufacturing facility. We currently plan to establish our own manufacturing facilities to support the formulation production of certain of our pipeline products. We collaborate with CDMOs to conduct and support our preclinical and clinical trials in line with industry practice. In terms of the involvement and contributions of each of the major CDMO partners to the development of our product candidates, we collaborate with our CDMO partners to manufacture certain raw materials and drug substances, such as the active pharmaceutical ingredients (“APIs”) of our product candidates to supply for preclinical studies and clinical trials. We did not experience any material product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period.

SUMMARY

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we held 72 issued patents and 117 patent applications (including 8 PCT applications). As of the Latest Practicable Date, we held (i) 2, 1, 1 and 8 issued patents related to GFH925 in China, the U.S., the E.U. and in other overseas jurisdictions respectively, and (ii) 5, 4, 3, 1 and 21 patent applications related to GFH925 in China, the U.S., the E.U., under the PCT and in other overseas jurisdictions, respectively. As of the same date, we have not received issued patents related to GFH375, but held 2, 1, 1, 1 and 22 patent applications related to GFH375 in China, the U.S., the E.U., under the PCT and in other overseas jurisdiction, respectively. We currently plan to file patent application related to GFH375 in Hong Kong in the second half of 2025 and in Macau after the receipt of the issued patent in China. As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that makes us to believe that any of the pending patent applications will be finally rejected. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our Core Products and significant clinical and preclinical product candidates as of the Latest Practicable Date:

Products	Name of Patent Family ⁽¹⁾	Jurisdiction	Status	Patent Application	Grant Date	Patent Expiration ⁽²⁾	Type	Owner/Applicant	Inventor ⁽³⁾
GFH925	Substituted Heterocyclic Fused Cyclic Compound, Preparation Method Therefor and Pharmaceutical Use Thereof	China, United States, EPO	Granted	2020-10-28	China: 2022-8-5; United States: 2024-8-6; EPO: 2024-10-9	2040-10-28	Invention	GenFleet, GenFleet Zhejiang	Fusheng Zhou, Tao Jiang, Chonglan Lin, Lijian Cai, Wan He, Jiong Lan
		China, United States, EPO	Pending		–	–	Invention	GenFleet, GenFleet Zhejiang	
	Polymorph of KRAS Inhibitor, Preparation Method Therefor, and Use Thereof	China, United States, EPO	Pending	2022-12-23	–	–	Invention	GenFleet, GenFleet Zhejiang	Fusheng Zhou, Jinzhu Zhao, Yudong Cao, Lun Xiong, Rongzhen Shi, Jiong Lan
	Pharmaceutical Composition, Use Thereof, and Method for Treating Cancer	China, United States, EPO	Pending	China: 2023-03-30; United States: 2023-03-31	–	–	Invention	GenFleet, GenFleet Zhejiang	Lili Tang, Xiang Yu, Jingyang Zhang, Huizhong Hu, Fusheng Zhou, Yu Wang, Jiong Lan, Qiang Lu
	Pharmaceutical Composition, and Preparation Method Therefor and Use Thereof	China, United States, EPO	Pending	2023-9-20	–	–	Invention	GenFleet	Yuanyuan Xie, Lina Qi, Can Huang, Jiong Lan, Qiang Lu

SUMMARY

Products	Name of Patent Family ⁽¹⁾	Jurisdiction	Status	Patent Application	Grant Date	Patent Expiration ⁽²⁾	Type	Owner/Applicant	Inventor ⁽³⁾
	Method for Preparation of Pyrazine-Naphthyridine Diketones and Intermediates Thereof	PCT	Pending	2024-8-15	–	–	Invention	GenFleet	Jin Zhu Zhao, Yudong Cao, Lun Xiong, Xiong Wei, Xiangchao Liu, Mengting Meng, Fusheng Zhou, JingRong Li, Jiong Lan, Qiang Lu
GFH375	Pyrimidine-Fused Ring Compound, and Preparation Method Therefor and Use Thereof	China, United States	Pending	2023-9-25	–	–	Invention	GenFleet, GenFleet Zhejiang	Tao Jiang, Fusheng Zhou, Tao Liang, Chonglan Lin, Lijian Cai, Zhuo Liu, Xiaoming Xu, Kai Ma, Leitao Zhang, Zhen Li, Jiong Lan
GFH312	Dihydronaphthyridinone Compound, and Preparation Method Therefor and Medical Use Thereof	China	Granted	2021-2-9	2024-2-9	2041-2-9	Invention	GenFleet, GenFleet Zhejiang	Fusheng Zhou, Xiaoming Xu, Leitao Zhang, Xin Li, Lili Tang, Jiong Lan
	Crystal Form of RIPK1 Inhibitor, Acid Salt Thereof, and Crystal Form of Acid Salt Thereof	United States, China, United States	Pending, Pending	2022-8-2	–	–	Invention	GenFleet, GenFleet Zhejiang	Fusheng Zhou, Yuanzhi Tao, Jin Zhu Zhao, Jiong Lan
GFH276	Macrocyclic Compounds, and Preparation Method Therefor and Use Thereof	PCT	Pending	2024-8-30	–	–	Invention	GenFleet	Jichen Zhao, Fusheng Zhou, Tao Liang, Yandong Lu, Tao Jiang, Chonglan Lin, Ling Peng, Jiong Lan, Qiang Lu
GFH009 ⁽⁴⁾	Inhibitor of Cyclin-Dependent Kinase CDK9	China, United States	Granted	China: 2017-4-19; United States: 2018-1-3	China: 2020-6-19; United States: 2021-3-23	China: 2037-4-19; United States: 2038-1-3	Invention	GenFleet, GenFleet Zhejiang	Gang Zhou
GFH018 ⁽⁴⁾	Benzotriazole-Derived α And β -Unsaturated Amide Compound Used as TGF- β R1 Inhibitor	China, United States	Granted	2017-6-8	China: 2021-2-26; United States: 2020-2-4	2037-6-8	Invention	GenFleet, GenFleet Zhejiang	Fei Sun, Lifang Wu, Charles Z. Ding, Guoping Hu, Jian Li, Shuhui Chen, Jianyu Lu

Abbreviations: PCT = Patent Cooperation Treaty; EPO = European Patent Office

SUMMARY

Notes:

- (1) Unless otherwise indicated, the name of patents and patent applications within the same family is the same and is therefore disclosed once.
- (2) The patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.
- (3) All the inventors of the patents and patent applications listed in this table were employees of the Group when the related inventions were conceived, except for the patents relating to GFH009 and GFH018, because these patents were transferred from third parties. As of the Latest Practicable Date, we have no dispute with these inventors regarding the ownership and disposition rights of the patents and patent applications listed in this table.
- (4) The U.S. patents in connection with GFH009 and GFH018, as listed in the table, are owned by GenFleet only.

We have identified that certain issued patents in China belonging to third parties appear to cover the chemical structure of GFH925 and may not expire before the anticipated commercial launch of GFH925 in China. To proactively manage any potential risks from these patents, we have entered into two license agreements with third party holders of such patents in China, to ensure activities relating to GFH925 in target markets will not be hindered by these patents. Pursuant to the two license agreements, we are required to make a total of RMB34.5 million to these third party patent holders, which has been fully paid as of the date of the document, and mid-teens royalties tied to the achievement of specific regulatory, commercialization milestones and receipt of royalties of GFH925 in Greater China to one of the patent holders. Such mid-teens royalties is contingent on our receipt of regulatory, commercial milestone payments and royalty payments from sublicensees (Innovent is currently the only sublicensee). As a result of such licensing agreements, we have pre-empted potential issues over GFH925 in China with those third-party patent holders, whose patents in China would not affect our freedom to operate GFH925 and its future commercialization in China, as advised by our IP counsel as to the PRC intellectual property laws. We are also aware of a U.S. patent whose claim scope is excessively broad and appears to cover the chemical structure formed by GFH925 bonded to certain residue of KRAS protein, which is a desired functional characteristic of GFH925. However, the U.S. patent may be subject to validity challenges, and therefore its potential impact on the freedom to operate GFH925 in the U.S. is low. For details, please see “Business — Intellectual Property.”

We conduct our business under the brand name of “GenFleet” and/or “勁方.” As of the Latest Practicable Date, we held five registered trademarks in Mainland China and three registered trademarks in Hong Kong. We are also the owner of eight registered software copyrights and one domain name. 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. For for information about our intellectual properties, please see “Business — Intellectual Property.”

SUMMARY

MAJOR COLLABORATION AND LICENSING ARRANGEMENTS

We have successfully entered into multiple cooperation and licensing agreements with domestic and international partners to accelerate the development and maximize the commercial value of our product portfolio. For details, see “Business — Major Collaboration and Licensing Arrangements.”

License Agreement with Innovent

On September 1, 2021, we entered into a license and option agreement (the “**GFH925 License Agreement**”) with Innovent. According to the GFH925 License Agreement, we grant to Innovent (i) an exclusive, royalty-bearing and sublicensable license to develop and commercialize GFH925 for the treatment, prevention or diagnosis of any disease in humans in Mainland China, Hong Kong, Macau and Taiwan (the “**Greater China**”); and (ii) an exclusive option (the “**Ex-China Option**”) to develop and commercialize GFH925 in the all countries and regions in the world other than Greater China (the “**Ex-China Territory**”). Prior to entering into the GFH925 License Agreement, we proactively identified and finalized the arrangement details with the lead principal investigator. Innovent later supported the clinical collaboration by expanding the trial from the eight clinical sites we initially arranged to a total of 55 clinical sites. After signing of the GFH925 License Agreement, Innovent became the sponsor of the GFH925X1101 trial in China and is thereafter solely responsible for the development and commercialization of GFH925 in the Greater China region. Also, Innovent is the marketing authorization holder (“MAH”) of GFH925 in Greater China. However, we retain a critical role in managing the CMC-related processes, including overseeing process development, finalizing agreements with key stakeholders, and selecting suitable vendors to ensure smooth trial execution. Innovent will pay our Company for the drug supply on an ongoing basis, with payments determined by the quantity required to support the trial’s development needs. On January 11, 2024, we further entered into a supplementary agreement (the “**GFH925 Supplementary Agreement**,” together with the GFH925 License Agreement, the “**Innovent Agreement**”) with Innovent. According to the GFH925 Supplementary Agreement, both parties agreed to terminate the Ex-China Option under the GFH925 License Agreement. We have the exclusive rights to develop, manufacture and commercialize GFH925 for any indication in the Ex-China Territory. As of the Latest Practicable Date, we had paid US\$2.0 million to Innovent under the GFH925 Supplementary Agreement. The remaining termination fees payment of US\$18.0 million will be paid in two installments by December 2026.

For additional information, please see “Business — Major Collaboration and Licensing Arrangements — License Agreement with Innovent” and “Business — Major Collaboration and Licensing Arrangements — Supplementary Agreement with Innovent.”

SUMMARY

Collaboration and Option Agreement with Verastem

On August 24, 2023, we entered into a collaboration and option agreement (the “**Verastem Agreement**”) with Verastem, pursuant to which, on a program-by-program basis, we granted Verastem options (the “**Verastem Option(s)**”) to acquire an exclusive license to develop and commercialize three product candidates, including GFH375, in territories outside of Greater China within the specified option exercise period. Verastem agreed to pay an upfront payment, certain development costs, as well as stipulated milestone payments, option exercise fees and royalties on future annual net sales. In January 2025, Verastem exercised the option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China.

For additional information, see “Business — Major Collaboration and Licensing Arrangements — Collaboration and Option Agreement with Verastem.”

License Agreement with SELLAS

On March 31, 2022, we entered into a license agreement (the “**SELLAS License Agreement**”) with SELLAS. Pursuant to the SELLAS License Agreement, we granted SELLAS an exclusive (even to ourselves), sublicensable and royalty-bearing right and license to develop, manufacture and commercialize GFH009 across all therapeutic and diagnostic uses worldwide outside of Greater China (Mainland China, Hong Kong, Macau and Taiwan).

On October 13, 2022, we entered into a clinical supply agreement supplement to the SELLAS License Agreement (the “**SELLAS Supplementary Agreement**”) with SELLAS.

According to the SELLAS Supplementary Agreement, we will manufacture and supply GFH009 in the applicable formulations as specified in each purchase order to SELLAS. We will ensure that we deliver GFH009 in conformation with the specifications, and regulatory standards (the “**Manufacturing Requirements**”). SELLAS will provide a purchase order to us every six months, specifying the quantity, formulations, and requested delivery dates.

For additional information, please see “Business — Major Collaboration and Licensing Arrangements — License Agreement with SELLAS” and “Business — Major Collaboration and Licensing Arrangements — Supplementary Agreement with SELLAS.”

SUMMARY

Collaboration and Supply Agreement with Merck

On June 30, 2022, we entered into a clinical trial collaboration and supply agreement (the “**Merck Agreement**”) with Merck Healthcare KGaA in relation to the clinical development of the GFH925/cetuximab combination therapy for a Phase Ib/II clinical trial (i.e., GFH925X0201) in the European Union. According to the Merck Agreement, Merck is obligated to provide cetuximab for the use in the clinical trial to us with a maximum number of 3,500 vials and schedule specified in the Merck Agreement according to the clinical trial status and subject to mutual agreement between Merck and our Company. Our Company shall bear all other costs associated with the subject clinical trial. The Merck Agreement does not affect our status as the sole sponsor of or our sole responsibility to conduct the KROCUS trial. The Merck Agreement does not provide for a joint steering committee. The Merck Agreement stipulates that all rights to all inventions that are directed to the combination therapy and variants thereof, except those inventions solely relating to GFH925 or cetuximab, shall be jointly owned by Merck and our Company. Those inventions solely relating to GFH925 or cetuximab shall be solely owned by GenFleet or Merck, respectively.

For additional information, please see “Business — Major Collaboration and Licensing Arrangements — Merck Agreement.”

CUSTOMERS

In 2023 and 2024 and the four months ended April 30, 2025, our revenue was mainly generated from three customers relating to multiple performance obligations including (1) grants of licenses to intellectual property rights, (2) the research and development services and (3) the supply of drugs in 2024. We generally grant a credit term of 30 days to 60 days from the first day of the following month after receipt of invoice to our customers. Neither of them is our supplier.

To the best of our knowledge, the two customers during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates or any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of the two customers during the Track Record Period. For additional information, please see “Business — Our Customers.”

SUMMARY

SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of CROs and CDMOs and we did not experience any material disputes with our suppliers. In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies. We generally have credit periods of 30 days. For the years ended December 31, 2023 and 2024 and the four months ended April 30, 2024 and 2025, our purchases from our five largest suppliers in each year/period in aggregate amounted to RMB94.1 million, RMB114.7 million, RMB26.9 million and RMB34.0 million respectively, representing 44.4%, 45.7%, 47.5% and 41.7% of our total corresponding purchases, and our purchases from the largest supplier in each period accounted for 11.3%, 13.3%, 17.1% and 11.6% of our total corresponding purchases, respectively.

All of our five largest suppliers in each year/period during the Track Record Period are Independent Third Parties. None of our Directors or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED], nor any of their respective associates had any interest in any of our five largest suppliers in each year/period during the Track Record Period. In 2023, we engaged 5 CROs and 15 CDMOs, for which we incurred expenses of RMB52.7 million and RMB86.1 million, respectively. In 2024, we engaged 5 CROs and 10 CDMOs, for which we incurred expenses of RMB42.5 million and RMB89.4 million, respectively. The decrease in the expenses incurred for engaging CROs and the number of engaged CDMOs were primarily due to the changed needs of many of our R&D projects. In the four months ended April 30, 2025, we engaged 5 CROs and 10 CDMOs, for which we incurred expenses of RMB12.9 million and RMB29.2 million, respectively. For additional information, please see “Business — Our Suppliers.”

OUR SHAREHOLDING STRUCTURE

Our Single Largest Group of Shareholders

Our Single Largest Group of Shareholders comprises Dr. Lu, Dr. Lan, GenFleet HK, and our ESOP Platforms. As of the Latest Practicable Date, GenFleet HK was held as to 53.69% by Dr. Lu and 46.31% by Dr. Lan. Pursuant to a concert party agreement dated March 25, 2022 entered into between Dr. Lu, Dr. Lan, GenFleet HK, Shanghai Kunjin, Shanghai Kunjue and Auspicious Delight, they acknowledged and confirmed their relationship of acting in concert in exercising the rights of the Shareholders and Directors of the Company. In the event the parties are unable to reach consensus on matters of our Company, each of the parties shall act in accordance with the instructions of Dr. Lu.

SUMMARY

As of the Latest Practicable Date, our Single Largest Group of Shareholders controlled approximately 25.23% of our total issued share capital. Immediately following the completion of the [REDACTED] (assuming that the [REDACTED] and the [REDACTED] are not exercised), our Single Largest Group of Shareholders will control approximately [REDACTED]% of our total issued share capital.

[REDACTED] Investments

We completed several rounds of [REDACTED] Investments since our inception with an aggregate amount of approximately RMB1,421 million raised. Our [REDACTED] Investors include established funds and venture capitals, such as HighLight Capital, Huagai Capital and Asia Investment Capital. For further details of the identity and background of the [REDACTED] Investors and the principal terms of the [REDACTED] Investments, see “History, Development and Corporate Structure — [REDACTED] Investments.” Our Sophisticated Investor which made meaningful investment to us include Ourea Biotech, which will hold approximately [REDACTED]% of our total issued share capital upon the completion of the [REDACTED] (assuming that the [REDACTED] and the [REDACTED] are not exercised).

SUMMARY OF KEY FINANCIAL INFORMATION

This summary of key financial information set forth below have been derived from, and should be read in conjunction with, our historical financial information, 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 “Financial Information” of this Document. Our historical financial information was prepared in accordance with IFRSs.

Summary of Consolidated Statements of Profit or Loss

The following table sets forth our consolidated statements of profit or loss for the periods indicated:

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			(unaudited)	
			(RMB in thousands)	
REVENUE	73,734	104,703	—	82,149
Cost of sales	<u>(684)</u>	<u>(20,095)</u>	<u>—</u>	<u>(8,693)</u>

SUMMARY

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
	<i>(unaudited)</i>			
	<i>(RMB in thousands)</i>			
Gross profit	73,050	84,608	–	73,456
Other income and gains	39,964	28,531	6,534	6,122
Research and development costs	(312,738)	(332,124)	(142,262)	(69,818)
Administrative expenses	(49,946)	(58,081)	(13,881)	(23,684)
Other expenses	(176)	(10)	(2)	(3)
Finance costs	(1,485)	(17,963)	(13,615)	(2,005)
Loss before change in fair value of redemption liabilities on equity shares	(251,331)	(295,039)	(163,226)	(15,932)
Change in fair value of redemption liabilities on equity shares	(256,993)	(382,602)	(241,461)	(50,692)
LOSS BEFORE TAX	(508,324)	(677,641)	(404,687)	(66,624)
Income tax expense	–	–	–	–
LOSS FOR THE YEAR/PERIOD	(508,324)	(677,641)	(404,687)	(66,624)
Attributable to:				
Owners of the parent	(508,324)	(677,641)	(404,687)	(66,624)

We recorded net losses of RMB508.3 million and RMB677.6 million for the years ended December 31, 2023 and 2024, respectively, and net losses of RMB404.7 million and RMB66.6 million for the four months ended April 30, 2024 and 2025, respectively. Our net losses recorded and the fluctuations during the Track Record Period were primarily in relation to: (i) our substantial investment in research and development activities, and (ii) the change in fair value of redemption liabilities on equity shares due to the increase in value of our Company.

Developing quality drug candidates requires significant investments of financial resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, we have invested a significant amount of financial resources in research and development to advance and expand our pipeline of clinical- and preclinical-stage drug candidates. The research and development costs we incurred for the years ended December 31, 2023 and 2024 and the four months ended April 30, 2024 and 2025 amounted to RMB312.7 million, RMB332.1 million, RMB142.3 million and RMB69.8 million, respectively.

SUMMARY

Our research and development costs increased from RMB312.7 million for the year ended December 31, 2023 to RMB332.1 million for the year ended December 31, 2024, primarily due to an increase of RMB28.8 million in others, primarily attributable to an one-time payment of RMB28.8 million under the patent licensing agreements, and was partially offset by a decrease of RMB9.2 million in staff costs. Our research and development costs decreased from RMB142.3 million for the four months ended April 30, 2024 to RMB69.8 million for the four months ended April 30, 2025, primarily due to incurred expenses of RMB45.4 million on termination of Ex-China option and RMB18.9 million under the patent licensing agreements, each in the first four months of 2024. No such costs incurred in the first four months of 2025.

Our change in fair value of redemption liabilities on equity shares increased from RMB257.0 million for the year ended December 31, 2023 to RMB382.6 million for the year ended December 31, 2024, primarily due to the increase in value of our Company. Our change in fair value of redemption liabilities on equity shares decreased from RMB241.5 million for the four months ended April 30, 2024 to RMB50.7 million for the four months ended April 30, 2025, primarily due to the moderate growth in value of our Company.

During the Track Record Period, our revenue was derived from our collaboration with Innovent regarding our Core Product GFH925, Verastem regarding our Core Product GFH375, and SELLAS regarding GFH009. For additional information about the relevant agreements, see “Business — Major Collaboration and Licensing Arrangements.” Most of the revenue that we recognized during the Track Record Period was generated from licenses of intellectual property under such collaboration and out-licensing arrangements. We also generated a small portion of revenue from provision of research and development services, clinical and regulatory support in connection with the collaboration with SELLAS, including medical monitoring, data management, statistics and regulatory document preparation. The following table sets forth components of our revenue.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Licenses of intellectual property	71,779	90,035	—	80,742
Sales of goods	—	14,668	—	127
Research and development services	1,955	—	—	1,280
Total	73,734	104,703	—	82,149

For details, see “Financial Information — Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income.”

SUMMARY

Summary of Consolidated Statements of Financial Position

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

	As of December 31,		As of April 30,
	2023	2024	2025
	<i>(RMB in thousands)</i>		
Total non-current assets	85,390	38,573	35,465
Total current assets	450,744	568,248	545,215
Total current liabilities	1,832,107	2,493,429	2,525,029
Net Current Liabilities	(1,381,363)	(1,925,181)	(1,979,814)
Total assets less current liabilities	(1,295,973)	(1,886,608)	(1,944,349)
Total non-current liabilities	21,338	69,653	69,290
Net liabilities	(1,317,311)	(1,956,261)	(2,013,639)

During the Track Record Period, we had net liabilities position, which was primarily due to the significant total comprehensive loss for the year/period in each year/period of the Track Record Period caused by the significant redemption liabilities on equity shares and research and development costs we incurred in each year/period of the Track Record Period. The increase of net liabilities from RMB1,956.3 million as of December 31, 2024 to RMB2,013.6 million as of April 30, 2025 was primarily due to the loss for the period year of RMB66.6 million mainly driven by the research and development costs we incurred and an increase in fair value of the Shares held by [REDACTED] Investors. The increase of net liabilities from RMB1,317.3 million as of December 31, 2023 to RMB1,956.3 million as of December 31, 2024 was primarily due to the loss for the year of RMB677.6 million mainly driven by the research and development costs we incurred and an increase in fair value of the Shares held by [REDACTED] Investors. Upon the [REDACTED], we expect to record equity shares issued in connection with [REDACTED] Investments as equity and do not expect to recognize any redemption liabilities on these equity shares, or recognize any future loss or gains in connection with such redemption liabilities on our consolidated statements of profit or loss and other comprehensive income. We therefore expect to have a net current asset and net asset position rather than a net current liability and net liability position upon the [REDACTED].

The increase of net current liabilities by RMB543.8 million from RMB1,381.4 million as of December 31, 2023 to RMB1,925.2 million as of December 31, 2024 was primarily driven by an increase of (i) redemption liabilities on equity shares by RMB577.6 million, (ii) trade and other payables of RMB98.9 million from the payables under the termination of the ex-China option and (iii) interest-bearing bank borrowings of RMB45.8 million, partially offset by an increase of (i) time deposits and cash and cash equivalents of RMB62.7 million and (ii) trade receivables of RMB36.8 million as well as a decrease in contract liabilities of RMB59.7

SUMMARY

million, primarily attributable to the termination in January 2024 of the ex-China option previously granted to Innovent for GFH925, as well as the recognition of contractual obligations under the Verastem Agreement following the receipt of payments in 2024.

Our net current liabilities as of April 30, 2025 remained relatively stable and increased by 2.8% to RMB1,979.8 million, primarily due to the increase of interest-bearing bank borrowings of RMB34.0 million and redemption liabilities on equity shares by RMB50.7 million, partially offset by a decrease in trade and other payables of RMB22.3 million and contract liabilities of RMB29.9 million.

Summary of Consolidated Statements of Cash Flows

The following table sets forth key items of our consolidated statements of cash flows for the periods indicated:

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Net cash used in operating activities	(202,060)	(206,400)	(136,945)	(34,045)
Net cash flows from/(used in) investing activities	263,443	730	(122,716)	33,140
Net cash flows from/(used in) financing activities	(29,059)	233,438	204,905	28,182
Net increase in cash and cash equivalents	32,324	27,768	(54,756)	27,277
Cash and cash equivalents at beginning of year/period . . .	295,321	332,197	332,197	362,125
Effects of foreign exchange rate changes, net	4,552	2,160	585	1,364
Cash and cash equivalents at end of year/period	<u>332,197</u>	<u>362,125</u>	<u>278,026</u>	<u>390,766</u>

During the Track Record Period, we incurred negative cash flows from our operations and our operating cash outflows mainly resulted from our research and development costs. Our operating activities used RMB202.1 million and RMB206.4 million for the years ended December 31, 2023 and 2024 and RMB136.9 million and RMB34.0 million for the four months ended April 30, 2024 and 2025, respectively. For details, see “Financial Information — Liquidity and Capital Resources — Cash Flows.”

SUMMARY

Key Financial Ratios

The table below sets forth the current ratio of our Group as of the dates indicated:

	As of December 31,		As of April 30,
	2023	2024	2025
Current ratio ⁽¹⁾	0.25	0.23	0.22

Note:

(1) Current ratio equals current assets divided by current liabilities as of the end of the year/period.

WORKING CAPITAL CONFIRMATION

During the Track Record Period, we incurred negative cash flows from our operations and our operating cash outflows mainly resulted from our research and development costs. Our operating activities used RMB202.1 million and RMB206.4 million in 2023 and 2024 and RMB136.9 million and RMB34.0 million for the four months ended April 30, 2024 and 2025, respectively. We expect to generate more cash flow from our operating activities, through income from launching and commercializing GFH925, forging productive collaboration agreements with third parties, advancing the development and eventually commercializing GFH925 overseas and other pipeline products, and enhancing our cost containment capacity and operating efficiency.

Our Directors are of the opinion that, taking into account the financial resources available, including cash and cash equivalents, the expected income from commercialization of GFH925 in China, and the estimated net [REDACTED] from the [REDACTED], as well as our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses for at least the next 12 months from the date of this Document.

Our cash burn rate refers to the average monthly amount of net cash used in operating activities, capital expenditures and lease payments. Assuming an average cash burn rate going forward of 1.1 times the level in 2024, we estimate that our cash at bank and on hand and other financial assets as of September 30, 2025 will be able to maintain our financial viability for [REDACTED] from September 30, 2025 taking into account the estimated net [REDACTED] from the [REDACTED]; or we estimate that we will be able to maintain our financial viability for [REDACTED] from September 30, 2025 without taking into account the estimated net [REDACTED] from the [REDACTED]. 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.

SUMMARY

[REDACTED]

SUMMARY

DIVIDEND

We have never declared or paid any dividends on our ordinary shares or any other securities. As of the Latest Practicable Date, we did not have a formal dividend policy. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not intend to declare or pay any dividends in the foreseeable future. [REDACTED] should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Directors subject to our Articles of Association and the PRC Company Law, and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. As confirmed by our PRC Legal Advisor, 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.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] or [REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] in this Document. We intend to use the net [REDACTED] we will receive from this [REDACTED] for the following purposes:

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund the clinical development of our Core Product GFH925;
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund the clinical development of our Core Product GFH375;
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund the further development of our other candidates including GFH312, GFS202A, GFH276, GFS784 and other preclinical product candidates in our pipeline; and

SUMMARY

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used for our working capital and other general corporate purposes.

For further details, see “Future Plans and Use of [REDACTED].”

RISK FACTORS

We are developing our Core Products and other product candidates in highly competitive markets with intense competition from multi-national and domestic pharmaceutical companies with multiple approved drugs and similar drug candidates at similar or more advanced clinical stages. For more details, see “Risk Factors — We face competition from existing drugs and drug candidates under development.”

Our licensing and collaboration agreements with partners may lead to uncertainties on the development and commercialisation of certain product candidates, because these agreements allowed our partners to control certain aspects of the development, commercialization, and patenting process of the product candidates. Especially, our receipt of development or commercialization milestone payments from our partners will depend upon their development and commercialization efforts, which are beyond our control and may be uncertain.

We believe that there are certain other risks involved in our operations, many of which are beyond our control. These risks are set out in the section headed “Risk Factors” in this document. Some of the major risks we face include:

- Our business and financial prospects depend substantially on the success of our pipeline products. If we are not able to successfully complete clinical development, obtain regulatory approval and commercialize our pipeline products, including our Core Products, or experience delays in doing so, our business prospects could be adversely affected.
- We may face intellectual property risks relating to third-party patents in China and the U.S. that appear to cover GFH925. While we have secured licenses from relevant Chinese patent holders to mitigate such risks, potential challenges from a broadly scoped U.S. patent remain, though our IP counsel assesses its impact on our freedom to operate in the U.S. as low. If we or our collaborators are unable to obtain and maintain adequate patent and other intellectual property protection for our pipeline products throughout the selected markets in the world, our ability to successfully commercialize our pipeline products may be adversely affected.
- We rely on our current and future collaborators’ willingness and ability to devote resources to the development and commercialization of our Core Products and other pipeline products and to otherwise support our business as contemplated in our collaboration agreements.

SUMMARY

- We may not receive some or all of the potential milestone and/or royalty payments from our collaboration and licensing agreements.
- We work with various third-party service providers to develop our pipeline products. If these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to obtain regulatory approvals for, or commercialize, our pipeline products, and our business, financial condition and results of operations could be materially and adversely affected.
- We face competition from existing drugs and drug candidates under development.
- Development of product candidates in combination with other therapies could expose us to additional risks.
- The regulatory approval processes for pharmaceutical products are time consuming and depend on numerous factors, and if we are ultimately unable to obtain regulatory approval for our pipeline products, our business could be substantially harmed.
- We depend on third parties to provide a stable and adequate supply of investigational drugs for our research and development efforts and supply of APIs for future commercial sales. Any disruptions of or significant price increases in such supply could adversely affect our business.
- The size of the actual markets for our pipeline products may be smaller than our estimates and our pipeline products may not be able to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for their commercial success.
- We may not be able to protect our intellectual property rights or prevent unfair competition by third parties.
- We may become subject to intellectual property infringement claims, which could expose us to substantial liability, harm our reputation, limit our research and development or other business activities and/or impair our ability to commercialize our product candidates.
- We are a biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.
- Any failure to comply with applicable laws and regulations and industry standards or obtain various licenses and permits could harm our reputation, business, financial condition, results of operations and prospects.

SUMMARY

[REDACTED] EXPENSES

Our [REDACTED] expenses represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. Assuming an [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED], we estimated that the total [REDACTED] expenses for the [REDACTED] are approximately HK\$[REDACTED], accounting for approximately [REDACTED] of the gross [REDACTED] from the [REDACTED] (assuming no H Shares are issued pursuant to the [REDACTED] or the [REDACTED]), of which approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss and other comprehensive income upon the completion of [REDACTED], and approximately HK\$[REDACTED] is expected to be accounted for as a deduction from equity upon the completion of [REDACTED]. The above expenses comprise of (i) [REDACTED] expenses, including [REDACTED] and other expenses, of HK\$[REDACTED]; and (ii) [REDACTED] expenses of HK\$[REDACTED] million, including (a) fee paid and payable to legal advisors and reporting accountants of HK\$[REDACTED], and (b) other fees and expenses of HK\$[REDACTED]. HK\$[REDACTED] of [REDACTED] expenses has been recognized in profit or loss during the Track Record Period. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS

Clinical Development

In August 2024, the NMPA approved the NDA for GFH925 for the treatment of NSCLC, making it the first KRAS G12C inhibitor approved in Mainland China and the third globally. We also initiated the Phase I/II clinical trial of GFH375 in July 2024. Among the 33 patients that have received administration of GFH375, antitumor activities have already been observed at the starting dosage. We completed the Phase I part of GFH375’s clinical trial in January 2025 and initiated the Phase II part in February 2025. In addition, we submitted an IND application for a Phase II clinical trial of GFH312 for the treatment of PBC to the NMPA in March 2025 and obtained NMPA’s approval in May 2025.

Expected Increased in Net Loss

We expect to record an increase in net loss for the year ending December 31, 2025 due to (i) a decrease in the recognized revenue from licenses of intellectual property, (ii) an increase in expenses in connection with the [REDACTED] incurred in 2025 and (iii) an increase in R&D expenses in line with the R&D activities. However, we have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

SUMMARY

Progress in Chemistry, Manufacturing and Controls

We are advancing the development of the second-generation manufacturing process for GFH925 and are fully responsible for all aspects of the process, including vendor selection. We have completed internal research, evaluation, and validation of the new process, which utilizes more cost-efficient starting materials and achieves higher yields compared to the first-generation process, resulting in improved cost control. We have directed our vendor to submit a post-marketing manufacturing process change application to the provincial drug regulatory authority in May 2025. This application is expected to be completed by the end of 2025, after which we anticipate an improvement in the current loss-making status of our drug supply due to the adoption of the second-generation manufacturing process.

We expect the second-generation process to substantially enhance the cost-efficiency of production. We believe that our CMC capabilities not only ensure drug safety and quality but also position us to independently pursue regulatory approvals outside of China and unlock future commercial opportunities for GFH925 as key regulatory milestones are achieved.

During the Track Record Period, the costs incurred in fulfilling drug supply arrangements for GFH925 exceeded the corresponding revenue from the sale of GFH925, mainly because production was based on the first-generation CMC process, which had a higher cost profile than the selling price to Innovent. We expect the cost of sales to be significantly reduced once the second-generation CMC process is successfully implemented. However, before that occurs, we expect to continue sell GFH925 at a gross loss in 2025 to Innovent. Such gross loss is expected to increase for the remainder of 2025 should our sales of GFH925 to Innovent increase.

It is of the Directors’ view that the continuous loss making transaction for sales of GFH925 to Innovent will not have a material adverse impact to the Group’s financial and operation, because it is necessary for us to develop second-generation CMC process for R&D and eventually, commercialization purposes, in Ex-China Territory, and we anticipate an improvement in the current loss-making status after the adoption of the second-generation manufacturing process in 2026.

For detailed discussion of our CMC capabilities, see “Business — Chemistry, Manufacturing and Controls (“CMC”)”. For discussion of our financial results related to the CMC, see “Financial Information — Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income — Cost of Sales.”

SUMMARY

Impact of COVID-19

During the Track Record Period and up to the Latest Practicable Date, we had not experienced material disruptions in our operations as a result of COVID-19. During the COVID-19 pandemic, we maintained operational continuity through remote work arrangements across our offices.

Through effective coordination with our CRO and CDMO partners across various locations, we sustained the smooth progress of our research activities and achieved key regulatory milestones. As COVID-19’s global impact continued to lessen as of the Latest Practicable Date, our Directors do not expect COVID-19 to have a material adverse impact on our business going forward. See also “Risk Factors —Risks Relating to Our Operations — We may be subject to disasters, health epidemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business.”

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, operational or trading positions or prospects since April 30, 2025, being the end of the period reported on as set out in the Accountants’ Report included in Appendix I to this Document.

DEFINITIONS

In this Document, unless the context otherwise requires, the following terms shall have the meanings set out below. Certain other terms are explained in the section headed “Glossary of Technical Terms” in this Document.

“2024 ASCO Cut-off Date”	April 19, 2024, the cut-off date for the purpose of reporting preliminary result of the KROCUS Study in 2024 ASCO Annual Meeting
“Accountants’ Report”	the accountants’ report prepared by Ernst & Young, details of which are set out in Appendix I
“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”	the Accounting and Financial Reporting Council of Hong Kong
“Articles of Association” or “Articles”	the articles of association of our Company, as amended, which shall become effective on the [REDACTED], a summary of which is set out in Appendix III
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Audit Committee”	the audit committee of the Board
“Auspicious Delight”	Auspicious Delight Limited, a limited liability company incorporated in the BVI on May 25, 2018, a member of our Single Largest Group of Shareholders and an ESOP Platform of our Group
“Board” or “our Board”	the board of Directors
“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
“BVI”	British Virgin Islands

[REDACTED]

DEFINITIONS

[REDACTED]

“CDE”	Center for Drug Evaluation (藥品審評中心) of NMPA
“Chairman”	chairman of the Board
“Chief Executive Officer”	chief executive officer of our Company
“Chief Medical Officer”	chief medical officer of our Company
“China”, “Mainland China” or “PRC”	the People’s Republic of China which, for the purpose of this Document and for geographical reference only, excluding Hong Kong Special Administrative Region of the People’s Republic of China, Macau Special Administrative Region of the People’s Republic of China, and Taiwan Region
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules
“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
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) as amended, supplemented or otherwise modified from time to time
“Company”, “our Company”, “the Company”, or “GenFleet”	GenFleet Therapeutics (Shanghai) Inc. (勁方醫藥科技(上海)股份有限公司), a company incorporated in the PRC as a limited liability company on August 23, 2017 and converted into a joint stock company with limited liability on September 29, 2024
“Competent Authority”	has the meaning ascribed thereto under Chapter 18A of the Listing Rules
“Compliance Advisor”	Guotai Junan Capital Limited
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“connected transaction(s)”	has the meaning ascribed thereto under the Listing Rules

DEFINITIONS

“Core Product(s)”	has the meaning ascribed thereto under Chapter 18A of the Listing Rules and are the products for the purpose of satisfying the eligibility requirements under Chapter 18A of the Listing Rule
“Corporate Governance Code”	the Corporate Governance Code set out in Appendix C1 to the Listing Rules
“CSCO”	Chinese Society of Clinical Oncology
“CSRC”	the China Securities Regulatory Commission (中國證券監督管理委員會)
“Director(s)” or “our Director(s)”	the director(s) of our Company
“Dr. Lan”	Dr. Jiong LAN, our co-founder, executive Director, Chief Executive Officer and General Manager, and a member of our Single Largest Group of Shareholders
“Dr. Lu”	Dr. Qiang LU, our co-founder, Chairman, executive Director, and a member of our Single Largest Group of Shareholders
“EIT”	the PRC enterprise income tax
“EIT Law”	the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), as amended, supplemented or otherwise modified from time to time
“EMA”	the European Medicines Agency
“ESOP Platform(s)”	Shanghai Kunjin, Shanghai Kunjue, Shanghai Kunqian and Auspicious Delight
“EU”	European Union
“EU IP Counsel”	2K Patent- und Rechtsanwälte — München, our IP counsel as to the laws of European Patent Convention (“EPC”) and the national patent laws of EPC contracting countries

[REDACTED]

DEFINITIONS

“Extreme Conditions” extreme conditions caused by a super typhoon as announced by the government of Hong Kong

“FDA” U.S. Food and Drug Administration

[REDACTED]

“General Manager” general manager of our Company

[REDACTED]

“GenFleet Australia” GENFLEET THERAPEUTICS (AUSTRALIA) PTY LTD, a limited liability company incorporated in Australia on July 15, 2020 and one of our Company’s subsidiaries

“GenFleet Beijing” GenFleet Therapeutics (Beijing) Co., Ltd. (勁方(北京)醫藥科技有限公司), a limited liability company established under the laws of the PRC on February 22, 2022 and one of our Company’s subsidiaries

“GenFleet Hangzhou” GenFleet Therapeutics (Hangzhou) Co., Ltd. (勁方藥業(杭州)有限公司), a limited liability company established under the laws of the PRC on September 26, 2023 and one of our Company’s subsidiaries

“GenFleet HK” GenFleet Therapeutics (H.K.) Limited (健發藥業(香港)有限公司), a limited liability company incorporated in Hong Kong on March 15, 2017 and a member of the Single Largest Group of Shareholders

“GenFleet Shanghai” GenFleet Biopharmaceutical (Shanghai) Co., Ltd. (勁方生物醫藥(上海)有限公司), a limited liability company established under the laws of the PRC on March 30, 2021 and one of our Company’s subsidiaries

DEFINITIONS

“GenFleet U.S.”	GenFleet Therapeutics Inc., a limited liability company incorporated in Delaware, the United States on April 13, 2020 and one of our Company’s subsidiaries
“GenFleet Zhejiang”	Zhejiang GenFleet Therapeutics Co., Ltd. (浙江勁方藥業有限公司), a limited liability company established under the laws of the PRC on April 8, 2018 and one of our Company’s subsidiaries
“GenFleet Zhuhai”	GenFleet Therapeutics (Zhuhai) Co., Ltd. (勁方藥業(珠海)有限公司), a limited liability company established under the laws of the PRC on November 1, 2023 and one of our Company’s subsidiaries
“GFH925X1101”	A Phase I/II clinical trial to evaluate safety, tolerability, PK and efficacy in patients with advanced solid tumors with KRAS G12C mutations in Mainland China sponsored by Innovent and originally initiated by us
	[REDACTED]
“Group”, “our Group”, “our”, “we” or “us”	our Company and our subsidiaries
“Guide for New Listing Applicants”	the Guide for New Listing Applicants issued by the Hong Kong Stock Exchange, as amended, supplemented or otherwise modified from time to time
“H Share(s)”	overseas [REDACTED] foreign share(s) in the share capital of our Company with a nominal value of RMB[REDACTED] each, which is/are to be subscribed for and [REDACTED] in HK dollars and to be [REDACTED] on the Stock Exchange
	[REDACTED]
“HighLight Capital”	an investment firm operating Ourea Biotech, a Sophisticated Investor, details of which are set out under “History, Development and Corporate Structure — [REDACTED] Investments — Information about our [REDACTED] Investors — HighLight Capital”

DEFINITIONS

“HK\$” or “Hong Kong Dollars” or “HK Dollars” and “HK cents” Hong Kong dollars, the lawful currency of Hong Kong

[REDACTED]

“Hong Kong” or “HK” the Hong Kong Special Administrative Region of the PRC

[REDACTED]

“Hong Kong Stock Exchange” or “Stock Exchange” The Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchange and Clearing Limited

DEFINITIONS

“Hong Kong Takeovers Code” or “Takeovers Code” the Codes on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time

[REDACTED]

“Independent Third Party(ies)” any entity(ies) or person(s) who is not a connected person of our Company within the meaning of the Hong Kong Listing Rules

“Innovent” Innovent Biologics, Inc., a limited liability company incorporated in the Cayman Islands in 2011 and listed on the Hong Kong Stock Exchange (stock code: 1801) and/or any of its subsidiaries, where the case may be

[REDACTED]

DEFINITIONS

“KROCUS” or “GFH925X0201” A Phase Ib/II trial to evaluate the safety, tolerability, PK, and efficacy of GFH925 in combination with cetuximab in patients with previously untreated advanced NSCLC harboring KRAS G12C mutation sponsored by us

[REDACTED]

“Latest Practicable Date” August 18, 2025, being the latest practicable date for the purpose of ascertaining certain information contained in this Document prior to its publication

[REDACTED]

“Listing Committee” the listing committee of the Hong Kong Stock Exchange

[REDACTED]

“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

“M&A Rules” the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》)

“Main Board” the stock exchange (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

DEFINITIONS

“MOFCOM” or “Ministry of Commerce”	the Ministry of Commerce of the PRC (中華人民共和國商務部) (formerly known as the Ministry of Foreign Trade and Economic Cooperation of the PRC (中華人民共和國對外經濟貿易部))
“Ms. Zhang”	Ms. ZHANG Wei (張巍), an executive Director, the secretary to the Board and a joint company secretary of our Company
“NDRC”	the National Development and Reform Commission (中華人民共和國國家發展和改革委員會)
“NHC”	the National Health Commission (formerly known as the National Health and Family Planning Commission) (中華人民共和國國家衛生健康委員會)
“NMPA”	the National Medical Products Administration of China (國家藥品監督管理局) or, where the context so requires, its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局), or CFDA
“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]

“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
“PRC and U.S. IP Counsel”	JunHe LLP and Jun He Law Offices P.C., our IP counsel as to the PRC and U.S. intellectual property law
“PRC Company Law”	Company Law of the People’s Republic of China (中華人民共和國公司法)
“PRC GAAP”	generally accepted accounting principles in the PRC
“PRC Legal Advisor”	Jia Yuan Law Offices, our legal advisor on PRC laws in connection with the [REDACTED]
“[REDACTED] Equity Incentive Scheme”	the [REDACTED] equity incentive plan of our Company approved and adopted in 2020 as amended and restated in July 2023
“[REDACTED] Investment(s)”	the investment(s) in our Group undertaken by the [REDACTED] Investors prior to this [REDACTED], the details of which are set out in “History, Development and Corporate Structure”
“[REDACTED] Investor(s)”	the investor(s) making investments in our Group prior to this [REDACTED] as set out in “History, Development and Corporate Structure — [REDACTED] Investments”

[REDACTED]

DEFINITIONS

[REDACTED]

“QIB”	a qualified institutional buyer within the meaning of Rule 144A
“Regulation S”	Regulation S under the U.S. Securities Act
“Remuneration Committee”	the remuneration committee of the Board
“Renminbi” or “RMB”	the lawful currency of the PRC
“Reporting Accountants”	Ernst & Young, the reporting accountants of our Company
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“SAMR”	the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局), the successor of the State Administration of Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局)
“SAT”	the State Taxation Administration of the PRC (中華人民共和國國家稅務總局)
“SELLAS”	SELLAS Life Sciences Group, Inc., a company headquartered in New York and listed on NASDAQ (stock code: SLS)
“SFC”	the Securities and Futures Commission of Hong Kong
“SFO” or “Securities and Futures Ordinance”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong, as amended, supplemented or otherwise modified from time to time
“Shanghai Kunjin”	Shanghai Kunjin Consulting Partnership (Limited Partnership) (上海坤勁企業管理諮詢合夥企業(有限合夥)), a limited partnership established in the PRC on April 2, 2021, a member of our Single Largest Group of Shareholders and an ESOP Platform of our Group of which Dr. Lu is the sole general partner

DEFINITIONS

“Shanghai Kunjue”	Shanghai Kunjue Consulting Partnership (Limited Partnership) (上海坤覺企業管理諮詢合夥企業(有限合夥)), a limited partnership established in the PRC on October 13, 2017, a member of our Single Largest Group of Shareholders, a limited partner of Shanghai Kunjin, and an ESOP Platform of our Group
“Shanghai Kunqian”	Shanghai Kunqian Consulting Partnership (Limited Partnership) (上海坤前企業管理諮詢合夥企業(有限合夥)), a limited partnership established in the PRC on March 26, 2021, a member of our Single Largest Group of Shareholders, a limited partner of Shanghai Kunjin, and an ESOP Platform of our Group
“Shanghai Stock Exchange”	the Shanghai Stock Exchange (上海證券交易所)
“Share(s)”	ordinary share(s) in the share capital of our Company with a nominal value of RMB[REDACTED] each upon the completion of the [REDACTED]; before the completion of the [REDACTED], ordinary share(s) in the share capital of our Company with a nominal value of RMB1.0 each
	[REDACTED]
“Shareholder(s)”	holder(s) of our Share(s)
“Shenzhen Stock Exchange”	the Shenzhen Stock Exchange (深圳證券交易所)

DEFINITIONS

“Single Largest Group of Shareholders” refers to Dr. Lu, Dr. Lan, GenFleet HK, and our ESOP Platforms

“Sole Sponsor” the sole sponsor of the [REDACTED] as named in “Directors, Supervisors and Parties Involved in the [REDACTED]”

[REDACTED]

“Sophisticated Investor(s)” has the meaning ascribed to it under Chapter 2.3 of the Guide for New Listing Applicants

[REDACTED]

“State Council” the State Council of the PRC (中華人民共和國國務院)

“subsidiary(ies)” has the meaning ascribed to it in section 15 of the Companies Ordinance

“substantial shareholder(s)” has the meaning ascribed to it under the Listing Rules

“Supervisor(s)” supervisor(s) of the Company

“Supervisory Committee” the committee of the Supervisors

“Track Record Period” the period comprising the financial years ended December 31, 2023 and 2024 and the four months ended April 30, 2025

“U.S. Government” the federal government of the United States, including its executive, legislative and judicial branches

“U.S. persons” U.S. persons as defined in Regulation S

“U.S. Securities Act” United States Securities Act of 1933, as amended, supplemented or otherwise modified from time to time

[REDACTED]

DEFINITIONS

[REDACTED]

“United States”, “USA” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“Unlisted Share(s)”	ordinary share(s) issued by our Company, with a nominal value of RMB[REDACTED] each (taking into account the [REDACTED]), which is/are not listed on any stock exchange
“US\$” or “U.S. dollars”	United States dollars, the lawful currency of the United States
“VAT”	value-added tax
“Verastem”	Verastem, Inc., a company headquartered in Massachusetts and listed on NASDAQ (stock code: VSTM)

[REDACTED]

“%” per cent

Certain amounts and percentage figures included in the Document have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them.

For ease of reference, the names of Chinese laws and regulations, governmental authorities, institutions, natural persons or other entities (including our subsidiary) have been included in this Document in both the Chinese and English languages and in the event of any inconsistency, the Chinese versions shall prevail. English translations of company names and other terms from the Chinese language are provided for identification purposes only.

GLOSSARY OF TECHNICAL TERMS

This glossary contains explanations of certain technical terms used in this Document in connection with our Group and its business. Such terminology and meanings may not correspond to standard industry meanings or usages of those terms.

“AEs”	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“AESIs”	adverse events of special interest, AEs of scientific and medical concern specific to the sponsor’s product
“AKT”	a serine/threonine protein kinase with three isoforms (AKT1, AKT2 and AKT3) that participate in multiple pathways regulating several cellular processes, including survival, proliferation, tissue invasion, and metabolism
“AML”	acute myeloid leukemia, a cancer that affects bone marrow and blood
“antibody”	also known as an immunoglobulin, a protein used by the immune system to recognize and bind an antigen
“API”	active pharmaceutical ingredient
“apoptosis”	a form of programmed cell death in which a programmed sequence of events leads to the elimination of cells
“ATP”	adenosine triphosphate, an organic compound and hydrotrope that provides energy to drive many processes in living cells
“BID”	twice-daily administration
“BIW”	twice-weekly administration
“BOR”	best overall response that the participant or patient has had at any visit during the study
“BTD”	Breakthrough Therapy Designation, a process designed to expedite the development and review of drugs that are intended to treat a serious condition

GLOSSARY OF TECHNICAL TERMS

“CAGR”	compound annual growth rate
“CDK”	cyclin-dependent kinases, a family of protein kinases regulating the cell cycle, also involved in regulating transcription, mRNA processing, and the differentiation of nerve cells
“CDMO”	contract development and manufacturing organization, a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“CDX”	cell line-derived xenograft
“DLT”	dose-limiting toxicity, side effects of a drug that are serious enough to prevent an increase in dose
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
“clinical trial/study”	a research study carried out in human for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs
“CLL/SLL”	chronic lymphocytic leukaemia/small lymphocytic lymphoma, a type of cancer in which the bone marrow makes too many lymphocytes
“CMC”	chemistry, manufacturing and controls
“CMO”	contract 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
“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”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease

GLOSSARY OF TECHNICAL TERMS

“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“CRC”	colorectal cancer, the development of cancer from the colon or rectum
“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
“CRR”	complete response rate, the proportion of patients who achieve a complete response to a treatment
“CSF”	cerebrospinal fluid, a clear, colorless, watery fluid that flows in and around your brain and spinal cord
“CTIS”	Clinical Trials Information System, a system maintained by EMA to support interactions throughout the lifecycle of a clinical trial
“CypA”	cyclophilin A, a ubiquitously distributed protein belonging to the immunophilin family
“DCR”	disease control rate, the proportion of patients who have achieved either a complete response, partial response, or stable disease after treatment
“DLBCL”	diffuse large B-cell lymphoma, a type of non-Hodgkin lymphoma characterized by the rapid growth of large B cells in lymphoid tissue
“DoR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“ERK”	extracellular signal-regulated kinase, a key protein in the mitogen-activated protein kinase signaling pathway
“EGFR”	epidermal growth factor receptor, a cell surface protein that plays a key role in cellular signaling and growth
“FADD”	Fas-associated death domain protein, a key adapter protein that plays a crucial role in apoptosis

GLOSSARY OF TECHNICAL TERMS

“FAScon”	functional antibody synergetic conjugate, a type of bioconjugate consisting of an antibody attached with another functionally synergistic molecule through a linker, such as a drug or a toxin, to enhance its efficacy in targeting cellular signaling pathways
“FGFR”	fibroblast growth factor receptor, a family of receptor tyrosine kinases that play a critical role in cell growth, differentiation, and tissue repair
“fibrosis”	a condition marked by increase of interstitial fibrous tissue
“right of first to file”	a contractual right granting one party the first opportunity to file patent or other intellectual property applications related to jointly developed or collaborative inventions. Exercising such right allows the right holder to lead the filing process, including decisions on timing, jurisdiction, and scope. It does not preclude the other party from retaining ownership or usage rights, which are typically defined separately in the collaboration agreement. If the right holder declines or chooses not to file, the other party may be permitted to lead the filing process, subject to agreed terms
“FLIP”	FADD-like IL-1 β -converting enzyme — inhibitory protein, a protein that plays a crucial role in regulating apoptosis and inflammation; it mainly has two isoforms, FLIP(S), the short isoform, and FLIP(L), the long isoform
“FTD”	Fast Track Designation
“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“GMP”	good manufacturing practice, the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of products

GLOSSARY OF TECHNICAL TERMS

“Grade,” which is in relation to AE	term used to refer to the severity of adverse events according to Common Terminology Criteria for Adverse Events (CTCAE), using Grade 1, Grade 2, Grade 3, etc.
“GDP”	guanosine diphosphate, a nucleotide that plays a significant role in cellular metabolism and signaling; it is composed of a guanine base, a ribose sugar, and two phosphate groups
“GTP”	guanosine triphosphate, a nucleotide that serves as an essential energy source and signaling molecule in various biological processes; it is composed of a guanine base, a ribose sugar, and three phosphate groups
“GTPase”	guanosine triphosphatase, an enzyme that catalyzes the hydrolysis of GTP to GDP and inorganic phosphate
“HRAS”	Harvey RAS, a member of the RAS family proteins
“IARC”	International Agency for Research on Cancer
“IC”	intermittent claudication, a disease characterized by pain, cramping, or heaviness in the legs or buttocks
“IC ₅₀ ”	half-inhibitory concentration
“immunodeficiency”	a state in which the immune system’s ability to fight infectious diseases and other invaders is compromised or absent
“immunotherapy”	use of the immune system to treat disease
“IMPD”	investigational medicinal product dossier, a document that provides information about a drug intended for use in clinical trials
“indication”	a specific condition, disease, or medical purpose for which a drug, treatment, or medical device is intended or approved for use
“ <i>in vitro</i> ”	studies that are performed with microorganisms, cells, or biological molecules outside their normal biological context

GLOSSARY OF TECHNICAL TERMS

“ <i>in vivo</i> ”	studies in which the effects of various biological entities are tested on whole, living organisms or cells, usually animals, including humans, and plants, as opposed to a tissue extract or dead organism
“IND”	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials
“irAEs”	immune-related adverse events, adverse events that occur as a result of immunotherapies
“KRAS”	Kirsten RAS, a member of the RAS family proteins
“lines of treatment”	different methods to treating cancer at different stages, such first-line, second-line, third-line etc.
“LUSC”	lung squamous cell carcinoma, a type of NSCLC characterized by the uncontrolled growth of squamous cells in the lung lining
“MAD”	multiple ascending dose, a type of clinical study designed to evaluate a drug after administering multiple doses over a specific period
“MAPK”	mitogen-activated protein kinase, a family of proteins involved in transmitting signals from cell surface receptors to the nucleus
“MCL1”	myeloid cell leukemia 1, a member of the B-cell lymphoma 2 family of proteins, which are crucial regulators of apoptosis
“MEK”	MAPK/ERK, a key protein kinase that plays a crucial role in the MAPK signaling pathway
“metastatic”	in reference to any disease, including cancer, disease-producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
“mechanism of action”	the specific biochemical interaction through which a drug substance produces its pharmacological effect

GLOSSARY OF TECHNICAL TERMS

“MLKL”	mixed lineage kinase domain like pseudokinase, a protein that plays a crucial role in the process of necroptosis, a form of programmed cell death distinct from apoptosis
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“MSC”	member state concerned, a country that is involved in a regulatory process within the context of the European Union
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
“multi-regional clinical trial”	a clinical trial that is conducted in different regions under a common trial design for simultaneous global new drug development
“NCC”	National Cancer Center
“NCCN”	National Comprehensive Cancer Network
“NDA”	new drug application, a process required by an regulatory authority to approve a new drug for sale and marketing
“NF- κ B”	nuclear factor kappa B, a key transcription factor that plays a crucial role in regulating immune response, inflammation, cell proliferation, and survival
“NRAS”	neuroblastoma RAS, a member of the RAS family proteins
“NSCLC”	non-small-cell lung carcinoma, any carcinoma (as an adenocarcinoma or squamous cell carcinoma) of the lungs that is not a small-cell lung carcinoma
“ODD”	Orphan Drug Designation
“ORR”	overall response rate, the proportion of patients who have a partial or complete response to therapy
“OS”	overall survival, a length of time that a patient with a specific disease is still alive, used as a measurement of a drug’s effectiveness

GLOSSARY OF TECHNICAL TERMS

“P-TEFb”	positive transcription elongation factor b, a crucial protein complex involved in the regulation of transcription elongation during gene expression
“PAD”	peripheral artery disease, a circulatory condition characterized by narrowed arteries
“PBC”	primary biliary cholangitis, an autoimmune liver disease resulting from a slow, progressive destruction of the intra-hepatic small bile ducts
“PCT”	Patent Cooperation Treaty, an international patent law treaty that provides a unified procedure for filing patent applications in its contracting states
“PD”	pharmacodynamics, the branch of pharmacology concerned with the effects of drugs and the mechanism of their action
“PD-1”	programmed death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages, acting 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
“PD-L1”	programmed death-ligand 1, a protein on the surface of a normal cell or a cancer cell that attaches to PD-1 on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“PDAC”	pancreatic ductal adenocarcinoma, a type of exocrine pancreatic cancer that develops from cells lining small tubes in the pancreas called ducts and accounts for over 90% of all pancreatic cancer cases
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works

GLOSSARY OF TECHNICAL TERMS

“Phase I clinical trial(s)”	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 I clinical trials can be divided into Phase Ia and Phase Ib clinical trials. Phase Ia typically involves dose-escalation studies, while Phase Ib generally focuses on combination therapy or dose-expansion studies
“Phase II clinical trial(s)”	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 clinical trial(s)”	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
“PI3K”	phosphoinositide 3 kinase, an important signaling pathway for many cellular functions such as growth control, metabolism and translation initiation
“PK”	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
“PMDA”	Pharmaceuticals and Medical Devices Agency of Japan
“PO”	per os, the Latin for “by mouth”
“PR”	partial response, a decrease in the size of a tumor or the extent of cancer in the body following treatment, but not a complete disappearance of the disease
“PI”	principal investigator, a key individual responsible for the overall design, conduct, and management of clinical trials

GLOSSARY OF TECHNICAL TERMS

“placebo”	a medical treatment or preparation with no specific pharmacological activity
“preclinical studies”	studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“primary endpoint”	the main or most important outcome at the end of a study to assess the effect of the drug being investigated
“PTCL”	peripheral T-cell lymphoma, a group of hematologic malignancies that arise from mature T-cells and natural killer cells
“QD”	once-daily administration
“QT interval”	a measurement made on an electrocardiogram used to assess some of the electrical properties of the heart
“QW”	once weekly administration
“R&D”	research and development
“RA”	rheumatoid arthritis, an inflammatory autoimmune disorder that primarily affects the joints
“RAF”	rapidly accelerated fibrosarcoma, a group of kinases that play a crucial role in the MAPK/ERK signaling pathway
“RALGDS”	Ral guanine nucleotide dissociation stimulator, a protein that functions as a guanine nucleotide exchange factor for RalA and RalB
“RAS”	rat sarcoma, a family of proteins that are critical regulators of cellular signaling pathways; it primarily includes HRAS, KRAS, and NRAS
“RDE”	recommended dose for expansion, the dosage of a drug that is suggested for use in clinical trials, particularly during the phase of expanding a treatment
“refractory”	disease or condition that does not respond to treatment

GLOSSARY OF TECHNICAL TERMS

“relapsed”	a patient initially responds to drug treatment, but the disease subsequently returns after a period of improvement or remission
“RIPK”	receptor-interacting serine/threonine-protein kinase, a family of serine/threonine kinases that play a significant role in apoptosis, necroptosis and inflammation
“RLBP1”	retinaldehyde-binding protein 1, a protein that plays a crucial role in the visual cycle
“RMS”	reporting member state
“RP2D”	recommended Phase II dose, the dosage of a drug that is suggested for use in Phase II clinical trials
“RTK”	receptor tyrosine kinase, a subclass of cell surface receptors that play a crucial role in cellular communication and signaling
“SAD”	single ascending dose, a clinical trial design used primarily to assess a drug by administering a single dose that gradually increases
“SAE”	serious adverse event
“SD”	stable disease, a situation where a patient’s cancer does not significantly worsen or improve after treatment
“SM”	substantial modification of the materials submitted through the CTIS
“SMO”	site management organization, an organization that provides clinical trial related services to a company or a clinical site
“ $t_{1/2}$ ”	half-life, the time required for the concentration to fall to 50% of its peak value
“TEAE”	treatment emergent adverse event, adverse events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment

GLOSSARY OF TECHNICAL TERMS

“TGA”	Therapeutic Goods Administration of Australia
“TGF- β ”	transforming growth factor- β , a multifunctional cytokine that signals through the binding with its receptors and plays a critical role in various cellular processes
“TGF- β R”	transforming growth factor- β receptor
“T _{max} ”	time of maximum concentration, the time point after administration of a drug at which the highest concentration of the drug is observed in the bloodstream or target tissue
“TNF- α ”	tumor necrosis factor- α , a cytokine that plays a central role in inflammation and immune responses
“TNFR1”	tumor necrosis factor receptor 1
“TRAE”	treatment-related adverse event, undesirable events not present prior to medical treatment or an already present event that worsens in intensity or frequency as a result of the treatment
“TTR”	time to response, the duration from the initiation of treatment to the first observable response in a patient
“UDCA”	ursodeoxycholic acid, a bile acid that is used primarily in the treatment of certain liver and gallbladder diseases

FORWARD-LOOKING STATEMENTS

We have included in this Document forward-looking statements. Statements that are not historical facts, including but not limited to statements about our intentions, beliefs, expectations or predictions for the future, are forward-looking statements.

This Document contains forward-looking statements and information relating to us and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this Document, the words “aim,” “anticipate,” “aspire,” “believe,” “could,” “expect,” “going forward,” “intend,” “may,” “ought to,” “plan,” “project,” “schedule,” “seek,” “should,” “target,” “vision,” “will,” “would,” and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements. 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 risk factors as described in “Risk Factors” and elsewhere in this Document, some of which are beyond our control and may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing us which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our operations and business prospects;
- future developments, trends and conditions in the industries and markets in which we operate or plan to operate;
- general economic, political and business conditions in the markets in which we operate, including but not limited to interest rates, foreign exchange rates;
- changes to the regulatory environment in the industries and markets in which we operate;
- our ability to maintain relationship with, and the actions and developments affecting, our major business partners, suppliers and future customers;
- our ability to maintain the market leading positions and the actions and developments of our competitors;
- our ability to effectively control costs and operating expenses;
- the ability of business partners to perform in accordance with contractual terms and specifications;
- our ability to retain senior management and key personnel and recruit qualified staff;

FORWARD-LOOKING STATEMENTS

- our business strategies and plans to achieve these strategies, including our drug development plans, commercialization strategies and geographic expansion plans; and
- all other risks and uncertainties described in “Risk Factors”.

By their nature, certain disclosures relating to these and other risks are only estimates and should one or more of these uncertainties or risks, among others, materialize, actual results may vary materially from those estimated, anticipated or projected, as well as from historical results. Specifically but without limitation, sales could decrease, costs could increase, capital costs could increase, capital investment could be delayed and anticipated improvements in performance might not be fully realized.

Subject to the requirements of applicable laws, rules and regulations, we do not have any and undertake no obligation to update or otherwise revise the forward-looking statements in this Document, whether as a result of new information, future events or otherwise. As a result of these and other 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 information. All forward-looking statements in this Document are qualified by reference to the cautionary statements in this section as well as the risks and uncertainties discussed in the section headed “Risk Factors” in this Document.

In this Document, statements of or references to our intentions or those of our Directors are made as of the date of this Document. Any such information may change in light of future developments.

RISK FACTORS

An [REDACTED] in our H Shares involves various risks. You should carefully consider all the information in this Document and in particular the risks and uncertainties described below before making an [REDACTED] in our H Shares. In particular, we are a biopharmaceutical company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the biopharmaceutical industry involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our H Shares. The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the [REDACTED] price of our H Shares could decline, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-looking Statements” in this Document. You should seek professional advice from your relevant advisors regarding your prospective [REDACTED] in the context of your particular circumstances.

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 the development, clinical trials and regulatory approval of our pipeline products, (ii) risks relating to dependence on third parties, (iii) risks relating to commercialization and manufacturing of our pipeline products; (iv) risks relating to our intellectual property rights; (v) risks relating to our financial position, (vi) risks relating to our operations, (vii) risks relating to doing business in jurisdictions where we operate and (viii) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also have a material adverse effect on our business, financial condition, results of operations and prospects. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

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RISKS RELATING TO THE DEVELOPMENT, CLINICAL TRIALS AND REGULATORY APPROVAL OF OUR PIPELINE PRODUCTS

Our business and financial prospects depend substantially on the success of our pipeline products. If we are not able to successfully complete clinical development, obtain regulatory approval and commercialize our pipeline products, including our Core Products, or experience delays in doing so, our business prospects could be adversely affected.

While one of our Core Products, GFH925, has received NDA approval from the NMPA, as of the Latest Practicable Date, our other drug candidates and GFH925 in jurisdictions outside China had not been approved for commercialization. We believe our future revenue and profitability will substantially depend on our ability to complete the development of our drug candidates, obtain requisite regulatory approvals and successfully manufacture and commercialize our drug candidates. We have invested a significant portion of our efforts and capital resources in the development of our existing drug candidates, and we expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future. However, development of new drugs, including developing our Core Products GFH375 in Greater China and GFH925 in overseas markets, can be time-consuming and costly, and the outcome may be uncertain. The success of our drug candidates will depend on several factors, including:

- successful enrollment 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;
- receipt of regulatory approvals;
- establishing sufficient manufacturing capabilities to ensure supply for clinical use and future commercialization, either by building facilities ourselves or making arrangements with third-party manufacturers;
- our ability to effectively and simultaneously design, manage and supervise a number and range of clinical trials in multiple jurisdictions;
- our ability to reach agreements on acceptable terms with prospective third-party service providers, such as CROs, and trial sites, the terms of which can be subject to negotiation and may vary among different third-party service providers and trial sites;
- the performance by contract research organizations, or CROs, or other third parties we may retain of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;

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- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- successfully launching our drug candidates, if and when approved;
- obtaining favorable reimbursement from third-party payors for drugs, if and when approved;
- competition with other products and drug candidates;
- continued acceptable safety profile following regulatory approval; and
- obtaining sufficient supplies of any drug products that may be necessary for use in clinical trials for evaluation of our drug candidates in combination with such drug products.

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

We are focused on development and commercialization of new drugs for the treatment of oncology and inflammatory-related diseases, and we have explored multiple modalities in the exploration process. A substantial part of our pipeline programs are therapies targeting RAS family members, against which it had been so challenging to develop selective inhibitors that RAS proteins earned the reputation of being “undruggable” for decades. RAS-targeting therapies under development by us not only include small molecules but also modalities involving conjugates of small molecule and antibody. Given their novelty and differentiated features, our pipeline products may carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. The successful development of certain pipeline products, such as our Core Product GFH925 in China, does not guarantee similarly successful development of other pipeline products. For related risks, see “— Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.”

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Furthermore, due to the novelty of our therapeutics, a substantial amount of education and training may need to be provided to patients and medical personnel in the future, which may potentially increase our sales and marketing expenses. These risks and uncertainties may have a material adverse effect on future profits generated from our drug candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.

If we or our collaborators are unable to obtain and maintain adequate patent and other intellectual property protection for our pipeline products throughout the selected markets in the world, our ability to successfully commercialize our pipeline products may be adversely affected.

Our commercial success depends, to a material extent, on our or our collaborators’ ability to protect our proprietary technologies and pipeline products from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the pipeline products and technologies that we consider commercially important primarily by filing patent applications in China, the United States, the EU and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we or our business partners may not be able to file all necessary or desirable patent applications and secure other intellectual property protection in all desirable jurisdictions in a timely manner.

As of the Latest Practicable Date, we held 72 issued patents and 117 patent applications (including 8 PCT applications), of which 12 issued patents and 61 patent applications (including 2 PCT applications) are related to our Core Products. We cannot assure you that all of our patent applications will be granted. Patent applications may not be granted for a number of reasons, including a later application date, known or unknown prior art, deficiencies in the patent application or the lack of novelty or non-obviousness of the underlying invention or technology. China, the U.S. and Europe have adopted the “first-to-file” system, under which the first inventor to file a patent application will be awarded the patent if all other patentability requirements are met. Moreover, patent applications in China, the U.S., Europe and other jurisdictions are typically not published until a 18-month waiting period after filing, or in some cases, not at all. 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 file in advance to CNIPA for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Therefore, we cannot be certain that we or our collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our collaborators were the first to file for patent protection of such inventions.

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As a result of the first-to-file system, waiting period before publication or other applicable laws and regulations, in the case that a third party and us/our collaborators independently invent proprietary molecules, compounds or other technologies with certain overlapping patentable aspects, but the third party files a relevant patent application prior to us and publish after 18 months or even no publication at all, such third-party patent application, even not issued yet, may become a conflicting application of which we/our collaborators would not be aware until its publication. If the third party can establish that we or our collaborators were not the first to file for patent protection of our proprietary or licensed inventions even only certain immaterial aspects thereunder, such inventions, though independently developed by us or our collaborators, may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable or have to be amended to delimit the previous protection scope, and third parties may be granted a patent relating to a compound, molecule or technology which we independently invented, and our pipeline candidates covered by such inventions may be subject to third-party infringement claims. In such cases, we may be required to obtain and maintain licenses from third parties. For instance, we independently invented compounds related to our Core Product, GFH925, and obtained issued patents for these compounds in the PRC and the U.S. We also filed patent applications related to GFH925 in other jurisdictions. However, through the freedom-to-operate analysis we conducted, which did not cover Taiwan, Hong Kong or Macau, we are aware of certain general formula compounds claimed in third-party patents issued in Mainland China that may cover the chemical structure of GFH925. Since then, we entered into agreements with holders of such third-party patents, to proactively manage any potential risks from these patents. In addition, given our freedom-to-operate analysis did not include Taiwan, Hong Kong and Macau, we cannot rule out potential patent infringement risks in these jurisdictions.

On November 20, 2023, we entered into a license agreement with such a third party, which granted us a non-exclusive and sublicensable license to practice a Chinese patent owned by the third party in the research, improvement, manufacture, use, offer to sell, sell, and import of medical products containing or using GFH925 within Mainland China. The patent was issued in 2022, and is expected to expire in 2040. The patent is directed to a chemical formula that appears to cover the chemical structure of GFH925. Under the licensing agreement, we will pay the third party a total of RMB4.5 million in three milestone payments, and we retain a right of first offer in the event that the third party intends to transfer-out or sub-license its rights related to the patent. All the three payments shall be made within 30 business days of our receipt of the third party's invoice for the respective amount. We have made the three payments to the third party timely and in full, as of the Latest Practicable Date. As provided in the licensing agreement, if we have made any one of the three payments timely and in full, the third party agrees not to assert infringement allegations or cause interference against our, our sub-licensees', our interested parties' or our related parties' research, improvement, manufacture, use, offer to sell, sell, develop, commercialize, export and import of a medical product containing GFH925 within Mainland China, including by instituting a lawsuit, arbitration or other government proceedings.

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On February 28, 2024, we entered into a license agreement with a third-party group which granted us a non-exclusive and sublicensable license to practice four patents owned by the third parties in Greater China, as well as their current and future related patents or patent applications the same patent family in Greater China, in the research, manufacture, use, offer to sell, sell, improvement, export and import of medical products containing GFH925 within Greater China. The four licensed patents are directed to a chemical formula that appears to cover the chemical structure of GFH925 and are expected to expire in 2040. We are required to make a total of RMB30.0 million to the third parties in two milestone payments and mid-teens royalties tied to the achievement of specific regulatory and commercialization milestones and the receipt of royalty payments. As of the Latest Practicable Date, we have paid such RMB30.0 million to the third parties pursuant to the license agreement. Provided that we and our related parties, our sub-licensees and sub-contractors abide by the license agreement, the third parties agree not to assert infringement allegations or otherwise cause interference against our, our sub-licensees', sub-contractors' or our related parties' commercialization of GFH925, including by instituting a lawsuit, arbitration or other government proceedings.

We also are aware that a third party's patent in the U.S. includes claims defining the compounds solely by functional characteristics, without specifying their chemical structure. To further assess the potential risk, we have conducted a comprehensive freedom-to-operate analysis with respect to our core products, including GFH925, in the U.S. and sought advice from our legal advisor as to the U.S. intellectual property laws. Based on this analysis, and considering the legal standards in the U.S. regarding claim validity, including enablement and written description requirements, we believe that these broadly defined claims, which are solely based on functional characteristics, may raise concerns about their validity and enforceability in U.S. courts due to insufficient enablement and written description support.

Accordingly, we do not believe that a license agreement similar to the ones we entered in China is currently necessary for GFH925 in the U.S., and therefore, we have not entered into license agreements with respect to this U.S. patent. We continue to monitor the IP landscape closely and will consider appropriate measures, including licensing or legal action, if new risks arise.

As for our products candidates GFH312 and GFH375, we have not identified patents and patent applications in China or the U.S. that may pose an infringement risk. However, even with reasonable due diligence, our patent search may not be exhaustive. In other words, we cannot guarantee that we are able to identify all the patents and patent applications that may lead to patent disputes regarding our product candidates.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future are issued as patents, they may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent positions of biotech and pharmaceutical companies often involve complex legal and factual questions and have been the subject of increasing litigations in recent years. Consequently, we cannot be sure that we will acquire or maintain patent protections with the desired scope over our pipeline products or technologies. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

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It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all. If any of the foregoing scenarios materialize, our ability to successfully commercialize our pipeline products may be adversely affected.

We rely on our current and future collaborators’ willingness and ability to devote resources to the development and commercialization of our Core Products and other pipeline products and to otherwise support our business as contemplated in our collaboration agreements, and we may not have adequate control over patents and patent applications covering the drug candidates that involve our current and future collaborators.

We rely on our current and future collaborators to support our business, including to assist with, or to conduct, clinical development and regulatory filings, manufacturing and/or commercialization of certain of our pipeline products. For example, we have granted Innovent exclusive rights to develop, manufacture and commercialize one of our Core Products, GFH925, in Greater China. GFH925 obtained the NDA approval from the NMPA in August 2024. Pursuant to the agreement, Innovent shall be solely responsible for commercializing GFH925 in Greater China, and we are entitled to certain royalties and commercial milestone payments that are keyed to the annual net sales of GFH925 in Greater China, in addition to other enumerated upfront and milestone payments. For additional information, see “Business — Major Collaboration and Licensing Agreements.” Therefore, our future financial position will partly depend on the commercialization efforts of Innovent.

However, as we may have little or no control over the marketing and sales efforts beyond the contractual terms, the actual revenue generated from the commercialization of GFH925 may be lower than the anticipated revenue, and we may not realize the contemplated benefits from this collaboration. There is also no assurance that our collaborators will not seek to change the terms of the collaboration agreement with the effect of diminishing benefits to us. If we do not realize the contemplated benefits from our current and expected collaborations, our business, financial condition and results of operations may be materially harmed.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the drug candidates that involve our current and future collaborators. For example, the Innovent Agreement granted to Innovent the first right (but not the obligation) to file and maintain the patents that cover inventions jointly developed by both parties. For more information, please see “Business — Major Collaboration and Licensing Arrangements — Innovent Agreement.” Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, maintained, enforced and defended in a manner consistent with the best interests of our business. If we continue to enter into collaboration agreements in the future, and such future collaborators fail to file, maintain, enforce or defend the patents we license in, or lose rights to those patents or patent applications, the rights we will have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject of such potential licensed rights could be adversely affected.

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We cannot assure you that our existing or future collaborations will not be terminated prior to the expiry of contemplated terms. Such terminations could significantly impact the development and commercialization of our pipeline products and impact our financial results and future prospects. Any failure by any current or future collaborators to perform their obligations under our agreements for any reason, including its obligations to make milestone payments or pay royalties, or modification or termination of such agreements, could have a material adverse effect on our financial performance.

Our collaboration and licensing agreements with certain third parties, including Verastem and Innovent, establish a joint steering committee (“JSC”) with decision-making authority relating to the performance of the collaboration and licensing agreements. The JSC makes decisions by voting. If a deadlock in voting occurs, the JSC would be unable to render a decision. Though our collaboration and licensing agreements provide alternative decision-making mechanisms upon such deadlock, such as negotiation by the parties’ senior executives, the deadlock may cause delay, disruption or loss of good faith in the parties’ collaboration. Moreover, the alternative decision-making mechanisms may still be unable to resolve the parties’ differences the performance of the collaboration and licensing agreement. In that case, the third party may have the final decision-making authority in the jurisdiction where the third party has acquired rights to the subject product candidate, such as under the collaboration and licensing agreements with Verastem and Innovent, such that the final decision may favor the third party but not us.

Our collaboration agreement with Merck did not establish a JSC. If the parties are unable to resolve a dispute, the Merck Agreement provided that the unresolvable dispute shall be finally settled at the competent courts of Geneva, Switzerland. We did not have an unresolvable dispute with Merck during the Track Record Period. However, such unresolvable dispute, if it occurs, may cause delay, disruption or loss of good faith in the parties’ collaboration.

We may continue to receive from certain of our current and future collaborators with information about the status, progress and results of clinical trials and regulatory processes that they are conducting, sponsoring or pursuing with respect to our partnered product candidates. We may not have direct access to the underlying data or direct communications with the relevant regulators. In addition, our collaboration with our current and future collaborators could subject us to a number of additional risks, including the following:

- our collaborators have significant discretion regarding whether and on what timeline to pursue planned activities;
- we cannot control the quantity and nature of the resources our collaborators may devote to the development, commercialization, marketing and distribution of products or product candidates;
- disputes between us and our collaborators may delay or terminate the research, development or commercialization of the applicable pipeline products or result in costly litigation or arbitration that diverts management’s attention and resources;

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- we may not receive stipulated milestone payments from our collaborators, at the expected time or at all, if our collaborators do not achieve future milestones or if we and our collaborators disagree about whether a milestone has been reached;
- with respect to collaborations, partnerships or other arrangements under which we have an active role, we and our collaborators may have differing opinions or priorities, or we may encounter challenges in joint decision making, which may delay or terminate the research, development or commercialization of the applicable products and product candidates;
- our collaborators may not properly maintain or defend relevant intellectual property rights, or may infringe the intellectual property rights of third parties, or may use our or third parties’ proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and
- business combinations, financial difficulties or significant changes in a collaborator’s business strategy may adversely affect that collaborator’s willingness or ability to continue to pursue our products or product candidates.

Any one or more of the foregoing risks, if realized, could have a material adverse effect on our business, financial condition and results of operations.

We may not receive some or all of the potential milestone and/or royalty payments from our collaboration and licensing agreements.

From time to time, we enter into collaboration and licensing agreements that include clauses regarding potential development and commercial milestone payments and/or royalties. The milestone payments will only be payable to us upon the achievement of certain milestones based on clinical development progress and achievement of specified amounts of annual net sales of the licensed products. We may also receive tiered royalties tied to the net sales amount of the licensed products. For example, pursuant to the Innovent Agreement, Innovent shall be solely responsible for commercializing GFH925 in Greater China, and we are entitled to certain royalties and commercial milestone payments that are keyed to the annual net sales of GFH925 in Greater China, in addition to other enumerated upfront and milestone payments. There is a risk that any or all of the milestone events under these various agreements might not be achieved, that our licensees may not achieve sales that would entitle us to royalty payments, and that any or all of the consideration tied to the achievement of the milestone events and/or royalties might not be received.

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We work with various third-party service providers to develop our pipeline products. If these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to obtain regulatory approvals for, or commercialize, our pipeline products, and our business, financial condition and results of operations could be materially and adversely affected.

We have worked with and may continue to work with third-party service providers on our ongoing preclinical and clinical programs. For example, we seek assistance from CROs, clinical trial sites, consultants and other third parties to monitor, support and/or conduct preclinical studies and clinical trials of our drug candidates. We work with these parties to execute 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 protocols, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA, the FDA, the EMA and other comparable regulatory authorities for all of our drug candidates in clinical development. If we or any of our CROs or clinical investigators fail to comply with the applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA, the EMA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with products produced under GMP regulations. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Furthermore, due to the involvement of third parties such as CROs, the data we gather in our research and development may be affected by factors unrelated to our drug candidates or out of our control, which could adversely affect the reliability of results derived from our research and development activities.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. 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 nonclinical programs. If CROs fail to duly perform their contractual obligations or meet expected timelines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approvals for, or successfully commercialize, our drug candidates. Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. Any of the foregoing events may cause increases in costs, restrict our ability to generate revenue and have a material adverse effect on our business, financial condition, results of operations and prospects.

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Our ability to generate future revenue is partly dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approvals. Our arrangements with collaborators will be critical to the successful commercialization of our drug candidates and future products. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process, and to assist with our commercialization efforts. We do not control our collaborators, and therefore there can be no assurance that these third parties will adequately and timely perform all of their obligations under their agreements with us. If they fail to complete the remaining studies successfully, or at all, it could delay or adversely affect the obtaining of regulatory approvals. There can be no assurance of the satisfactory performance of any of our collaborators, and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the product which could materially and adversely affect our business, financial condition, cash flows and results of operations.

We face competition from existing drugs and drug candidates under development.

We face competition from existing drugs and drug candidates under development in the global innovative drug market. Competition in therapeutic areas such as oncology and immunology diseases, to which our Core Products and many other pipeline assets belong, is intense given the abundance of existing competing oncology therapy options, approved drugs and drug candidates that continue to increase. For instance, with respect to our Core Product GFH925, an inhibitor of KRAS protein that harbors the G12C mutation (“**KRAS G12C**”), adagrasib and sotorasib, both of which have been approved for marketing in the United States and the EU and garsorasib recently approved in China, address the same target, and there are a number of competing drug candidates currently under different development stages. Beyond drugs addressing RAS proteins, there have also been a number of approved drugs, such as a variety of tyrosine kinase inhibitors, for the treatment of NSCLC globally. For additional information on the market landscape, see “Industry Overview.”

In addition, the wide application of traditional cancer therapies, such as surgeries, radiotherapies and chemotherapies, also poses significant competition for our drug candidates. Our drug candidates and lines of treatments may not be selected unless and until one or more of these more conventional and widely adopted cancer treatments have been adopted, which could potentially negatively affect the size of our total addressable market for our drug candidates.

Our commercial opportunities may be adversely impacted if our competitors develop and commercialize drugs that are safer, more effective, more convenient, or less expensive than any of the drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, the FDA, the EMA or other comparable regulatory authorities for their drugs more quickly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. This may render our pipeline products obsolete or less competitive before we can recover the expenses of developing and commercializing our pipeline products. Additionally, even if approved and commercialized, our drug candidates

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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. See “— The size of the actual markets for our pipeline products may be smaller than our estimates and our pipeline products may not be able to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for their commercial success.”

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial, technical and human resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions in the pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. 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.

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

Clinical development is capital-intensive and may demand years of effort to complete, while its outcomes are inherently uncertain and may not be favorable. We may encounter unexpected difficulties while executing our clinical development plans for our drug candidates. Failure can occur at any time or stage during the clinical development process, which would result in a material and adverse effect on our business, financial condition and results of operations.

Furthermore, the results of preclinical studies and early clinical trials may not be predictive of the success of later-phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily indicate the success of final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy profiles despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have experienced significant setbacks in advanced clinical trials due to unsatisfactory efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. It is also common that various aspects of the development programs, such as manufacturing and formulation, are altered along the entire research and development stage in an effort to optimize processes and results, and there can be no assurance that such alterations would help achieve the intended objectives.

There may be significant variability in safety or efficacy results among different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in size and demographics of the enrolled patients (such as genetic differences and patient adherence to the dosage regimen) and the dropout rate among

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enrolled patients in clinical trials. Differences in the number of clinical trial sites and countries involved may also lead to variability among clinical trials. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and deviate from our expectation, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates.

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

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy profiles of our drug candidates in humans. We may experience certain unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to: regulators, institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; manufacturing issues, including problems with manufacturing, supply quality, compliance with drug Good Manufacturing Practice, or GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; our third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks.

Adverse events (“AEs”) and undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a narrowed scope of indications or a more restrictive label of our drug candidates, a delay or denial of regulatory approval by the NMPA, the FDA, the EMA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. Results of trials conducted by us or by our collaborators with respect to our drug candidates could reveal a high and unacceptable severity or prevalence of certain AEs. In such an event, such trials could be suspended or terminated and the NMPA, the FDA, the EMA or other comparable regulatory authorities could order us or our licensing partners, as applicable, to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. AEs related to our drug candidates may also affect subject recruitment or the ability of enrolled subjects to complete the trial and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

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If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used;
- be unable to obtain reimbursement for use of the drug; or
- be held liable for harm caused to our patients and be subject to litigation and product liability claims.

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

Development of product candidates in combination with other therapies could expose us to additional risks.

In addition to monotherapies, we are developing certain pipeline products with other commercialized therapies as combination therapies to achieve potential synergistic effects and improved efficacy profile. For instance, we are investigating the safety and efficacy of one of our Core Products, GFH925, in combination with cetuximab developed and commercialized by Merck for the treatment of NSCLC harboring the KRAS G12C mutation in Europe. For additional information, see “Business — Core Product GFH925: A Small Molecule Inhibitor of KRAS G12C — Licenses, Rights and Obligations — Merck Agreement.” However, development of any of our product candidates in combination with one or more other therapies could expose us to additional risks. For instance, we may be unable to successfully develop or market our pipeline products or may experience significant regulatory delays, if safety, efficacy or other issues arise from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates. Additionally, as combination therapies may increase the rate of serious or unexpected AEs, which could result in a clinical hold as well as pre-approval and post-approval restrictions by the regulatory authorities on the proposed combination therapy, including narrowing of the indication, warnings, additional safety data

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collection and monitoring procedures, even if the cause of such serious or unexpected AEs is not directly attributed to our product candidate. Any of these events or restrictions could have a material adverse effect on our business, delay our regulatory approval, and decrease the market acceptance and profitability of our product candidate if approved for a combination therapy.

Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing approved therapies, we would continue to be subject to multiple risks, such as the possibility that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment, which could adversely affect the market perception and acceptance of the combination therapy. In such scenarios, we may need to identify other potential combination therapies for our product candidates and conduct additional preclinical and clinical studies before these alternative therapies receive regulatory approvals for marketing. Additionally, components of the combination therapies, other than our product candidates, may not be under our control, and it is possible that we may encounter difficulties in obtaining sufficient quantities for clinical trials or, when commercialized, patients may not have adequate access to such components for their treatment regimes. Historically, we had not experienced shortages of supply that affected our development of combination therapies, however, in any of aforementioned scenarios, the development efforts and commercialization prospects regarding our product candidates would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll enough participants who remain in the trial until its conclusion. We may experience difficulties in participant enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the clinical trial protocol, the resources we have to facilitate timely subject enrollment in our clinical trials, the efforts made by trial execution personnel including our CROs to screen and recruit eligible subjects, the ability to obtain and maintain informed consents, epidemics, and the proximity and availability of clinical trial sites for prospective subjects, among others.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates. Such competition will likely reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Even if we are able to enroll a sufficient number of subjects in our clinical trials, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent the completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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Interim and/or preliminary data derived from our clinical trials that we announce or publish from time to time may change as more valid data becomes available and are subject to verification procedures that could result in material changes in the final results.

From time to time, we may publish interim and/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 data also remain subject to 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 should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly affect our business prospects and may cause the [REDACTED] of H Shares to fluctuate significantly after the [REDACTED].

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.

Many of our product 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 product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the NMPA, the EMA or other regulatory authorities will accept our proposed clinical programs or 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 the contemplated clinical development of our preclinical drug candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND applications or similar applications will result in the FDA, the NMPA, the EMA or other regulatory authorities allowing clinical trials to begin.

We may allocate our limited resources to pursue particular drug candidates or indications 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 product pipeline on research programs and drug candidates that we identify for selected 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 investments in current and future research and development programs and drug candidates for selected indications may not yield commercially viable products. Furthermore, 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 licensing, collaboration or royalty arrangements in cases where 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.

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We invest substantial human and capital resources in research and development to develop our pipeline products, but we cannot guarantee that such efforts will lead to successful outcomes.

The global biopharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For example, we have made efforts to develop our pipeline products. For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, our R&D costs were RMB312.7 million, RMB332.1 million and RMB142.3 million and RMB69.8 million, respectively. We intend to continue to strengthen our technical capabilities in CMC, technology platforms and the development of our existing and future drug candidates, which requires substantial capital and time investment. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products in a timely and cost-effective manner. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our technology platforms and drug candidates, and harm our business and prospects.

We may fail to sufficiently and promptly respond to rapid scientific and technological changes, clinical demand and market changes in the pharmaceutical industry, and we may be unable to maintain or enhance our market share in this industry for a variety of reasons.

The global pharmaceutical industry is characterized by rapid advances in science and technology and the continuous emergence of new treatment options. Our future success partially depends on our ability to launch new products that meet evolving market demands, in particular, new drugs that are effective in treating oncology and immunology diseases. We cannot assure you that we will be able to respond to emerging or evolving trends by improving our product portfolio in a timely manner, or at all.

In addition, clinical demand for pharmaceutical products may change rapidly and significantly. Our success depends on our ability to anticipate product offering lead-time and demand, identify preferences of patients and physicians and adapt our products to these preferences. We may need to adjust our research and development plan, production scale and schedule, product portfolio, and inventory levels based on market demand, sales trends and other market conditions. There can be no assurance that we will be able to sufficiently and promptly respond to changes in clinical demand and purchasing patterns in the future, and such failure may have a material and adverse effect on our business, financial condition, results of operations and profitability.

The pharmaceutical industry is highly competitive and fragmented. We face competition from both domestic and international competitors across most of our product lines based on safety and efficacy, the timing and scope of the regulatory approvals, prices, sales and marketing capabilities, the availability and cost of supply, patent position and other factors. In

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general, we have faced and will continue to face pricing competition from domestic competitors, and competition on product quality and brand recognition from international competitors. In particular, some of our domestic competitors may have, among other things, greater pricing flexibility and more robust sales networks, which may enable them to offer products with similar functions but lower prices to the end users. We may not be able to successfully compete with our competitors and cannot ensure you that we will be able to demonstrate compelling advantages in safety and efficacy to overcome price competition and to be commercially successful.

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

Our relationships with principal investigators (“**PIs**”), key opinion leaders (“**KOLs**”), physicians and experts play an important role in our research and development and future marketing activities. We have established extensive interaction channels with PIs, 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 drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with our PIs and 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 research and development process, may be inaccurate and lead us to develop products that do not have significant market potential. 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 want to collaborate with us and our marketing strategy may no longer be able to yield results that are commensurate to our efforts spent. If we are unable to develop new drugs 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.

All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with relevant laws and regulations may adversely affect our business, financial condition, results of operations and prospects.

All jurisdictions in which we intend to conduct our biopharmaceutical industry activities regulate these activities in great depth and detail. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ extensive regulations governing the development, approval, manufacturing, marketing, sales and distribution of pharmaceutical products. For additional information, see “Regulations” in this Document. Differences in regulatory regimes across jurisdictions may lead to a higher compliance burden.

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The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires spending of substantial time and financial resources. Any recently enacted and future legislation may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical industry, such as a relaxation in regulatory requirements; the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors; or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations, and prospects.

Failure to comply with the applicable requirements at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include, but are not limited to, a regulator’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially adversely affect our business, financial condition, results of operations and prospects.

The regulatory approval processes for pharmaceutical products are time consuming and depend on numerous factors, and if we are ultimately unable to obtain regulatory approval for our pipeline products, our business could be substantially harmed.

The regulatory approval processes of pharmaceutical products depend on numerous factors, some of which may be outside our control. Generally, such approvals take years to be obtained following the commencement of preclinical studies and clinical trials. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate’s clinical development and may vary among jurisdictions. While our Core Product GFH925 received NDA approval from the NMPA, we may not obtain marketing approval in other markets for GFH925, and we cannot guarantee that we will be able to obtain regulatory approvals for our other existing drug candidates or any drug candidates we may discover in the future.

Our pipeline products could fail to receive the regulatory approval of the NMPA, the FDA, the EMA or a comparable regulatory authority for many reasons, including but not limited to:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective and potent for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approval;

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- failure of our clinical trial process to pass relevant GCP inspections;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of an NDA or other submissions or to obtain regulatory approval;
- failure of the manufacturer of our drug candidates to pass GMP inspections during the regulatory review process or across the production cycle of our drug candidates;
- failure of our clinical sites to pass audits carried out by the NMPA, the FDA, the EMA or other comparable regulatory authorities, resulting in a potential invalidation of our research data;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for obtaining approvals; or
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The NMPA, the FDA, the EMA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We depend on third parties to provide a stable and adequate supply of investigational drugs for our research and development efforts and supply of APIs for commercial sales. Any disruptions of or significant price increases in such supply could adversely affect our business.

During the Track Record Period, we did not have in-house manufacturing facility and we outsourced manufacturing activities to reputable third-party manufacturing service providers. Going forward, we may continue to engage third-party CMOs and CDMOs to manufacture a portion of our pipeline products for research and development activities and commercial sales. For instance, we engage third-party manufacturing service providers to provide the APIs for commercial sales. In particular, we rely on third party manufacturers for the production of GFH925 supplied to Innovent for commercial sales. During the Track Record Period, the costs

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incurred in fulfilling drug supply arrangements for GFH925 exceeded the corresponding revenue from our sales of GFH925 to Innovent, mainly because production was based on the first-generation CMC process, which had a higher cost profile than the selling price to Innovent. To reduce the production cost, we are actively developing a second-generation manufacturing process, which we expect to adopt in 2026. We anticipate the second-generation manufacturing process, which is expected to be implemented by third party manufacturers, will lead an improvement in the current loss-making status of our drug supply. However, we cannot assure you that there will not be delay or failure in developing and implementing this cost-effective production method of GFH925. Our engagement with third-party CMOs and CDMOs exposes us to certain risks, including but not limited to the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA, the FDA, the EMA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and GMP-compliance inspections by the NMPA, the FDA, the EMA or other comparable regulatory authorities;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, or may otherwise fail to perform as agreed;
- manufacturers are subject to ongoing periodic unannounced inspection by the regulatory authorities to ensure strict compliance with GMP and other government regulations. We do not have control over third-party manufacturers’ compliance with these regulations and requirements;
- manufacturers may not properly obtain, protect, maintain, defend or enforce 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;
- manufacturers may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, natural or man-made disasters, or other events beyond control, which may lead to interruption of the manufacturing process.

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As we are exploring combination therapies consisting of our pipeline products and other drugs developed by third parties, we also depend on such third parties to provide us with access to certain drug products developed by these collaborators. For example, we entered into a clinical trial collaboration and supply agreement with Merck Healthcare KGaA (“**Merck**”), pursuant to which Merck agreed to supply certain amount of cetuximab to us to be used in our clinical investigation of the GFH925 in combination with cetuximab for the treatment of NSCLC in Europe. For additional information, see “Business — Core Product GFH925: A Small Molecule Inhibitor of KRAS G12C — Licenses, Rights and Obligations — Merck Agreement.”

In the event that our suppliers are unable to provide adequate supplies of products or services to us, our operations, including in-house CMC functions and the research and development of our pipeline products, may be adversely affected. We may also be exposed to the possibility of increased costs, which we may not be able to pass on to purchasers of our pipeline products and as a result, lower our profitability. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs, and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely. The risks discussed above could also jeopardize our ability to provide any future approved drug candidates for commercial sale.

We believe that we have stable relationships with our existing large third-party manufacturing service providers and collaborators that supply drug products to us. However, the stability of operations and business strategies of our service providers and collaborators are beyond our control, and we cannot assure you that we will be able to secure a stable relationship and high-quality outsourced services or materials. If any of our large manufacturing service providers or collaborators terminates its business relationship with us, we may encounter difficulty in finding a replacement that can provide services or materials of equal quality at a similar price, and our operations, financial position and business prospect may be materially and adversely affected.

We may face difficulties in forming additional collaboration and strategic alliances in the future.

We have in the past formed and may in the future form or seek strategic alliances, create collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our other drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

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We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration, partnership, licenses or other arrangement will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, partnership, licenses or other arrangement and the proposed collaborator’s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the NMPA, the FDA, the EMA or applicable regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to its ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Moreover, we may not be successful in our efforts to establishing or maintaining our collaborations, partnerships, licenses or other arrangements for our drug candidates 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 potential. If and when we collaborate with a third party for the 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.

RISKS RELATING TO COMMERCIALIZATION AND MANUFACTURING OF OUR PIPELINE PRODUCTS

We have no experience in launching and marketing drug products and may not be able to successfully do so in the future.

While GFH925 is approved for marketing in China, our collaborator Innovent will be solely responsible for the commercialization activities. For risks associated with this arrangement, see “— Risks Relating to Dependence on Third Parties — We rely on our current and future collaborators’ willingness and ability to devote resources to the development and commercialization of our Core Products and other pipeline products and to otherwise support our business as contemplated in our collaboration agreements, and we may not have adequate control over patents and patent applications covering the drug candidates that involve our current and future collaborators.” Since none of our other pipeline products has reached the commercialization stage, we have not yet demonstrated an ability to launch and commercialize drug products. Given our lack of experience, we may require a longer time frame or be less cost-efficient in the commercialization process than a company with more experience launching and marketing drug products. This inexperience may subject our business operations to greater risk. We cannot assure you that we will succeed in the commercialization process.

Furthermore, 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 pipeline products. 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.

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If we choose to pursue this path, we may have little or no control over the marketing and sales efforts of such third parties beyond contractual terms, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel and any revenue we receive will depend upon the efforts of such third parties. Therefore, we cannot assure you that we will be able to establish or maintain relationships with third-party partners to successfully commercialize any product. As a result, we may not be able to generate the anticipated product sales revenue.

The size of the actual markets for our pipeline products may be smaller than our estimates and our pipeline products may not be able to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for their commercial success.

Our projections of the number of patients who have the potential to benefit from treatment with our pipeline products are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our pipeline products may be smaller than our estimates.

Furthermore, there is no guarantee that any of our pipeline products, even if approved, would be approved for the line of therapy we are ultimately aiming for. For example, oncology therapies may be characterized as first line, second line or later line therapy depending on options for treatment and prior treatments received. For indications with well-established standard of care therapies, the NMPA, the FDA, the EMA and other comparable regulatory authorities may approve new therapies initially only for second or later lines of therapy. While we may seek approval for our pipeline products as an early-line therapy for certain indications, there is no guarantee that they will be approved as such. As a result, even if we obtain market approval for our drug candidates, we may not achieve the anticipated market size and revenue unless such market approval is for the intended lines of therapy or for additional indications.

Additionally, our pipeline products may not be able to gain sufficient market acceptance in the medical community and physicians, patients or third-party payers may prefer other products to ours. If our pipeline products do not achieve an adequate level of acceptance, we may not realize sufficient income from sales that turns us profitable. The degree of market acceptance of our pipeline products, once approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our pipeline products are approved;
- physicians, hospitals, medical treatment centers and patients considering our pipeline products;

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- efficacy and safety profile of our pipeline products;
- the potential and perceived advantages of our pipeline products over alternative treatments;
- the prevalence and severity of any side effects;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our pipeline products 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;
- price control or downward adjustment by the government authorities or other pricing pressure;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- 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 sales and marketing efforts regarding our pipeline products and competing drug products.

Even if our approved pipeline products achieve market acceptance, such market acceptance may not be maintained over time if new drug products or technologies are introduced that are more favorably perceived than our pipeline products, have better safety and efficacy profiles or render our drug candidates obsolete. Inability to achieve and maintain market acceptance for our pipeline products could materially adversely affect our business, financial condition, results of operations and prospects.

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Inability to conduct effective sales and marketing activities either by ourselves or through third parties would negatively affect the sales volume of our pipeline products after they are approved for commercialization, and our operations, revenue, profitability and business prospects could be adversely affected.

Successful sales and marketing are crucial to increase the market penetration of our pipeline products after they are commercialized, expand coverage of hospitals and other medical institutions and promote new products in the future. If we or our collaborators are unable to increase or maintain the effectiveness and efficiency of sales and marketing activities, the sales volumes and business prospects could be adversely affected.

In particular, sales and marketing efforts regarding our pipeline products, once they are commercialized, will consist of raising awareness and knowledge of our products and product candidates among medical professionals, hospitals, other medical institutions and pharmacies. Therefore, the sales and marketing force must possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication skills. If we or our commercialization collaborators are unable to effectively train the sales representatives, sales and marketing of our pipeline products may be less successful than desired.

Moreover, to the ability to attract, motivate and retain a sufficient number of qualified sales professionals, either by us or by our collaborators, is important. Competition for experienced marketing, promotion and sales personnel is intense. If we or our collaborators are unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals, sales volume of our products may be adversely affected, and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

The commercialization of our pipeline products, if approved, may be subject to uncertainties from national, provincial or other third-party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from jurisdiction to jurisdiction. In China and some other markets, the pricing of drug products remains subject to continuing governmental control even after initial approval, and the pricing negotiations can take considerable time. As a result, the commercial launch of our drug candidates, once approved, can be delayed due to price regulation, which will negatively impact our revenues. The 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.

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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. Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any commercialized pipeline products 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 pipeline products may be difficult. 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, the FDA, the EMA or other comparable regulatory authorities. For instance, in the United States, 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 approved pipeline products 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.

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. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates or any new drugs that we develop could have a material adverse effect on our business, our results of operation, and our overall financial condition.

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Guidelines, recommendations and studies published by various organizations could disfavor our pipeline products.

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. Currently, there are not any unfavorable guidelines, recommendations and studies published by various organizations in relation to our pipeline products. However, any such guidelines, recommendations or studies that reflect negatively on our pipeline products, either directly or relative to competing drug products, could result in current or potential decreased use and/or sales of, and revenue from one or more of our pipeline products. Furthermore, our success depends in part on the ability to educate healthcare providers and patients about our pipeline products, and these education efforts could be rendered ineffective by, among other things, third parties’ guidelines, recommendations or studies.

We may not be able to maintain effective quality control and quality assurance over our drug products.

During the Track Record Period, we primarily procured third-party manufacturing services to produce pipeline products for clinical development. For risks associated with third-party manufacturing, see “— Risks Relating to Dependence on Third Parties — We depend on third parties to provide a stable and adequate supply of investigational drugs supply for our research and development efforts and supply of APIs for future commercial sales. Any disruptions of or significant price increases in such supply could adversely affect our business.” The quality of drug products manufactured by the third-party service providers will depend significantly on the effectiveness of our established standards and protocol of quality control and quality assurance, which in turn depends on factors such as the production processes used in the manufacturing facilities, the quality and reliability of equipment used, the quality of manufacturing staff and related training programs and the ability to ensure that the manufacturing staff adheres to quality control and quality assurance protocol. We have been refining the CMC aspects of our pipeline products to establish manufacturing processes that ensure the pipeline products, from a manufacturing perspective, to be safe and with consistent quality, even in a setting of scaled-up and repeated manufacturing. However, we cannot assure you that the established quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. We may be unable to detect or cure quality defects as a result of a number of factors, many of which are outside our control, including but not limited to:

- manufacturing errors;
- technical or mechanical malfunctions in the manufacturing process;
- human error or malfeasance;

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- tampering by third parties; and
- quality issues with the raw materials we purchase or produce.

Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, jeopardize any GMP certifications we may have in the future and/or harm our market reputation and relationship with business collaborators. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

We have limited experience in manufacturing pharmaceutical products, including scaled-up product formulation and filling, and our business could be materially and adversely affected if we encounter problems in manufacturing our future pipeline products.

We have limited experience in manufacturing biopharmaceutical products, which is a complex process requiring significant expertise and capital investment, in part due to strict regulatory requirements. While we currently plan to continue to engage third-party manufacturing service providers to produce the APIs, we intend to carry out certain aspects of drug manufacturing, including final drug product formulation and filling, for certain pipeline products in-house in the future. Various problems may arise during the 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 APIs;
- changes in the types of products produced;
- advances in manufacturing techniques;
- inability to procure adequate raw materials from our suppliers, or inability to do so at a reasonable cost; and
- man-made or natural disasters and other environmental factors.

Furthermore, if contaminants are discovered in our pipeline products or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our pipeline products will not

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occur in the future, either relating to our third-party CDMOs or on our manufacturing facilities we plan to build in the future. If problems arise during the production process of a drug product, a batch or several related batches of such product may have to be discarded and cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation. If problems are not discovered before the relevant products are released for the clinical development or to the market, we may incur additional costs in connection with product recalls and product liability.

Manufacturing methods and formulations 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 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 with achieving adequate products that meet the NMPA, the FDA, the EMA or other comparable regulatory agency standards or specifications, and maintaining consistent and acceptable production costs. We may also experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or equipment. In these cases, we may be required to delay or suspend our future 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. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities. Occurrence of such events would restrict our manufacturing capacity and could delay our clinical trials and/or the availability of our products for commercial sale, or render us unable to meet the increasing demand for our drug candidates and future drug products, and may materially and adversely affect our business and financial condition.

Our planned establishment of manufacturing facilities may not be as successful as we have planned.

As we accumulate deeper experience in CMC and advance more pipeline products to later stages of development, we plan to establish manufacturing facilities to internalize certain aspects of drug product manufacturing, including formulation production and filling, for certain pipeline products. We are also advancing the development of the second-generation manufacturing process for GFH925 and are fully responsible for all aspects of the process. As of the Latest Practicable Date, we were in the process of formulating a detailed establishment plan and had not acquired a parcel of land to construct the facilities. The completion of such a contemplated facility establishment plan will involve regulatory approvals and reviews by various authorities, including, but not limited to, urban planning, construction and environmental protection authorities. We cannot assure you that we will be able to obtain all

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of the required approvals, permits and licenses. In addition, the establishment of the contemplated manufacturing facilities also may not be completed on the anticipated timetable or within budget. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources. We may also be unable to fully utilize the production capacity after we construct the facilities. Any of the foregoing factors could materially and adversely affect our results of operations and prospects.

Our future manufacturing facilities may be subject to ongoing, periodic inspection by the NMPA, the FDA, the EMA or other comparable regulatory agencies to ensure compliance with applicable GMP standards. Our failure to follow and document our adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our drugs, if approved.

Should deficiencies or manufacturing issues arise in our future manufacturing facilities, or instances of failure to comply with applicable regulations occur, we may also be subject to sanctions for failure to comply with applicable regulations, including fines, injunctions, penalties, suspension of clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, suspension or withdrawal of approvals, supply disruptions, seizures or recalls of our pipeline products, or operating restrictions, any of which may harm our operations, financial position and business prospect.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

Our patent rights may be challenged and invalidated.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S., the EU and other jurisdictions. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings challenging our patent rights or the patent rights of others. If we are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which our intellectual properties are subject, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we are unsuccessful in any inventorship disputes to which we are subject, we may lose valuable intellectual property rights, such as exclusive ownership. If we 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

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narrowing of our 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.

Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated due to non-compliance.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (the “CNIPA”), the United States Patent and Trademark Office (the “USPTO”) and other applicable patent agencies in several stages over the lifetime of a patent. The CNIPA, the USPTO and other applicable patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. 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 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.

If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed.

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for inventions in China and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. Even if patents covering our drug candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications. The expiration of our issued patents or patents that may issue from our 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. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension or 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 business could be harmed.

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In addition, some of our patents and patent applications 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. Besides this, 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.

Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

In the United States, the Federal Food, Drug, and Cosmetic Act, as amended by the law generally referred to as the “Hatch-Waxman Amendments,” provides the opportunity for patent-term restoration of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. The Hatch-Waxman Amendments also have a process for patent linkage, pursuant to which FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Finally, the Hatch-Waxman Amendments provide for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the United States to the first applicant to obtain approval of a new chemical entity (as defined) and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where FDA designates the product 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 FDA grants marketing approval for the innovative product.

In China, the amendment to the PRC Patent Law which was promulgated in October 2020 introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the patent owner to submit applications for a patent term extension of up to a maximum length of five years, and after the new drug is approved for marketing, the total effective term of the patent shall not exceed 14 years. 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.

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Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the relevant governmental authorities will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we requested. In such instances, a lower-cost generic drug can emerge onto the market much more quickly, leading to early generic competition that may have a material and adverse effect on our financial position and business prospect.

We may not be able to protect our intellectual property rights or prevent unfair competition by third parties.

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than do those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing drugs made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, may develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, or may export otherwise infringing drugs to certain jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in certain other countries. 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.

The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions 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. Proceedings to enforce our intellectual property and proprietary 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 at risk of being invalidated or interpreted narrowly, could put 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 significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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We may become subject to intellectual property infringement claims, which could expose us to substantial liability, harm our reputation, limit our research and development or other business activities and/or impair our ability to commercialize our product candidates.

Our commercial success depends significantly on our ability to develop, manufacture, market and sell pharmaceutical products and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could also be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and invention patent applications are filed. Even after reasonable investigation, we may not know with certainty whether any third party may have filed a patent application without our knowledge while we are still developing or producing that product or other relevant technology. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any product candidates we may develop.

Third parties may assert infringement claims against us based on patents or other proprietary rights that they currently hold or may be granted in the future, regardless of their merit. We may receive in the future, notices that claim our technologies or certain other aspects of our business have infringed, misappropriated or misused other parties' intellectual property rights. Whether or not third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. We are not currently involved in any material patent litigations. We, however, are aware that a third party's patent claims in the U.S. define a group of compounds solely by functional characteristics, without specifying their chemical structures. The scope of this protection is excessively broad and appears to cover GFH925, which covalently binds to the KRAS protein. Our legal advisor as to the U.S. intellectual property laws advised that under the U.S. patent law, functional languages in patent claims may lead to written description and enablement issues if not properly supported by the specification, thereby rendering the patent invalid under 35 U.S.C. § 112. Here, the functional language in the claims of the U.S. patent defines a broad group of compounds, and such functional language lacks sufficiently specified corresponding chemical structures described in the patent specification. Moreover, the actual chemical structures described in the patent specification are substantially different from that of GFH925. Accordingly, as advised by our legal advisor as to the U.S. intellectual property laws, we believe that these broadly defined claims, which are solely based on functional characteristics,

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may raise concerns about their validity and enforceability in U.S. courts due to insufficient enablement and written description support. As a result, the likelihood of these claims having a significant impact on the freedom to operate GFH925 in the U.S. is low.

Also, under the licensing agreements we entered with Innovent, Verastem and SELLAS, we, as the licensor, have an obligation to indemnify our collaboration partners for the potential penalties arising from patent infringement of IP claims asserted by a third party in the licensed jurisdiction. For example, we have an obligation to indemnify Innovent for the potential penalties arising from patent infringement of IP claims asserted by a third party in Greater China. In addition, we have an obligation to indemnify Verastem the potential penalties arising from patent infringement of IP claims asserted by a third party outside Greater China.

However, whether a product infringes a patent involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and the burden of proof required to successfully challenge a third-party patent may be high. Such legal proceedings, regardless of their merits, could lead to considerable legal costs and be a distraction to our management. If we are found to infringe on a third party’s intellectual properties, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, one or more of the following may occur:

- we may have to reformulate the affected product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be very costly and time-consuming;
- we may be forced to discontinue production and sales of the affected product(s) or cease developing and commercializing the affected product candidate(s);
- we may be prevented from commercializing our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law; and
- we may be required to obtain royalty-bearing licenses from such third party to such patents, which may not be available on commercially reasonable terms, or at all, and even if we were able to obtain such licenses, they could be non-exclusive, thereby giving our competitors and other third parties’ access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments.

Furthermore, potential disputes with our business partners or collaborators may arise if we are unable to agree on whether the product candidates under collaboration involve freedom-to-operate concerns. In addition, some of our competitors are larger than we are and have substantially greater resources than we do. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research projects, in-license needed technologies, or enter into strategic partnerships that would help us bring our product candidates to market.

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Claims that we have misappropriated the confidential information or trade secrets of third parties could have a material adverse effect on our business, financial condition, results of operations, and prospects. Even if we are successful in litigation or administrative proceedings, such litigation and proceedings may be costly and could result in a substantial diversion of management resources. If any of the foregoing events occurs, our business may be materially and adversely affected.

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

We own registered trademarks in China and have a pending trademark application in the United States. Our registered or unregistered 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 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, then 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 and could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to our issued patents and 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, CROs, clinical research coordinators, contract manufacturers, consultants, advisors and other third parties that have access to them.

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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.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our pipeline products.

The laws and regulations governing patents could be revised from time to time that would affect our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Our existing patent rights and future patent applications may face certain potential influence. Such changes may impact the value of our patent rights or our other intellectual property rights. For instance, the United States has enacted wide-ranging patent reform legislation. The United States Supreme Court rulings have 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.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees and consultants were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees 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 our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee’s former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and our specific personnel.

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We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Also, former employees may become employed by competitors who develop similar technology, and could assist the competitor in designing around our patents. While we typically require our employees and contractors who may be involved in the 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. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily protect us from all potential threats.

Intellectual property rights do not necessarily protect us from all potential threats, because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any candidates we may develop while our candidates are not protected by our intellectual property rights;
- we or our current or future collaborators might not have been the first to develop drug candidates covered by the issued patent that we license or may own in the future;
- we or our current or future collaborators might not have been the first to file patent applications covering certain of our, or their, candidates;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed (if any) intellectual property rights;
- it is possible that our pending patent applications or those that we may file in the future will not lead to issued patents;

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- issued patents that we hold rights to may not provide us with a competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- we may obtain patents for certain technologies many years before we commercialize candidates leveraging such technologies, and because patents have a limited life, which may begin to run prior to the commercial sale of the related candidates, the commercial value of our patents may be limited;
- our competitors or other third parties might conduct research and development activities in jurisdictions where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- the validity and scope of any claims relating to copyrights or other intellectual property may involve complex legal and factual questions and analyses and, as a result, the outcome may be highly uncertain;
- we may not develop additional proprietary technologies that are patentable; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

RISKS RELATING TO OUR FINANCIAL POSITION

We are a biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a biopharmaceutical company with a limited operating history. Our operations to date have focused on establishing our intellectual property portfolio, conducting drug discovery, preclinical studies and clinical trials of our drug candidates, organizing and staffing our operations, business planning and raising capital. To date, we have one product approved for commercial sale and have not become profitable from product sales.

Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate, the inherent uncertainties in drug research and development, and the changing regulatory and market environments we encounter, may make it difficult to evaluate our prospects for future performance. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business may suffer and you may lose all of your [REDACTED] in us.

RISK FACTORS

We have incurred significant operating losses since inception, and we anticipate that we will continue to incur operating losses and may fail to achieve or maintain profitability in the future. As a result, you may lose substantially all of your [REDACTED] in us.

[REDACTED] in the development of innovative biopharmaceutical products can be highly speculative as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, while we generated a limited amount of revenue from the collaboration agreements with Innovent Verastem and SELLAS, we continue to incur significant research and development costs and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred operating losses since our inception. For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, our total losses were RMB508.3 million, RMB677.6 million and RMB404.7 million and RMB66.6 million, respectively. Substantially all of our operating losses during the Track Record Period resulted from costs and expenses incurred by our research and development activities, including those in relation to our preclinical studies and clinical trials, which exceeded the revenue we recognized in the same periods. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing innovative drug candidates into later stages of clinical development, and obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

We expect to continue to incur losses in the near future and that these net losses may increase as we continue to carry out certain activities relating to our development, including but not limited to the following:

- continue to advance the clinical trials and preclinical studies of our pipeline products;
- seek regulatory approvals for our pipeline products and commence commercialization;
- identify additional drug candidates with significant market potential;
- respond to scientific advancements, new technologies and market developments;
- maintain, protect and expand our intellectual property portfolio; and
- enter into additional strategic collaborations to maximize the value of our pipeline products.

RISK FACTORS

Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our operating losses have had, and will continue to have, an adverse effect on our working capital and shareholders’ equity. Our inability to become and remain profitable may affect [REDACTED] perception of the potential value of our Company and could impair our ability to raise additional capital, expand our business or continue our operations. Failure to become and remain profitable may also adversely affect the [REDACTED] of our H Shares. A decline in the [REDACTED] of our H Shares could cause potential [REDACTED] to lose all or part of their [REDACTED] in our business.

We had net operating cash outflows during the Track Record Period.

Since our inception, our operations have consumed substantial amounts of cash. We had net cash used in operating activities of RMB202.1 million and RMB206.4 million for the years ended December 31, 2023 and 2024 and RMB136.9 million and RMB34.0 million for the four months ended April 30, 2024 and 2025, respectively. Additionally, we are exposed to credit risk on the cash and cash equivalents deposited in financial institutions. In the event that any of them becomes insolvent and is taken into receivership by the relevant government agencies, there will be uncertainty as to the timing and extent to which we will be able to recover our cash on deposit at such financial institution.

While we believe we have sufficient working capital to fund our current operations for the next 12 months, we expect that we may experience net cash outflows from our operating activities for the foreseeable future. We may need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or other sources. 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 reasonable terms, we could have to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

We incurred net liabilities and net current liabilities during the Track Record Period, which may continue into the foreseeable future and expose us to liquidity risk.

As of December 31, 2023 and 2024 and April 30, 2025, we had net liabilities of RMB1,317.3 million, RMB1,956.3 million and RMB2,013.6 million, respectively. In addition, we recorded net current liabilities of RMB1,381.4 million, RMB1,925.2 million and RMB1,979.8 million as of December 31, 2023 and 2024 and April 30, 2025, respectively. A net liabilities position can expose us to liquidity and financial risks. This in turn could require us to seek financing from external sources such as bank borrowings, which may not be available on terms favorably or commercially reasonable to us, or at all. If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.

During the Track Record Period, we financed our operations, including our research and development activities in relation to our preclinical studies and clinical trials, primarily through proceeds from our financing activities. We expect to fund our future operations primarily with existing cash and cash equivalents, net [REDACTED] from the [REDACTED], payments received from our license and collaboration agreements, including royalties from the sales of GFH925 in Greater China, proceeds from commercial loans, and future sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. Although we are conducting this [REDACTED], we may nevertheless require substantial additional capital to meet our continued operating cash requirements, especially to fund our research and development activities, commercialization of our drug candidates and development of manufacturing capabilities. As our business continues to expand, we may seek additional funding through equity offerings, debt financings, license and collaboration arrangements and other sources, which may not be available on terms favorable or commercially reasonable to us or at all.

We face exposure to fair value change of financial assets at FVTPL and valuation uncertainty due to the use of unobservable inputs.

For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, we recorded fair value gains on financial assets measured at FVTPL of RMB3.6 million, RMB0.4 million, RMB0.2 million and nil, respectively. We did not have any financial assets at FVTPL as of December 31, 2023 or 2024 or April 30, 2025, because our financial assets at FVTPL reached maturity in 2023, and our financial assets at FVTPL purchased in 2024 reached maturity before December 31, 2024 and we did not make any purchases of such financial assets in the first four months of 2025. After [REDACTED], we may continue to purchase low-risk wealth management products with a short maturity period based on our operational needs. We therefore face exposure to fair value change of financial assets measured at FVTPL.

We cannot assure you that we can recognize comparable fair value gains in the future, and we may on the contrary recognize fair value losses, which would affect our result of operations for future periods. In addition, the valuation of financial assets at FVTPL is subject to uncertainties due to the use of unobservable inputs. Such estimated fair values involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. As such, the valuation of financial assets at FVTPL has been, and will continue to be, subject to uncertainties in estimations, which may not reflect the actual fair value of these financial assets and result in fluctuations in profit or loss from year to year.

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

We have granted share-based payments to, among others, attract and retain outstanding individuals to serve the Company. We believe the granting of share-based payment is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based payment to employees in the future. For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, we incurred equity-settled share-based payment expenses of RMB37.0 million, RMB26.9 million, RMB9.6 million and RMB8.8 million, respectively. See Note 29 of the Accountants’ Report set out in Appendix I to this Document. As a result, our expenses associated with share-based payment may increase, which may have an adverse effect on our results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective share incentive plans and any subsequently adopted share incentive plans from time to time. If we choose to do so, we may experience substantial change in our share-based payment charges. In addition, such share-awards may dilute the shareholding percentage of our existing Shareholders and could result in a decline in the value of our H Shares.

We are subject to credit risk arising from trade receivables.

As of December 31, 2023 and 2024 and April 30, 2025, we had trade receivables of RMB72.4 million, RMB109.2 million and RMB97.5 million, respectively. We may be exposed to credit risk with our counterparties and may not be able to collect all of such receivables due to a variety of factors that are outside of our control. If the relationship between us and any of our counterparties is terminated or deteriorated, or if our counterparties experience financial or operational difficulties, the recoverability of our receives may be negatively affected, which may have a material and adverse effect on our business, financial condition and results of operations.

Certain of our subsidiaries currently enjoy, and other subsidiaries may in the future enjoy, preferential tax treatment, including reduced tax rates. The expiration of, or changes to, any of these preferential tax treatments could adversely affect our business, financial condition, and results of operations.

We have received preferential tax treatments and currently benefit from certain preferential tax treatments that reduce our overall tax obligations. These benefits include reduced tax rates, tax refunds, or other favorable tax policies provided by governmental authorities in certain jurisdictions where we operate. However, these preferential tax treatments are typically subject to review and renewal by the relevant tax authorities and are dependent on our compliance with applicable rules and regulations. There is no assurance that we will continue to qualify for such preferential tax treatment or that these benefits will be renewed upon expiration. In addition, changes to existing laws, regulations, or interpretations of tax policies could result in the reduction or elimination of these benefits. Furthermore, some of the government grants or preferential tax treatments are subject to the satisfaction of certain conditions, including compliance with requirements of the applicable incentive programs. We

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cannot guarantee that we have satisfied or will continue to satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. Any such change, non-renewal, or failure to qualify could significantly increase our tax obligations and adversely affect our business, financial condition, and results of operations.

RISKS RELATING TO OUR OPERATIONS

We may encounter difficulties in managing our anticipated growth or expand our operations successfully.

As we seek to advance our pipeline products through clinical trials and eventually achieve commercialization, we will need to expand our development, regulatory, manufacturing, sales and marketing capabilities or contract with third parties to provide these capabilities for us. In addition, we may need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant additional responsibilities on our management. Our future financial performance and our ability to commercialize our pipeline products and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We cannot assure you that we will be able to successfully develop and commercialize our drug candidates and build suitable, or procure for external providers, manufacturing, sales, marketing and managerial functions to meet our growth targets. Our inability to accomplish any of these tasks could prevent us from successfully growing our company.

Managing our growth and executing our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global pharmaceutical market, effective coordination and integration of our teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, increased sales and marketing activities, effective quality control, and management of our suppliers and collaborators. If we are not able to effectively manage our growth or execute our growth strategies, our business, financial condition, results of operations and prospects could be adversely affected.

We, our management and directors may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.

We, our management or directors may from time to time become party to litigation, legal disputes, claims or administrative proceedings arising in the ordinary course of our business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and intellectual property rights. For example, we may be sued if our pipeline products 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.

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Involvement in litigation, legal disputes, claims or administrative proceedings may distract our management’s or directors’ attention and consume our time and other resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate due to the various factors involved, such as the facts and circumstances of the cases, the likelihood of winning or losing, the monetary amount at stake and the parties concerned, and such factors may result in these cases becoming of material importance to us. If we cannot successfully defend ourselves against the claims, we may incur substantial liabilities or be required to limit commercialization of our pipeline products.

In addition, negative publicity arising from litigation, legal disputes, claims or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. In addition, if any verdict or award is rendered against us, we could be required to pay significant monetary damages, assume other liabilities, and suspend or terminate the related business ventures or projects. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

Our future success depends in part on our ability to retain key executives and to attract, hire, retain and motivate other qualified and highly skilled personnel.

We depend on the continued contributions of our senior management, especially the executive officers listed in the section headed “Directors, Supervisors and Senior Management” in this Document, and other key employees, many of whom may be difficult to replace. Replacing executive officers, scientific employees, and other qualified personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. The loss of the services of any of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives.

Our future success is dependent on our ability to attract qualified employees and retain existing key employees, especially our drug development and technology professionals. We believe that there is, and will continue to be, intense competition for highly skilled management, technical, sales and other personnel with experience in our industry in the cities where our offices are located. Our need to increase the number of our qualified employees and retain key employees may cause us to materially increase compensation-related costs, including stock-based compensation. We must provide competitive compensation packages and a high-quality work environment to hire, retain and motivate employees. To the extent we hire personnel from competitors, we also may be subject to allegations that they have been improperly solicited or divulged proprietary or other confidential information. If we are unable to retain and motivate our existing employees and attract qualified personnel for important positions, we may be unable to manage our business effectively, including the development, marketing and sale, which could adversely affect our business, operating results and financial condition, and the price of our H Shares could suffer.

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If we, our CROs, CDMOs or business partners fail to comply with environmental, health and safety laws and regulations, we could be subject to fines or penalties and other negative consequences that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals materials, and may produce hazardous wastes. For additional information, see “Business — Environmental, Social and Governance.” We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials and wastes, whether arising from our own operations or those of our CROs, CDMOs or other business partners, now or in the future. In the event of such contamination or injury, we could be held liable for any resulting damages, and such liabilities could exceed our resources. We could also incur significant costs associated with civil or criminal fines and penalties.

In addition, we may incur substantial costs to ensure compliance with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may affect our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions that could have a material adverse effect on our business.

Any failure to comply with applicable laws and regulations and industry standards or obtain various licenses and permits could harm our reputation, business, financial condition, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our collaborators’ failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our reputation, business, financial condition, results of operations and prospects.

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. For additional information, see “Business — Permits, Licenses and Other Approvals.” Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or impose fines and penalties which could materially and adversely affect our business, financial condition, results of operations and prospects. If the interpretation or implementation of laws and regulations is adjusted in the future or new regulations come into effect, or the criteria used in reviewing applications for, or renewals of permits, licenses and certificates change to adapt to new developments, we may be required to obtain any additional approvals, permits, licenses or

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certificates and we cannot assure you 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.

Any government investigation of alleged violations of laws could require us to expend significant time and resources in response and generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our H Shares and our results of operations will be adversely affected.

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 are required under the applicable laws and regulations as well as based on our assessment of our operational needs and industry practice. For more details, please see “Business — Insurance.” Although we maintain insurance coverage for adverse events in our clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations. Our insurance coverage may also be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Our risk management and internal control system may not be so adequate or effective to detect potential risks in our business as intended.

We have an internal control system in place to monitor and control potential risk areas relevant to our business operations. For additional information, see “Business — Risk Management and Internal Controls.” However, due to the inherent limitations in the design and implementation of our internal control system, it may not be sufficiently effective in identifying, managing and preventing all risks if external circumstances change substantially or extraordinary events take place. Our risk management and internal controls also depend 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 risks that our internal control system is designed to manage materializes, our operations, financial position and business prospect may be adversely affected.

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Our information technology systems, or those used by our partners or other contractors or consultants, may fail or suffer security breaches.

We make use of information technology systems to obtain, process, analyze and manage data. We use these systems to, among other things, monitor the daily operations of our business, record research and development activities, maintain operating and financial data, as well as manage our quality control systems. Despite the implementation of security measures, our information technology systems and those of our CROs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations. 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.

There can be no assurance that we will be able to effectively handle a failure of our information systems, or that we will be able to restore our operational capacity in a timely manner to avoid disrupting our business. The occurrence of any of these events could adversely affect our ability to effectively manage our business operations. In addition, if the capacity of our information systems fails to meet the increasing needs of our expanding operations, our ability to expand may be constrained.

Negative publicity on us or failure to maintain and enhance our recognition and reputation may materially and adversely affect our business.

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may engage various third parties, such as contract sales organizations, to expand our commercialization network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties.

Any negative publicity, including disputes concerning us, our business partners or our affiliates, even if untrue, could adversely affect our reputation and prospects. Moreover, if we are unable to maintain a good reputation, our ability to attract and retain key employees and business partners could be harmed which, in turn, may materially and adversely affect our business, financial condition, results of operations and prospects.

Our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. Negative publicity about us, such as alleged misconduct or improper activities, or negative rumors relating to us, our management, employees, business partners or affiliates, can harm our business, financial condition, results of operations and prospects, even if they are unsubstantiated or are later satisfactorily addressed. Any regulatory inquiries or investigations or other actions against our management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived

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wrongdoing by any key member of our management team or other employees, our business partners or our affiliates, could harm our reputation and materially and adversely affect our business. Regardless of the merits or final outcome of such regulatory inquiries, investigations or actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent and business partners and grow our business.

Moreover, any negative media publicity about the pharmaceutical industry in general, including issues and allegations solely involving other companies in the industry, may also negatively impact our reputation. In the event that such negative publicity relates to our own products and business, the adverse impact on our financial condition or results of operations might be more significant. Any such negative publicity may undermine the public confidence in our products, reputation, brand image, business prospects, and impair the development and commercialization of our pipeline products, all of which may adversely affect our business operations and financial performance. Investigations and increasingly stringent regulations arising from such negative publicity, if any, may draw time and attention from our management team, which would have otherwise been devoted into our business operations, or may incur additional compliance expenses.

We may be subject to disasters, health epidemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business.

Natural disasters, acts of war, terrorism or other force majeure events beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations, and those of our third-party collaborators, suppliers and other contractors and consultants, may be under the threat of natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, force majeure events such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or potential wars or terrorist attacks.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments could materially disrupt our business and operations. For example, since the end of December 2019, the outbreaks of a novel strain of coronavirus COVID-19 have materially and adversely affected the global economy. Many countries and regions had been affected by the COVID-19 outbreaks. There is no assurance that such kind of health epidemic or even a more severe pandemic will not occur again in the future.

There also could occur serious natural disasters, which may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Damage or extended periods of interruption to our, our collaborators’ or our suppliers’ corporate, development, research or manufacturing facilities due to fire, disaster, epidemics, 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 pipeline products. As we rely on third

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parties on various services and supplies, the occurrence of any of the foregoing events could seriously harm ability to obtain services or supplies if such third parties are affected by disasters, epidemics, business interruptions and other force majeure events. In addition, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

Acts of war or terrorism may also injure our employees, disrupt our business network and destroy our markets. In addition, in response to acts of war or conflicts, the United States, the EU, the United Kingdom and other countries may impose certain economic sanctions and export control restrictions against certain countries involved in such wars or conflicts, which could restrict our business opportunities and impact our business. In addition, as monitoring and ensuring compliance with such economic sanctions and export control restrictions can be challenging, we may be subject to both civil and criminal penalties, including substantial fines, possible incarceration of responsible individuals for willful violations, possible loss of our export or import privileges and reputation harm, in case there are any failure to comply with these regimes.

Any of the foregoing events and other events 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 condition, results of operations and prospects.

We may be exposed to the risks of conducting business in multiple jurisdictions.

Overseas markets are an important component of our growth strategy. We are exploring and plan to continue to explore market opportunities overseas, where we believe there is substantial demand for our pipeline products, and we intend to continue to identify and collaborate with reputable local partners that have proven track record to maximize the global value of our pipeline products. We will also continue seeking licensing and co-development opportunities to expand our global clinical programs.

However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including but not limited to:

- efforts to enter into license and collaboration arrangements with third parties may increase our expenses or divert our management’s attention from the development of drug candidates;
- political and economic instability as well as geopolitical tensions, including the threat of war or terrorist attacks (notably the Russia-Ukraine conflicts and the reaction of the international community, the consequences of which on the financial markets and the global business climate remain uncertain);
- differing regulatory requirements for drug approvals and marketing internationally;

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- potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- unexpected changes in tariffs, trade barriers and regulatory requirements, and delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions;
- significant adverse changes in currency exchange rates;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences; and
- business interruptions resulting from geo-political actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

In addition, changes in international trade policies may also adversely affect various aspects of our business operations. For example, the U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies towards China. It remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to international trade agreements, the imposition of tariffs on goods imported into the U.S., tax policy related to international commerce, or other trade matters. It is unknown whether new tariffs will be imposed, or whether new laws and regulations will be enacted, or the effect that any such actions would have on us or our industry. While we have not commenced commercial sales of drug candidates overseas markets, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the import or export of raw materials and disrupt our drug development and the manufacturing of our drug candidates. Such unfavorable policies may also negatively impact the hiring of scientists and other research and development personnel, the demand for and competitiveness of our drugs, or prevent us from selling our drugs in certain countries.

On September 9, 2024, the U.S. House of Representatives passed the BIOSECURE Act. The BIOSECURE Act prohibits entities that receive federal funds from using biotechnology that is from a company associated with a foreign adversary. WuXi Biologics and WuXi Apptech, which are our major suppliers, were named as “companies of concern” under the BIOSECURE Act. However, the BIOSECURE Act was not included in the last legislation during the 118 United States Congress and as a result, it did not become law in 2024. Because the BIOSECURE Act has not been enacted, it would not have any material impact on our business operations and financial conditions.

If any new tariffs, policies, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

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RISKS RELATING TO DOING BUSINESS IN JURISDICTIONS WHERE WE OPERATE

We may be subject to the approval, filing or other requirements of the CSRC or other PRC governmental authorities in connection with future capital raising activities, and, if required, we cannot predict whether we will be able to obtain such approval or complete such filing.

On July 6, 2021, the General Office of the State Council, together with another regulatory authority, jointly promulgated the Opinions on Strictly Combating Illegal Securities Activities in Accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》), which calls for, among others, enhanced administration and supervision of [REDACTED] China-based companies, proposes to revise the relevant regulation governing the [REDACTED] and [REDACTED] by such companies, and clarifies the responsibilities of competent domestic industry regulators and government authorities.

On February 17, 2023, the CSRC released the Trial Administrative Measures of 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》) and certain supporting guidelines (together, “**Trial Measures**”), which came into effect on March 31, 2023. Pursuant to the Trial Measures, domestic companies that seek to [REDACTED] overseas, both directly and indirectly, should fulfill the filing procedure and report relevant information to the CSRC. The filing is required to be conducted within three business days after the submission of the [REDACTED] for [REDACTED] and [REDACTED] overseas to the overseas regulators. The CSRC will review the filing application and may have queries and may consult with other relevant regulators. Filings granted by the CSRC will have a valid term of one year during which the issuer should complete the [REDACTED]. Further follow-up [REDACTED] after [REDACTED] also require a filing or a report submitted to the CSRC in accordance with the Trial Measures, and the [REDACTED] companies will need to report to the CSRC upon the occurrence and public disclosure of certain significant matters such as a change in control, penalty received from overseas securities regulators or relevant PRC regulators, a switch of [REDACTED] status and a termination of [REDACTED]. There is uncertainty as to whether we will be able to complete the filing procedures for this [REDACTED] in a timely manner or at all. If a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as orders to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

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Our PRC Legal Advisor is of the view that this [REDACTED] shall be deemed as a direct overseas [REDACTED] by PRC domestic enterprise, and we are required to submit filings with the CSRC within three business days after we submit filing to Hong Kong Stock Exchange for this [REDACTED]. On June 25, 2025 the CSRC has issued a notification on our Company’s completion of the PRC filing procedures necessary for the [REDACTED] of our H Shares on the Stock Exchange and the [REDACTED]. We may also be subject to filing requirements with the CSRC under the Trial Measures with respect to our future [REDACTED] or any other capital raising activities. We cannot assure you that we could meet such requirements or complete such filing in accordance with the Trial Measures in a timely manner. Any failure may restrict our ability to complete the [REDACTED] or any future equity capital-raising activities.

We are subject to privacy laws and information security policies related to data privacy and security, and we may be exposed to risks relating to personal or other sensitive information.

We are subject to privacy, data protection and information security laws and regulations that apply to the collection, transmission, storage and use of personal information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy, data protection and information security continues to evolve in jurisdictions worldwide, and there has been an increasing focus on these issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, fines, imprisonment of company officials and public censure, claims for damages by 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. However, our ongoing efforts to comply with evolving laws and regulations may be costly and require ongoing modifications to our policies, procedures and systems.

On December 28, 2021, the Cyberspace Administration of China (“CAC”), jointly with 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, if a critical information infrastructure operator purchases network products and services or a network platform operator conducts any data processing activity that affects or may affect national security, a cybersecurity review shall be carried out according to the MCR. In accordance with Article 7 of the MCR, a network platform operator possessing personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when [REDACTED] abroad (國外[REDACTED]).

As of the Latest Practicable Date, (i) we had not been notified of the results of any determination that we have been identified as a critical information infrastructure operator by the relevant governmental authorities; (ii) we had been focused on the discovery, development and commercialization of therapeutics primarily for oncology, autoimmune and inflammatory diseases, and had not conducted any business involving the collection, usage, storage or processing of personal information of users through network information technology or via

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internet; (iii) we had not received any notification of cybersecurity review from the relevant governmental authorities, nor had we been involved in any investigations on cybersecurity review initiated by CAC or received any inquiry, notice, warning, or sanctions in such respect; and (iv) the [REDACTED] is a [REDACTED] in Hong Kong, rather than a [REDACTED] abroad (國外[REDACTED]). Therefore, as advised by our PRC Legal Advisor, taking into consideration the above and provided that there is no material change to our current business and no further rules are introduced and no significant changes to the MCR is made by the relevant governmental authorities, our Directors believe cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us.

However, the MCR was released recently, certain provisions of which are subject to clarification by the relevant governmental authorities. If we were deemed having conducted any data processing activity that “affects or may affect national security” by the relevant regulatory authorities, we may be subject to cybersecurity review under the MCR. 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 penalties and/or actions by the competent governmental authorities.

In addition, on September 24, 2024, the State Council released the Regulation on the Administration of Cyber Data Security (《網絡數據安全管理條例》) (the “**Cyber Data Security Regulation**”), which would come into effect on March 31, 2025. Cyber Data Security Regulation stipulated certain requirements on data processors in their daily operations and, among others, required an internet data processor to apply for a cybersecurity review pursuant to relevant laws and regulations if such internet data processor processing activities that affect or may affect national security. However, as the Cyber Data Security Regulation provided no further explanation or interpretation for “affect or may affect national security,” there remains uncertainty as to whether we would be subject to cybersecurity review under the Cyber Data Security Regulation.

On July 7, 2022, CAC promulgated the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), which took effect on September 1, 2022 and required that the data processors providing data overseas and falling under any of the circumstances provided in Article 4 of the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) shall apply for the security assessment of cross-border data transfer. On March 22, 2024, CAC further promulgated the Provisions on Facilitating and Regulating Cross-border Data Flow (《促進和規範數據跨境流動規定》), providing the latest circumstances for the security assessment of cross-border data transfer. According to the Provisions on Facilitating and Regulating Cross-border Data Flow (《促進和規範數據跨境流動規定》), where a data processor transfers any data overseas and has any of the following circumstances, it shall apply to the CAC for security assessment: (i) where a data processor provides important data overseas; (ii) where a critical information infrastructure operator or a data processor processing the personal information of more than 1 million individuals provides personal information; or (iii) where a data processor transfers overseas the personal information of more than 100,000 individuals (excluding sensitive personal information) or the sensitive personal information of more than 10,000 individuals on

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a cumulative basis starting from January 1 of the said year. As of the Latest Practicable Date, as our business operations had not fallen under any of the above-mentioned circumstances, our Directors believed the security assessment of cross-border data transfer under the Measures for the Security Assessment of Cross-border Data Transfer shall not be applicable to us currently.

Laws in all 50 U.S. states require businesses to provide notice under certain circumstances generally to governmental authorities and affected individuals in connection with certain breaches of personal information, and, in the future, we may be required to notify applicable governmental authorities and affected individuals in the event of a data breach or other data security incident. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. Other states also have enacted laws and regulations relating to privacy and information security and comprehensive privacy laws. The laws are not consistent, as certain 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. These laws may apply directly to our business or indirectly by contract when we enter into collaboration arrangements to other companies. If we become subject to these new or additional privacy laws, the risk of enforcement actions against us could increase.

In addition, the European Union’s General Data Protection Regulation (EU) 2016/679, or GDPR, went into effect on May 25, 2018 in respect of processing operations carried out in the context of the activities of an establishment in the European Economic Area, or EEA, and any processing relating to the offering of goods or services to individuals in the EEA and/or the monitoring of their behavior in the EEA. The GDPR provides that EEA member states may make their own further laws and regulations to introduce specific requirements in certain areas, including related to the processing of “special categories of personal data,” including personal data related to health and genetic data. This may lead to greater divergence among the laws and regulations that apply to the processing of personal data across the EEA and United Kingdom, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such laws and regulations could also limit our ability to collect, use, share and otherwise process personal data in the context of our EEA and/or UK establishments (regardless of where any such processing occurs), and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business and financial condition.

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We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, if and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities. In addition, according to the Administration of Human Genetic Resources (《人類遺傳資源管理條例》) promulgated in March 2024 and the PRC Biosecurity Law (《生物安全法》) promulgated in April 2024, if any scientific data falls within the scope of Chinese human genetic resources, any transfer of such data outside of China will be subject to the prior approval of the PRC Ministry of Science and Technology. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all.

The data collected by us mainly includes personal information of patients participating in clinical trials and clinical trial data, and the relevant data are processed in accordance with the informed consent forms agreed by the patients. To the best of our knowledge, we believe that all the personal information of patients generated in our clinical trials has been de-identified to the extent necessary. According to the cooperation agreements entered with our overseas collaboration partners, we provide online access of certain clinical data to them.

According to Article 22 of the Administration of the Management of Human Genetic Resources, approval is not required where clinical institutions, in order to obtain the marketing licenses of relevant drugs and medical devices in China, carry out international cooperation in clinical trials by utilization of China’s human genetic resources by the clinical institutions but not involving the export of physical materials of human genetic resources. However, the two cooperating parties shall, before conducting such clinical trials, submit the types, quantities and uses of the human genetic resources to be used to the health department of the State Council for filing. We transfer clinical trial data to our collaboration partners online, which does not involve the export of physical materials of human genetic resources, and have filed with the Human Genetic Resource Administration of China certain reports regarding the use of human genetic materials in clinical studies.

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In addition, our transfer of the clinical trial data to our overseas collaboration partners does not involve data export security assessment under the Measures for the Security Assessment of Cross-Border Data Transmission, because we are not critical information infrastructure operator, we do not process personal information of more than 1 million people, and we do not provide personal information of more than 100,000 people or sensitive personal information of more than 10,000 people to our overseas collaboration partners. With respect to our cross-border transfer of clinical trial data, we have signed with our overseas collaboration partner SELLAS the standard contract for the cross-border transfer of personal information.

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which our drug products, for which marketing approvals are obtained, are marketed, sold and distributed.

For instance, the marketing and sales activities of GFH925 and our other pipeline products, once they are approved by the NMPA, will be subject to various PRC fraud and abuse laws, including the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) and the PRC Criminal Law (《中華人民共和國刑法》). After receiving marketing approvals from the FDA, our operations will be subject to federal and state fraud and abuse laws United States, including the federal Anti-Kickback Statute and the False Claims Act, as well as physician payment transparency laws and regulations, including the Physician Payments Sunshine Act, among others.

Furthermore, we are subject to anti-bribery laws in China and overseas that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. In addition, although currently our business operations are primarily in China, we are subject to the Foreign Corrupt Practices Act (FCPA) of the United States, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs.

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Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and regulations, and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws or regulations. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or 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 damage, 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 material adverse effect on our business, financial condition, results of operations and prospects.

We are also exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties. Those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

There might be uncertainties in effecting service of legal process and enforcing foreign judgments against us and our management in the PRC.

We are a company incorporated under the laws of the PRC, and a significant portion of our assets and the majority of our Directors and senior management are located in the PRC. As a result, it may be difficult for the [REDACTED] to directly effect service of process outside the PRC upon us or most of our Directors and senior management in the PRC.

On July 14, 2006, the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by Courts of the Mainland and the Hong Kong Special Administration 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,

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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 pursuant to 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 judgment rendered by a Hong Kong court may not be enforced in Mainland China if the parties in dispute have not agreed to enter into a choice of court agreement in writing.

On January 18, 2019, the Supreme People’s Court and the government of the 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 (《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》) (the “**New Arrangement**”), which seeks to establish a mechanism with further clarification on and certainty for reciprocal recognition and enforcement of judgments in a wider range of civil and commercial matters between Mainland China and Hong Kong. The New Arrangement does not include the requirements for a choice of court agreement in writing by the parties. The New Arrangement has come into effect on January 29, 2024 and superseded the Arrangement. After the New Arrangement became effective, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing.

Required procedures on the remittance of Renminbi into and out of the PRC may affect our ability to pay dividends and other obligations and affect the value of your [REDACTED].

Procedures on the remittance of Renminbi into and out of the PRC are required under the relevant PRC laws and regulations. A substantial majority of our future revenue 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 H Shares. Shortages in the availability of foreign currency may affect our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under the relevant PRC laws and regulations, foreign exchange transactions under the current account conducted by us do not require advance approval from China’s State Administration of Foreign Exchange (“SAFE”), but we are required to present relevant documentary evidence 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 Renminbi 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.

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Holders of H Shares may be subject to PRC income taxes.

Under the current PRC tax laws and regulations, non-PRC resident individuals and non-PRC resident enterprises are subject to different tax obligations with respect to the dividends paid to them by us and the gains realized upon the sale or other disposition of H Shares.

Non-PRC resident individuals are required to pay PRC individual income tax at a 20% rate for the income derived in China under the PRC Individual Income Tax Law (the “**IIT Law**”) and its implementation guidelines. Accordingly, we are required to withhold such tax from dividend payments, unless applicable tax treaties between China and the jurisdiction in which the foreign individual resides reduce or provide an exemption for the relevant tax obligations. However, pursuant to the Circular on Certain Policy Questions Concerning Individual Income Tax (《財政部、國家稅務總局關於個人所得稅若干政策問題的通知》) (Cai Shui Zi [1994] No. 020) issued by the MOF and SAT on May 13, 1994, the income gained by individual foreigners from dividends and bonuses of enterprises with foreign investment are exempted from individual income tax for the time being. In addition, under the IIT Law and its implementation regulations, non-PRC resident individual holders of H shares are subject to individual income tax at a rate of 20% on gains realized upon the sale or other disposition of H shares. However, pursuant to the Circular of 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》) (Cai Shui Zi [1998] No. 61) issued by the MOF and the SAT on March 30, 1998, from January 1, 1997, the income of individuals from the transfer of the shares of [REDACTED] enterprises continues to be exempted from individual income tax.

As of the Latest Practicable Date, no aforesaid provisions had expressly provided that individual income tax shall be levied on non-PRC resident individual holders on the transfer of shares in PRC resident enterprises [REDACTED] on overseas stock exchanges, and to our knowledge, no such individual income tax was levied by PRC tax authorities in practice. However, there is no assurance that the PRC tax authorities will not change these practices which could result in levying income tax on non-PRC resident individual holders on gains from the [REDACTED] of H shares.

For non-PRC resident enterprises that do not have establishments or premises in China, and for those that have establishments or premises in China but whose income is not related to such establishments or premises, under the PRC Enterprise Income Tax Law and its implementation regulations, dividends paid by us and gains realized by such foreign enterprises upon the sale or other disposition of H Shares are subject to PRC enterprise income tax at a 10% rate. In accordance with the Circular on Issues Relating to Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-PRC Resident Enterprise Shareholders of H Shares (《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》) (Guo Shui Han [2008] No. 897) issued by SAT on November 6, 2008, the withholding tax rate for dividends payable to non-PRC resident enterprise holders of H Shares will be 10% and we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including

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[REDACTED]). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty or arrangement will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities’ approval.

Despite the arrangements mentioned above, the interpretation and application of applicable PRC tax laws and regulations by the competent tax authorities shall be in accordance with the then effective laws and regulations, and new taxes may be imposed which may materially and adversely affect the value of your [REDACTED] in our H Shares.

We are subject to risks in relation to our social insurance and housing provident fund contributions.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to the social insurance plans and the housing provident fund under the relevant PRC laws and regulations for our employees.

As of April 30, 2025, we did not make full social security insurance contributions for certain employees who are not PRC citizens, in accordance to their own preference, which we estimate to be approximately RMB1.1 million during the Track Record Period. We also engaged a third-party human resources agency to pay social insurance premium and housing provident funds for one employee. Pursuant to the agreement entered into between such third-party human resources agency and us, the third-party human resources agency would pay social insurance premium and housing provident funds for such employee on behalf of us. As of the Latest Practicable Date, (i) the employees had confirmed such arrangement and had raised no objections in relation thereto; (ii) there had been no disputes between us, such employees and/or the third-party human resources agency with regard to such arrangement, as the case may be; and (iii) we had not received any notice of rectification from, or been imposed any administrative penalty by, the relevant governmental authorities as a result of such arrangement or nonpayment for employees who are not PRC citizens. If the relevant governmental authorities determine the use of the third-party agency to pay social insurance premium and housing provident funds to be non-compliant in the future or such human resources agency fails to pay the social insurance premium or housing provident funds for our employee as required by applicable PRC laws and regulations, or if the relevant government authorities require us to pay social insurance premium for employees who are not PRC citizens despite their own preference not having us make such payments, we may be subject to additional contribution, late payment fee and/or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance premium and housing provident funds as an employer or be ordered to rectify. This in turn may adversely affect our financial condition and results of operations.

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We are subject to risks associated with our leased properties.

We have leased certain properties in China as our offices and laboratories. Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we had not registered seven lease agreements as tenant, which were primarily used as offices and laboratories. Although failure to register does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future. In addition, as our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

RISKS RELATING TO THE [REDACTED]

There has been no public market for our H Shares, and an active [REDACTED] market for our H Shares may not develop or be sustained.

Prior to the [REDACTED], there was no public market for our H Shares. We cannot assure you that a public market for our H Shares with adequate liquidity will develop and be sustained following the completion of [REDACTED]. The initial [REDACTED] for our H Shares to the [REDACTED] will be the result of negotiations between us and the [REDACTED] (for itself and on behalf of [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of the H Shares following the [REDACTED].

We have applied to the Hong Kong Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the H Shares (including any H Shares which may be issued pursuant to the exercise of the [REDACTED] and the [REDACTED]). A [REDACTED] on the Hong Kong Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] market for the H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the H Shares will not decline following the [REDACTED]. If an active public market for our H Shares does not develop following the completion of the [REDACTED], the [REDACTED] and liquidity of our H Shares could be materially and adversely affected.

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The price and [REDACTED] volume of our H Shares may be volatile, which could lead to substantial losses to [REDACTED].

The price and [REDACTED] volume of our H 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 [REDACTED] of the shares of other companies engaging in similar business may affect the price and [REDACTED] volume of our H Shares. In addition to market and industry factors, the price and [REDACTED] volume of our H Shares may be highly volatile for specific business reasons, such as fluctuations in our revenue, earnings, cash flows, investments, expenditures, regulatory developments, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies [REDACTED] on the Hong Kong Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in price not directly related to our performance but related to the overall political and economic conditions in Hong Kong, the PRC or elsewhere in the world.

Our Single Largest Group of Shareholders have substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders.

Immediately upon the completion of the [REDACTED], without taking into account any H Shares which may be issued pursuant to the exercise of the [REDACTED] or the [REDACTED], our Single Largest Group of Shareholders will collectively control approximately [REDACTED]% of the voting power at our general meetings. Our Single Largest Group of Shareholders will thus have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional Shares or other equity securities, timing and amount of dividend payments, and our management. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a sale of our Company and might reduce the price of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Single Largest Group of Shareholders may differ from the interests of our other Shareholders. We cannot assure you that our Single Largest Group of Shareholders will not exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

RISK FACTORS

Future sales or perceived sales or conversion of significant amounts of our H Shares in the public market following the [REDACTED] could materially and adversely affect the price of our H Shares.

The [REDACTED] of our H Shares could decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the public market, or the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or anticipated sales, of substantial amounts of our securities, including any future [REDACTED], could also materially and adversely affect our ability to raise capital at a specific time and on terms favorable to us. In addition, our Shareholders may experience dilution in their holdings if we issue more securities in the future. New shares or shares-linked securities issued by us may also confer rights and privileges that take priority over those conferred by the H Shares.

In addition, while [REDACTED] shares in the [REDACTED] are not subject to any restrictions on the disposal of the H Shares they [REDACTED] (except otherwise disclosed in this Document), they may have existing arrangements or agreement to dispose part or all of the H Shares they hold immediately or within certain period upon completion of the [REDACTED] for legal and regulatory, business and market, or other reasons. Such disposal may occur within a short period or any time or period after the [REDACTED].

Any sale of the H Shares [REDACTED] by such [REDACTED] pursuant to such arrangement or agreement could adversely affect the [REDACTED] of our H Shares and any sizeable sale could have a material and adverse effect on the [REDACTED] of our H Shares and could cause substantial volatility in the [REDACTED] volume of our H Shares.

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

The [REDACTED] of the H Shares is higher than the net tangible asset value per H Share immediately prior to the [REDACTED]. Therefore, [REDACTED] of the H Shares in the [REDACTED] will experience an immediate dilution. In order to expand our business, we may consider [REDACTED] and issuing additional Shares in the future. Purchasers of the H Shares may experience dilution 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. Furthermore, we may issue Shares through the employee incentive platforms, which would further dilute Shareholders’ interests in our Company.

RISK FACTORS

Payment of dividends is subject to restrictions under the PRC law and there is no assurance whether and when we will pay dividends.

Under PRC law and the constitutional documents of our Company and our PRC operating subsidiaries, dividends may be paid only out of distributable profits, which refer to after-tax profits as determined under PRC GAAP less any recovery of accumulated losses and required allocations to statutory capital reserve funds. Any distributable profits that are not distributed in a given year are retained and become available for distribution in subsequent years. As a result, our Company and our PRC operating subsidiaries may not be able to pay a dividend in a given year if our Company or our PRC operating subsidiaries do not have distributable profits as determined under PRC GAAP even if they have profits as determined under IFRS. During the Track Record Period, no dividend had been paid or declared by us. See “Financial Information — Dividends” for further details of our dividend policy.

There can be no assurance that future dividends will be declared or paid. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors, after taking into account our results of operations, financial condition, cash requirements and availability and other factors as they may deem relevant, and subject to the approval at Shareholders’ meeting. We may not have sufficient or any profits to enable us to make dividend distributions to our Shareholders in the future, even if our financial statements indicate that our operations have been profitable.

Certain facts, forecasts and statistics in this Document relating to the biopharmaceutical industry are derived from a third-party report or publicly available sources and may not be fully reliable.

Certain statistics, information and data contained in this Document relating to China and elsewhere in the world, and the industry in which we operate have been derived from various official government publications or other third-party reports. In particular, we have extracted and disclosed in this Document certain statistics, information and data from publications and other publicly available sources relating to the drugs and drug candidates of third parties and scientific research, theories and mechanisms. We have taken reasonable care in the reproduction or extraction of the official government publications and other third-party reports for the purpose of disclosure in this Document. However, we cannot guarantee the quality or reliability of such source materials. They have not been prepared or independently verified by us, the [REDACTED] or any of their respective affiliates or advisors and, therefore, we make no representation as to the accuracy of such statistics, information and data, which may not be consistent with other information compiled within or outside the PRC. Due to possibly flawed or ineffective collection methods and analysis or discrepancies between published information and market practice, such statistics, information and data in this Document may be inaccurate or may not be comparable to statistics, information and data produced with respect to other economies. Further, there is no assurance that they are stated or compiled on the same basis or with the same degree of accuracy as the case may be in other jurisdictions. In all cases, [REDACTED] should give consideration as to how much weight or importance they should attach to or place on such facts.

RISK FACTORS

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].

Prior to the publication of this Document, there has been coverage in the media regarding us and the [REDACTED], which contained among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for the accuracy or completeness of such media coverage or forward-looking statements. We make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the media. We disclaim any information in the media to the extent that such information is inconsistent or conflicts with the information contained in this Document. 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.

WAIVERS AND EXEMPTION

In preparation for the [REDACTED], our Company has sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and exemption from strict compliance with the Companies (Winding up and Miscellaneous Provisions) Ordinance.

WAIVER IN RESPECT OF MANAGEMENT PRESENCE IN HONG KONG

According to Rule 8.12 of the Listing Rules, a new applicant for a primary [REDACTED] on the Stock Exchange 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. Rule 19A.15 of the Listing Rules further provides that the requirement in Rule 8.12 of the Listing Rules may be waived by having regard to, among other considerations, our arrangements for maintaining regular communication with the Hong Kong Stock Exchange.

We do not have a sufficient management presence in Hong Kong for the purpose of satisfying the requirement under Rule 8.12 and Rule 19A.15 of the Listing Rules. Our management headquarters, senior management, business operations and assets are primarily based outside Hong Kong. The Directors consider that either by means of relocation of our existing executive Directors or appointment of additional executive Directors who will be ordinarily resident in Hong Kong would not be beneficial to, or appropriate for, our Group and therefore would not be in the best interests of our Company or the Shareholders as a whole. As such, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us a waiver from strict compliance with Rule 8.12 and Rule 19A.15 of the Listing Rules. We will ensure that there is a regular and effective communication between us and the Stock Exchange by way of, among others, the following conditions:

- (a) pursuant to Rule 3.05 of the Listing Rules, we have appointed Ms. Zhang and Mr. NG Tung Ching Raphael (“**Mr. Ng**”) as our authorized representatives (the “**Authorized Representatives**”), who will act as our principal channel of communication with the Stock Exchange and ensure that our Company complies with the Listing Rules at all times. Mr. Ng is based in Hong Kong and our Authorized Representatives will be available to meet with the Stock Exchange in Hong Kong within a reasonable time frame upon the request of the Stock Exchange and will be readily contactable by telephone and email to deal promptly with enquiries from the Stock Exchange. Our Company has provided contact details of the Authorized Representatives to the Stock Exchange and will inform the Stock Exchange promptly in respect of any change in the Authorized Representatives;
- (b) both Authorized Representatives have means to contact all Directors (including the independent non-executive Directors) promptly at all times as and when the Stock Exchange wishes to contact our Directors for any matters. Our Company has implemented a policy whereby (1) each Director has provided their respective valid phone numbers or other means of communication to the Authorized Representatives; (2) in the event that a Director expects to travel or is otherwise out of office, he/she will endeavor to provide his/her phone number or the place of his/her

WAIVERS AND EXEMPTION

accommodation to the Authorized Representatives or maintain an open line of communication via his/her mobile phone; and (3) each Director has provided his/her mobile phone number, office phone number, e-mail address and, where available, fax number to the Stock Exchange and will inform the Stock Exchange promptly if there are any changes to the contact details of the Directors;

- (c) pursuant to Rule 3.20 of the Listing Rules, each Director has provided his/her contact information to the Stock Exchange and to the Authorized Representatives. This will ensure that the Stock Exchange and the Authorized Representatives should have means for contacting all Directors promptly at all times as and when required;
- (d) all our Directors who are not ordinarily resident in Hong Kong have confirmed that they possess or can apply for valid travel documents to visit Hong Kong and will be able to meet with relevant members of the Stock Exchange in Hong Kong upon reasonable notice, when required;
- (e) pursuant to Rule 3A.19 of the Listing Rules, we have retained the services of Guotai Junan Capital Limited as Compliance Advisor upon [REDACTED] 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], which will act as an additional channel of communication with the Stock Exchange and will be available to respond to enquiries from the Stock Exchange. The contact details of the Compliance Advisor have been provided to the Stock Exchange;
- (f) our Authorized Representatives, Directors and other officers of our Company will provide promptly such information and assistance as the Compliance Advisor may reasonably require in connection with the performance of the Compliance Advisor’s duties as set forth in Chapter 3A of the Listing Rules. There will be adequate and efficient means of communication between our Company, Authorized Representatives, Directors and other officers of our Company and the Compliance Advisor, and to the extent reasonably practicable and legally permissible, we will keep the Compliance Advisor informed of all communications and dealings between the Stock Exchange and us; meetings between the Stock Exchange and our Directors could be arranged through our Authorized Representatives or the Compliance Advisor, or directly with our Directors within a reasonable time frame. We will inform the Stock Exchange as soon as practicable in respect of any change of Authorized Representatives and/or the Compliance Advisor; and
- (g) we will appoint other professional advisors (including legal advisors in Hong Kong) after the [REDACTED] to assist us in dealing with any questions which may be raised by the Stock Exchange and to ensure that there will be prompt and effective communication with the Stock Exchange.

WAIVERS AND EXEMPTION

WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules and Chapter 3.10 of the Guide for New Listing Applicants, a new applicant for [REDACTED] on the Stock Exchange must appoint a company secretary who, by virtue of his/her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary.

Note 1 to Rule 3.28 of the Listing Rules provides that the Stock Exchange considers the following academic or professional qualifications to be acceptable:

- (a) a member of The Hong Kong Chartered Governance Institute;
- (b) a solicitor or barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong); and
- (c) a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong).

Note 2 to Rule 3.28 of the Listing Rules further provides that the Stock Exchange considers the following factors in assessing the “relevant experience” of the individual:

- (a) length of employment with the issuer and other issuers and the roles he/she played;
- (b) familiarity with the Listing Rules and other relevant laws and regulations including the SFO, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (c) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and
- (d) professional qualifications in other jurisdictions.

Our Company has appointed Ms. Zhang and Mr. Ng as our joint company secretaries. See “Directors, Supervisors and Senior Management — Joint Company Secretaries” for their biographical details.

Ms. Zhang joined our Group in August 2017 and is our executive Director and secretary to the Board. She has extensive experience in supervising financing and corporate governance matters of our Company. The Company believes that it would be in the best interests of the Company and the corporate governance of the Group to have a person such as Ms. Zhang as its joint company secretary, who is our secretary to the Board and has day-to-day knowledge of the Company’s affairs. Ms. Zhang has the necessary nexus to the Board and close working relationship with management of the Company in order to perform the function of a joint company secretary and to take the necessary actions in the most effective and efficient manner.

WAIVERS AND EXEMPTION

However, Ms. Zhang presently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules, and may not be able to solely fulfill the requirements of the Listing Rules. Therefore, we have appointed Mr. Ng, who is an Associate Member of both The Hong Kong Chartered Governance Institute (the “**HKCGI**” formerly known as the Hong Kong Institute of Chartered Secretaries) and The Chartered Governance Institute in the United Kingdom. He also possesses the practitioner’s endorsement from HKCGI and fully meets the requirements stipulated under Rules 3.28 and 8.17 of the Listing Rules, to act as the other joint company secretary and to provide assistance to Ms. Zhang for an initial period of three years from the [REDACTED] to enable Ms. Zhang to acquire the “relevant experience” under Note 2 to Rule 3.28 of the Listing Rules so as to fully comply with the requirements set forth under Rules 3.28 and 8.17 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules such that Ms. Zhang may be appointed as a joint company secretary of our Company.

The waiver is valid for an initial period of three years from the [REDACTED], and is granted on the condition that Mr. Ng, as a joint company secretary of our Company, will work closely with Ms. Zhang to jointly discharge the duties and responsibilities as company secretaries and assist Ms. Zhang in acquiring the relevant experience as required under Rules 3.28 and 8.17 of the Listing Rules. Mr. Ng will also assist Ms. Zhang in organizing Board meetings and Shareholders’ meetings of our Company as well as other matters of our Company which are incidental to the duties of a company secretary. Mr. Ng is expected to work closely with Ms. Zhang and will maintain regular contact with Ms. Zhang, the Directors and the senior management of our Company. In addition, Ms. Zhang will comply with the annual professional training requirement under Rule 3.29 of the Listing Rules and will enhance her knowledge of the Listing Rules during the three-year period from the [REDACTED]. Ms. Zhang will also be assisted by (a) the Compliance Advisor, particularly in relation to compliance with the Listing Rules; and (b) the Hong Kong legal advisors of our Company, on matters concerning our Company’s ongoing compliance with the Listing Rules and the applicable laws and regulations.

Pursuant to Chapter 3.10 of the Guide for New Listing Applicants, the waiver will be revoked immediately if Mr. Ng ceases to provide assistance to Ms. Zhang as a joint company secretary for the three-year period after the [REDACTED] or where there are material breaches of the Listing Rules by our Company.

Prior to the expiration of the initial three-year period, the qualifications and experience of Ms. Zhang will be re-evaluated to determine whether the requirements as stipulated in Rules 3.28 and 8.17 of the Listing Rules can be satisfied and whether the need for ongoing assistance will continue. We will liaise with the Stock Exchange to enable it to assess whether Ms. Zhang, having benefited from the assistance of Mr. Ng for the preceding three years, will have acquired the skills necessary to carry out the duties of company secretary and the relevant experience within the meaning of Note 2 to Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

WAIVERS AND EXEMPTION

EXEMPTION FROM STRICT COMPLIANCE WITH SECTION 342(1)(b) OF THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE IN RELATION TO 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 documents to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance (the “**Third Schedule**”), and set out the reports specified in Part II of the Third Schedule.

Paragraph 27 of Part I of the Third Schedule requires a [REDACTED] applicant 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.

Paragraph 31 of Part II of the Third Schedule further requires a [REDACTED] applicant 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 the 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 [REDACTED] 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 [REDACTED] document be included in the accountants’ report to the document.

Our Company is a Biotech Company as defined under Chapter 18A of the Listing Rules and is seeking a [REDACTED] under Chapter 18A of the Listing Rules. 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 [REDACTED] 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 [REDACTED] document.

WAIVERS AND EXEMPTION

In compliance with the abovementioned requirements under the Listing Rules, the Accountants' Report set out in Appendix I is prepared to cover the two financial years ended December 31, 2023 and 2024 and the four months ended April 30, 2025. As such, we have applied to the SFC for, and the SFC [has granted], 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 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 R&D 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;
- (b) the Accountants' Report for the two financial years ended December 31, 2023 and 2024 and the four months ended April 30, 2025 has been disclosed in the document of our Company and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (c) notwithstanding that the financial results set out in this Document are only for the two financial years ended December 31, 2023 and 2024 and the four months ended April 30, 2025 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;
- (d) furthermore, as Chapter 18A of the Listing Rules provides track record period of two years for biotech companies in terms of financial disclosure, strict compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unnecessary and/or irrelevant in the circumstance of the Company. Substantially all of our revenue in 2023 and 2024 was derived from our collaboration with Innovent relating to our Core Product GFH925. In contrast, the majority of our 2022 revenue came from our collaboration with SELLAS regarding GFH009, which commenced in March 2022. As we continue to monitor evolving treatment paradigms in hematological malignancies and assess the broader landscape for CDK9 inhibitors, we may consider future development or business development pathways to maximize the value of GFH009. However, we do not anticipate generating any meaningful revenue from our collaboration with SELLAS in the near term. Given the non-recurring nature of the revenue in 2022 and its limited relevance to our current business operations and revenue model, we believe the financial information in 2022 do not provide meaningful insight into our

WAIVERS AND EXEMPTION

ongoing performance and are not necessary for [REDACTED] understanding and assessment of the business, assets and liabilities, financial position, management and prospects of the Group; and

- (e) the Accountants’ Report covering the two financial years ended December 31, 2023 and 2024 and the four months ended April 30, 2025 (as set out in Appendix I), together with other disclosure in this Document, have already provided the potential [REDACTED] with adequate and reasonably up-to-date information in the circumstances to form a view on the track record of our Company; and our Directors confirm that all information which is necessary for the [REDACTED] to make an informed assessment of the business, assets and liabilities, financial position, management and prospects has been included in this Document. Therefore, the exemption would not prejudice the interests of the [REDACTED].

The SFC [has granted] us 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 on the condition 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]

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. Qiang LU	No. 21, Lane 2466 Jinxu Road Pudong New Area Shanghai PRC	American

Dr. Jiong LAN	No. 1, Lane 408 Qingtong Road Pudong New Area Shanghai PRC	American

Ms. ZHANG Wei (張巍)	Building No. 4 Lanting Xuan Dongli District Tianjing PRC	Chinese

Non-executive Directors

Mr. ZHU Jingyang (朱競陽) (formerly named ZHU Daqiang (朱大強))	Floor 2, Building 1 No. 1 Courtyard Shuijun Chang'an Jiayuan Chaoyang District Beijing PRC	Chinese

Ms. TAO Sha (陶莎)	Unit 1 Centrium Residence No. 3 BaiJiaZhuang Bei Li Chaoyang District Beijing PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Independent non-executive Directors

Ms. Christine Shaohua LU-WONG (盧韶華)	Flat A, 9/F Block 19 Mei Foo Sun Chuen Nassau Street Kowloon Hong Kong	American
Dr. ZHOU Demin (周德敏)	10/F, Building 26 No. 38 Xueyuan Road Haidian District Beijing PRC	Chinese
Mr. LI Bo (李波)	No. 10, Lane 1500 Changyi Road Pudong New Area Shanghai PRC	Chinese

SUPERVISORS

Name	Address	Nationality
Mr. XUE Mengjun (薛孟軍)	No. 52, Lane 588 Lianhua South Road Minhang District Shanghai PRC	Chinese
Mr. LIN Chonglan (林崇懶)	No. 16, Lane 7677 Shenjiang South Road Pudong New Area Shanghai PRC	Chinese
Ms. MA Rui (馬睿)	No. 18, Lane 550 Heyun Road Pudong New Area Shanghai PRC	Chinese

See “Directors, Supervisors and Senior Management” for further details of our Directors and Supervisors.

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Sole Sponsor

CITIC Securities (Hong Kong) Limited

18/F, One Pacific Place

88 Queensway

Hong Kong

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

Legal advisors to our Company

As to Hong Kong and United States laws:

Davis Polk & Wardwell
10/F, The Hong Kong Club Building
3A Chater Road
Central
Hong Kong

As to PRC laws:

Jia Yuan Law Offices
32F, Building S1
The Bund Finance Center
No. 600, Zhongshan No. 2 Road (E)
Huangpu District, Shanghai
PRC

As to PRC intellectual property law:

JunHe LLP
26/F, HKRI Centre One
HKRI Taikoo Hui
288 Shimen Road (No.1)
Shanghai
PRC

As to United States intellectual property law:

Jun He Law Offices P.C.
20380 Town Center Lane, Suite 128
Cupertino, CA 95014
USA

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

As to the laws of European Patent Convention and the national patent laws of EPC contracting countries:

2K Patent- und Rechtsanwälte — München

Bajuwarenring 14
82041 Oberhaching
Germany

Legal advisors to the Sole Sponsor and [REDACTED]

As to Hong Kong and United States laws:

Sullivan & Cromwell (Hong Kong) LLP

20th Floor, Alexandra House
18 Chater Road
Central
Hong Kong

As to PRC laws:

Jingtian & Gongcheng

45/F, K. Wah Centre
1010 Huai Hai Road (M)
Xu Hui District
Shanghai
China

Auditor 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.

Suite 2504
Wheelock Square
1717 Nanjing West Road
Shanghai
China

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Compliance Advisor

Guotai Junan Capital Limited

26/F-28/F, Low Block

Grand Millennium Plaza

181 Queen’s Road Central

Hong Kong

[REDACTED]

CORPORATE INFORMATION

**Registered Office, headquarter and
Principal Place of Business in the PRC**

Floors 2, 3, 4, and 5, Building 8
1206 Zhangjiang Road
(Shanghai) Pilot Free Trade Zone
PRC

Principal Place of Business in Hong Kong

46/F., Hopewell Centre
183 Queen’s Road East
Wan Chai, Hong Kong

Company’s Website

<http://www.genfleet.com>

*(the information contained on this website
does not form part of this Document)*

Joint Company Secretaries

Ms. ZHANG Wei (張巍)

Floors 2, 3, 4, and 5, Building 8
1206 Zhangjiang Road
(Shanghai) Pilot Free Trade Zone
PRC

Mr. NG Tung Ching Raphael (吳東澄)

*(Associate Member of both The Hong Kong
Chartered Governance Institute and The
Chartered Governance Institute in the
United Kingdom)*

46/F., Hopewell Centre
183 Queen’s Road East
Wan Chai
Hong Kong

Authorized Representatives

Ms. ZHANG Wei (張巍)

Floors 2, 3, 4, and 5, Building 8
1206 Zhangjiang Road
(Shanghai) Pilot Free Trade Zone
PRC

Mr. NG Tung Ching Raphael (吳東澄)

46/F., Hopewell Centre
183 Queen’ Road East
Wan Chai
Hong Kong

CORPORATE INFORMATION

Audit Committee

Ms. Christine Shaohua LU-WONG (盧韶華)
(*chairperson*)
Mr. ZHU Jingyang (朱競陽)
Dr. ZHOU Demin (周德敏)

Remuneration Committee

Mr. LI Bo (李波) (*chairperson*)
Dr. Jiong LAN
Dr. ZHOU Demin (周德敏)

Nomination Committee

Dr. Qiang LU (*chairperson*)
Ms. Christine Shaohua LU-WONG (盧韶華)
Mr. LI Bo (李波)

[REDACTED]

Principal Banks

Bank of Ningbo Co., Ltd. (Shanghai Branch)
1/F, Haiyin Financial Centre
No. 8 Middle Yincheng Road
Pudong New Area
Shanghai
PRC

China Merchants Bank Co., Ltd. (Shanghai Zhangjiang Branch)
1/F, Building 2
German Centre
No. 88 Ke Yuan Road
Zhangjiang Town
Pudong New Area
Shanghai
PRC

INDUSTRY OVERVIEW

Certain information and statistics set out in this section have been extracted from various official government publications, available sources from public market data providers and an Independent Third-Party source, Frost & Sullivan. The report prepared by Frost & Sullivan and cited in this document was commissioned by us. We believe that the sources of this information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. 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. The information from official government sources has not been independently verified by us, the Sole Sponsor, [REDACTED], any of their respective directors, employees, agents or advisors or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy, fairness and completeness. For discussion of the risks relating to our industry, see “Risk Factors” in this Document.

OVERVIEW OF ONCOLOGY DRUG MARKET

Overview

Cancer is a broad group of diseases that involve uncontrolled growth and development of cells in the body, and is one of the foremost reasons of deaths throughout the world. Over the past century, cancer treatments have experienced significant evolution from surgery, radiotherapy, chemotherapy, immuno-oncology therapies to targeted therapies, such as small molecule targeted therapies and antibody-based therapies. Among these advancements, the development of Rat sarcoma (“**RAS**”)-targeting therapies has answered to the long-term struggles by directly targeting Kirsten rat sarcoma (“**KRAS**”), one of the most frequently mutated oncogenes in cancer and which has historically been considered “undruggable.”

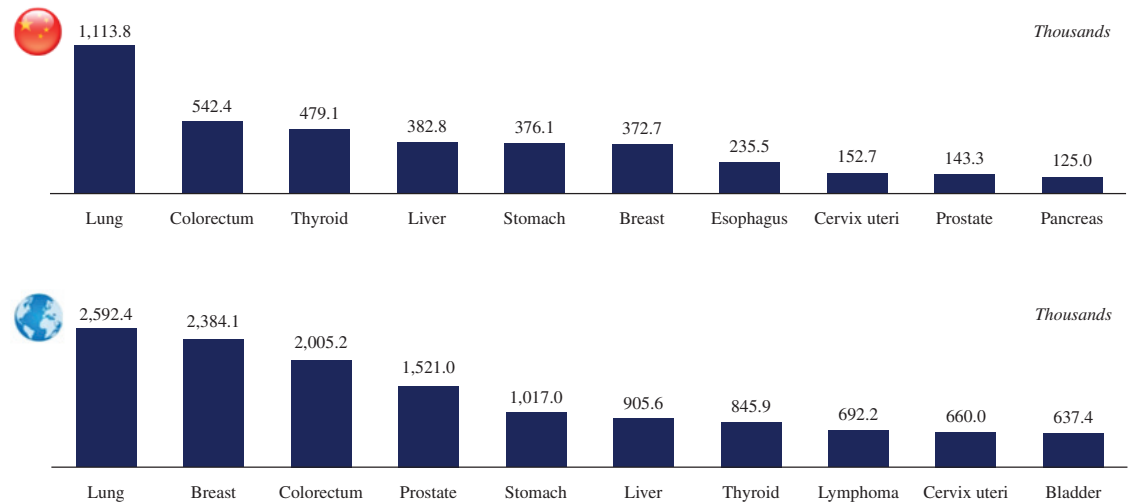
With the advanced cancer treatments today, there continue to be growing medical needs for differentiated therapeutics to improve duration of response and overall survival in oncology patients. Carcinogenesis is a highly complex biological process, and certain treatment methods that have shown to be effective for certain types of cancers may be less effective for others. Cancer cells could also become resistance to certain treatments due to, for example, activation of a signaling pathway through overactivation of downstream components. Additionally, the aging population and unhealthy lifestyle choices also drive up the cancer incidence globally.

Market Size of Oncology Drugs

Cancer is the leading cause of death worldwide, resulting in approximately 10 million deaths globally each year. There were 21.3 million new cancer cases globally in 2024, and it was estimated that as of 2033, there would be 26.0 million new cancer cases. The diagram below illustrates the top 10 cancer types by incidence globally in 2024, among which lung cancer, breast cancer and colorectal cancer were the top three cancers by global incidence. In China, lung cancer, colorectal cancer and thyroid cancer were the top three cancers by incidence as of 2024.

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China and Global Top 10 Cancers by Incidence in 2024



Note: Head and neck cancer is a collective term for cancers that occur in various parts of the head and neck, so it is not included in the ranking of single cancer incidence.

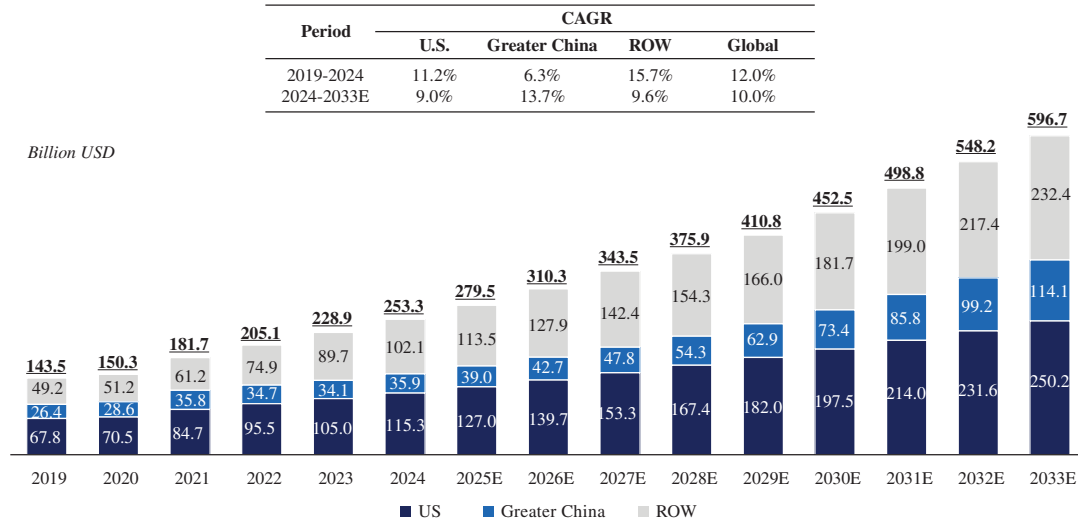
Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

The global oncology drug market has expanded significantly in the past and is projected to further grow. The global oncology drug market grew from US\$143.5 billion in 2019 to US\$253.3 billion in 2024 with a CAGR of 12.0%, and is expected to further grow to US\$596.7 billion in 2033 with a CAGR of 10.0% from 2024 to 2033. Greater China’s oncology drug market has also grown rapidly in recent years. Its size grew from US\$26.4 billion in 2019 to US\$35.9 billion in 2024 with a CAGR of 6.3%, and is expected to further grow to US\$114.1 billion in 2033 with a CAGR of 13.7% from 2024 to 2033.

In recent years, an increasing number of innovative cancer therapies have been approved globally. It is expected that more innovative drugs with better efficacy and/or less adverse effects than currently available therapies will continue to emerge. The following charts illustrate the historical and projected expansion of global and Greater China’s oncology drug markets.

INDUSTRY OVERVIEW

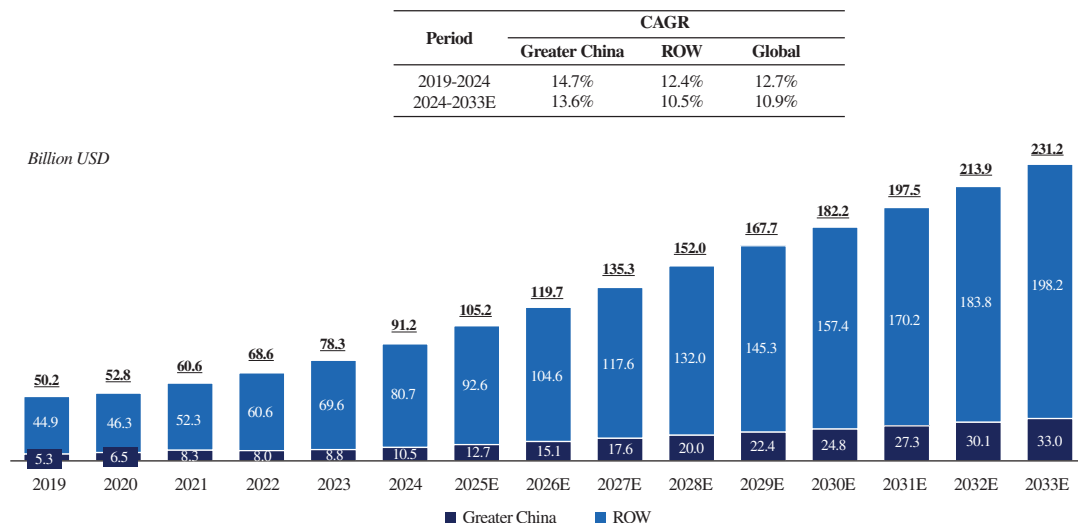
Global and Greater China Oncology Drug Market, 2019-2033E



Source: Frost & Sullivan Analysis

The global oncology drug markets for the treatment of NSCLC, CRC and pancreatic cancer represent considerable market size and growth potential in light of their prevalence and relatively large proportion of patients with unresectable tumor and/or at advanced stages. The diagrams below set forth the historical and projected market size of these three cancer types from 2019 to 2033, respectively.

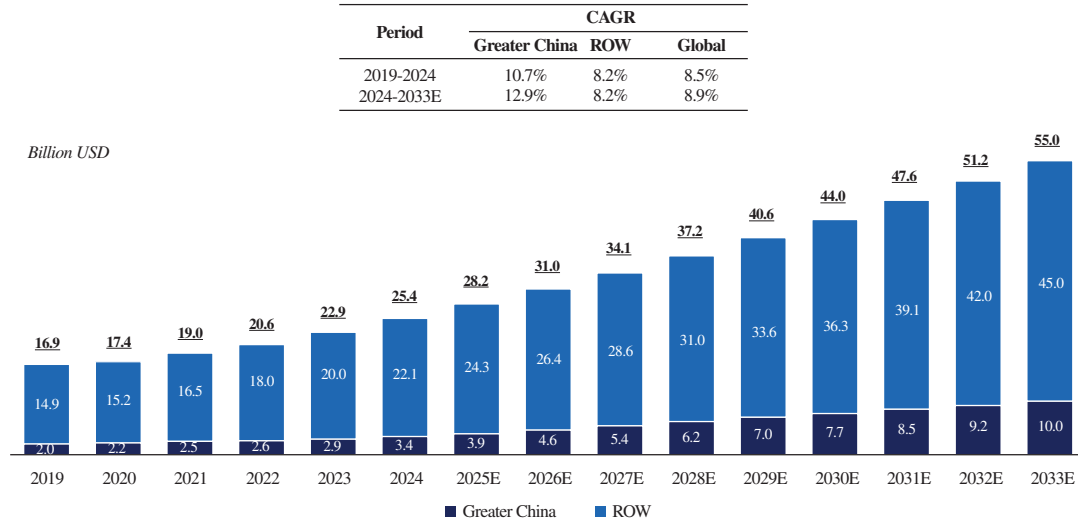
Global and Greater China NSCLC Drug Market Size, 2019-2033E



Source: NMPA, FDA, Annual Reports, Frost & Sullivan Analysis

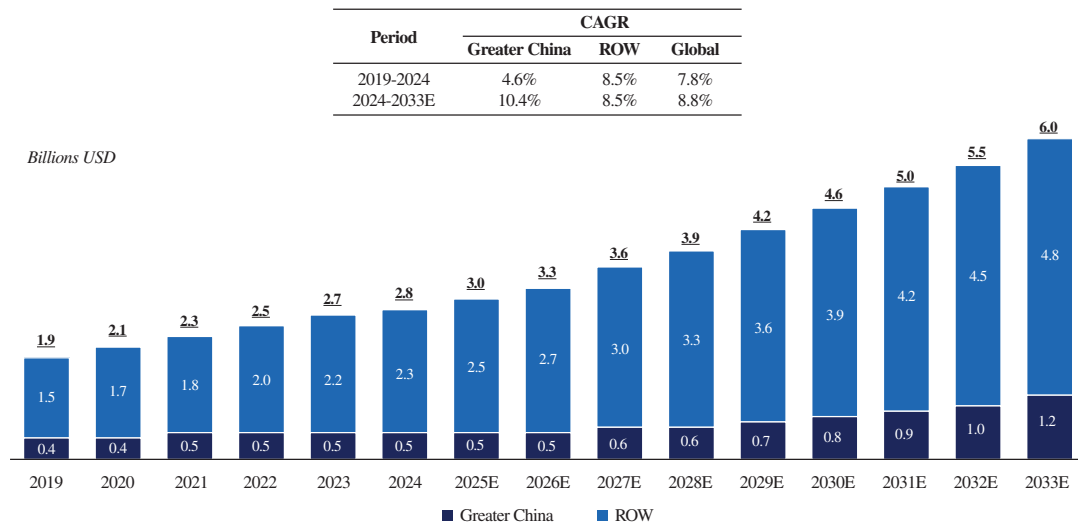
INDUSTRY OVERVIEW

Global and Greater China CRC Drug Market Size, 2019-2033E



Source: NMPA, FDA, Annual Reports, Frost & Sullivan Analysis

Global and Greater China Pancreatic Cancer Drug Market Size, 2019-2033E



Source: NMPA, FDA, Annual Reports, Frost & Sullivan Analysis

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The table below sets forth the proportion of unresectable and/or advanced stages of NSCLC, CRC and pancreatic cancer cases, respectively.

Proportion of Different Stages of Major Cancer Types

	 NSCLC	 CRC	 PC
	22% of patients were diagnosed as early stage (stage I-II), 21% as locally advanced stage (stage III), and 53% as late stage patients 30% to 55% of patients with NSCLC develop recurrence and die of their disease despite curative resection	35% of patients were diagnosed as early stage (stage I-II), 36% as locally advanced stage (stage III), and 23% as late stage patients - After treatment with curative intent, 30% to 40% of the patients develop recurrent disease; thus 43.8% were diagnosed at late stage	14% of patients were diagnosed as early stage (stage I-II), 29% as locally advanced stage (stage III), and 51% as late stage patients - At present, radical surgery is the only way to cure pancreatic cancer, while the recurrence rate within 2 years after surgery is 66%~92%
	16% of patients were diagnosed as early stage (stage I-II), 22% as locally advanced stage (stage III), and 57% as late stage patients - Surgical treatment is the first choice for early to mid stage patients, however, the postoperative recurrence and metastasis rate is still as high as 45.4%	56.2% of patients were diagnosed as early to mid stage, thus 43.8% were diagnosed at late stage - The recurrence rate after radical surgery for colorectal cancer is 30% to 40%	- The early diagnosis rate of pancreatic cancer was only 5%, the resectable pancreatic cancer was 15%~20%, thus 80%~85% should accept drug treatment at diagnose; - The tumor recurrence rates at 2 years after radical resection is 79%
	20%-40% are resectable cancers, including most stage I-IIIa and a small proportion of stage IIIB lung cancers	Almost all patients with initially diagnosed non-metastatic and partially metastatic CRC can be resected, and systemic treatment can transform partially unresectable CRC into resectable. There is no relevant research on the specific proportion	Resectable PC accounts for only approximately 10%-15% of total PC
Legends: - patients targeted by GFH925 and GFH375. - patients targeted by GFH375.			

Source: Literature review, Frost & Sullivan Analysis

Growth Drivers and Future Trends of Oncology Drug Market

According to Frost & Sullivan, the growth of oncology drug market has primarily been driven by the following factors:

- Unmet Clinical Needs.* In 2024, the global cancer incidence reached 21.3 million cases, which can be attributed to various factors such as an aging population, environmental pollution, and the prevalence of unhealthy lifestyle choices including smoking, physical inactivity and high-calorie diets. As a result, the number of cancer patients worldwide is expected to increase, leading to a corresponding expansion of the oncology drug market.
- Emerging Innovative Therapies.* Innovative therapies such as ADCs and targeted inhibitors are emerging treatment modalities for certain types of cancers. These therapies have made significant clinical progress with the increasing understanding of tumorigenesis mechanism and the use of evolving techniques to formulate such innovative therapies.

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- *Targeted Therapies.* Targeted therapy is an approach to diagnose and treat cancer that leverages information of an individual’s genotypes and associated factors. Statistics show that over 85% of the oncology market is now centered around targeted therapies. Targeted therapy enables physicians to formulate personalized and effective treatment options by incorporating cancer DNA (such as oncogenes) analysis into tailored cancer therapies with enhanced treatment outcomes.
- *General Support Care.* Supportive care services focus on supportive therapy that helps relieve pain, distress and other symptoms that can accompany serious illness. Substantial needs have developed around support care. For instance, around 30% of cancer-related deaths are associated with cachexia, symptoms not only impact patient tolerability to treatment but also significantly deteriorate their quality of life. Developing treatments for chronic diseases-induced symptoms is crucial for prolonging patient survival, improving quality of life, and saving medical costs.
- *Expanding Combination Therapy.* Combining different therapies, such as small molecule inhibitors with immunotherapy, has the potential of increasing the efficacy of cancer treatment and represents a promising direction for the development of oncology drugs.

OVERVIEW OF RAS DRUG MARKET

RAS is a family of proteins that exhibits a guanosine triphosphatase (“**GTPase**”) activity and cycles between “on” guanosine triphosphate (“**GTP**”)-bound and “off” guanosine diphosphate (“**GDP**”)-bound states. RAS protein regulates multiple signal transductions and plays a role in the cascade of cell process control, including cell proliferation and cell division. Three RAS genes encode for protein isoforms, namely KRAS, Harvey Ras (“**HRAS**”) and Neuroblastoma Ras (“**NRAS**”). KRAS is one of the most frequently mutated oncogenes in human cancers and it represents approximately 75% of all RAS isoforms contributing to cancer. KRAS mutations are detected in approximately 90% of pancreatic cancer, 30-40% of colorectal cancer (“**CRC**”), and 15-20% of lung cancer patients. These mutations are often associated with resistance to targeted therapies and poor outcomes in cancer patients.

The major players in the RAS drug industry include Mirati (acquired by Bristol Myers Squibb (NYSE: BMS) in 2024) and Revolution Medicines (NASDAQ: RVMD). The following table sets forth the RAS product matrix of Mirati and Revolution Medicines.

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Mirati RAS Product Matrix

Drug	Indication	Treatment Line	Approach	Stage
KRAZATI (adagrasib, KrasG12C Inhibitor)	NSCLC	2L+	Mono	Approved
	CRC	2L	Combo with Cetuximab	Approved
	Other 5+pepelines exploring different drug combinations and expanding indications			
MRTX0902 (SOS1:KRAS Inhibitor)	Solid tumors	1L+	Mono/Combo with KRAZATI	Phase I/II

Revolution Medicines RAS Product Matrix

Drug	Indication	Treatment Line	Approach	Stage
RMC-6236 (Pan-Ras Inhibitor)	PDAC	2L+	Mono	Phase III
	NSCLC	2L+	Mono	Phase III
			Combo with Pembrolizumab	Phase I/II
	Gastrointestinal solid tumors	1L+	Combo with chemo/anti EGFR	Phase I/II
	Solid tumors	2L+	Mono	Phase I
RMC-6291 (Kras G12C Inhibitor)	Solid tumors	2L+	Mono/Combo with RMC-6236	Phase I
	NSCLC	2L+	Combo with Pembrolizumab	Phase I/II
RMC-9805 (Kras G12D Inhibitor)	Solid tumors	2L+	Mono/Combo with RMC-6236	Phase I

Source: Official Website, Annual Report, ClinicalTrials.gov, Frost & Sullivan

Overview of KRAS G12C Drugs

One of the most common mutations in the KRAS gene is G12C, accounting for approximately 15% of all KRAS mutations, and it is also the most prevalent variant of KRAS mutations in non-small-cell lung cancer (“NSCLC”). The KRAS G12C variant favors the active form of the KRAS protein, resulting in a predominantly GTP-bound KRAS oncoprotein. This leads to enhanced proliferation and survival in tumor cells. The KRAS G12C mutation occurs in approximately 13% of NSCLC and in 3% to 4% of CRC.

While the first commercially-available KRAS G12C inhibitors have shown promising efficacy results, drug resistance including secondary mutations and bypass activation of other signaling pathways, and certain side effects such as gastrointestinal toxicity have been observed in their clinical applications. Therefore, emerging KRAS G12C inhibitor drugs to further combat resistance and with improved safety profiles could potentially bring additional clinical benefits to patients.

Market Size of KRAS G12C Inhibitor Drugs

GFH925 (fulzerasib) was the first KRAS G12C inhibitor drug that received approval for commercialization in China. Globally, there were four other KRAS G12C inhibitor (adagrasib, sotorasib, garsorasib and glecirasib) drugs that have been approved as of the Latest Practicable Date. GFH925, as a KRAS G12C inhibitor, is not designed or expected to eliminate drug resistance or certain side effects, such as gastrointestinal toxicity, associated with other approved KRAS G12C inhibitor drugs. The following table sets forth such marketed products.

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KRAS G12C Inhibitor Drugs Approved Globally

Brand Name	Generic Name	Company	Indication	Treatment Line	Nature of Drug Program	First Approval Time	Route of Administration	Efficacy	Safety	Treatment schedules	Annual Cost (thousand USD)	Annual Sales (2023)	Reimbursement coverage
建伯特	Fulzerasib	Innovent/GentFleet	KRAS G12C mutated advanced NSCLC adult patients	2L+	Mono	2024/08/21 (NMPA)	oral	ORR 49.1% DCR 90.5% mPFS 9.7 months OS 13.3 months	SAE 14.0%, TRAEs led to dose reduction 18.3%, drug interruption 32.6%, permanent discontinuation 2.7%	600 mg, BID	31.0	–	No
安方寧	Garsorasib	Chia Tai Tianqing/Inventisbio	KRAS G12C mutated advanced NSCLC adult patients	2L+	Mono	2024/11/08 (NMPA)	oral	ORR 52.0% DCR 88.6% mPFS 9.1 months OS 14.1 months	TRAEs 95.9%, TRAEs led to dose reduction 30.1%, drug interruption 41.5%, permanent discontinuation 0%	600 mg, BID	35.0	–	No
艾瑞凱	Glecirasib	Jacobio/Allist	KRAS G12C mutated advanced NSCLC adult patients	2L+	Mono	2025/5/20 (NMPA)	oral	ORR 49.6% DCR 86.3% mPFS 8.2 months OS 13.6 months	TRAEs 97.5%, TRAEs led to dose reduction 37.8%, drug interruption 18.5%, permanent discontinuation 5%	800 mg, QD	NA	–	No
Krazati	Adagrasib	BMS	KRAS G12C mutated locally advanced or metastatic NSCLC adult patients	2L+	Mono	2022/12/12 (FDA) 2024/01/05 (EMA)	oral	ORR 42.9% mPFS 6.5 months OS 12.6 months	TRAEs led to dose reduction 28%, drug interruption 77%, permanent discontinuation 13%	600 mg, BID	280.0	126 million USD	
			KRAS G12C mutated metastatic CRC	2L	Combo with cetuximab	2024/06/21 (FDA)		ORR 34% DCR 85.1% mPFS 6.9 months mOS 15.9 months	TRAEs led to dose reduction 35%, drug interruption 62%, permanent discontinuation 2 patients (about 0.02%)				
Lumakras	Sotorasib	Amgen	KRAS G12C mutated locally advanced or metastatic NSCLC adult patients	2L+	Mono	2021/05/28 (FDA) 2022/01/06 (EMA) 2022/01/20 (PMDA)	oral	ORR 37.1% DCR 80.6% mPFS 6.3 months mOS 12.5 months	SAE 14.0%, TRAEs led to dose reduction 5%, drug interruption 34%, permanent discontinuation 9%	960 mg, QD	266.9	350 million USD	
			KRAS G12C mutated metastatic CRC	2L	combo with panitumumab	2025/1/17 (FDA)		ORR 26% mPFS 5.6 months mOS Not Reached	TRAE 45.3%				

Notes:

1. The annual cost is calculated based on the patient using the product for one year and price in 2025. The significant differences of annual costs of approved KRAS G12C inhibitor drugs in China and U.S. are due to the differences in healthcare systems between the two countries, including pricing mechanism, insurance payment system, spending power and R&D costs.
2. The reimbursement coverage only applies to drugs approved by the NMPA, and drugs listed in the United States are covered by different commercial insurances, which cannot be exhaustive.

Source: Annual Report, FDA, EMA, PMDA, NMPA, Frost & Sullivan Analysis

With the continuous market penetration of the commercialized KRAS G12C inhibitor drugs and development of new drugs, the global KRAS G12C inhibitor drug market is expected to grow rapidly from US\$489.1 million in 2024 to US\$3,490.7 million in 2033 with a CAGR of 24.4%.

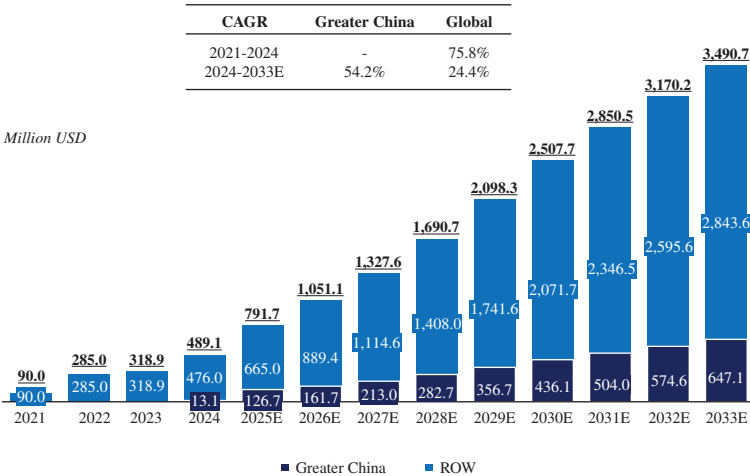
The Global KRAS G12C inhibitor drug market for NSCLC rose from US\$90.0 million in 2021 to US\$464.7 million in 2024 with a CAGR of 72.8% during the period. It is expected to continue increasing to US\$2,757.6 million by 2033, reflecting a CAGR of 21.9% from 2024. The Global KRAS G12C inhibitor drug market for CRC was US\$24.5 million in 2024 and is expected to continue increasing to US\$733.0 million by 2033, reflecting a CAGR of 45.9% from 2024.

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The Greater China KRAS G12C inhibitor drug market for NSCLC was US\$13.1 million in 2024 and is expected to continue increasing to US\$559.8 million by 2033, reflecting a CAGR of 51.7% from 2024. The Greater China KRAS G12C inhibitor drug market for CRC is expected to develop in 2027 with a market size estimated to be US\$4.3 million in 2027 and is expected to continue increasing to US\$87.4 million by 2033.

The diagram below sets forth the historical and projected global market size of KRAS G12C inhibitor drugs from 2021 to 2033.

Global KRAS G12C Inhibitor Drug Market, 2021-2033E



Source: NMPA, FDA, Annual Reports, Frost & Sullivan Analysis

The assumptions for the future market forecast of KRAS G12C inhibitor drugs globally are as follows.

1. Rich global clinical pipeline

There are multiple drug candidates that have reached the Phase III stage or further, and we assume that there will be more drugs being approved in the near future. Also, ongoing global R&D efforts are expected to expand the indications of KRAS G12C inhibitor drugs to CRC and other cancer types. Lumakras has been approved by the FDA for second-line treatment of CRC patients worldwide in January 2025, and China, as one of the major markets, also have one more approved product (Garsorasib, 安方寧) and one NDA product (JMKX001899) in 2025, which will jointly drive market growth. In addition, we expect the first-line treatment approval in NSCLC patients around 2028. Thus, the market size of KRAS G12C inhibitor drugs has considerable growth potential.

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2. *Improved drug accessibility enables faster drug penetration and domestic products expanding overseas*

The first KRAS G12C inhibitor in China, Fluzeleise (達伯特), has reduced its price by 25.3% in the second year after its launch, and plans to participate in the adjustment of the national medical insurance catalog in 2025. The Glecirasib (艾瑞凱) commercial insurance project will provide insurance support for patients starting from June 2025. These will enable more patients to afford treatment and improve patient compliance. Besides, KRAS G12C inhibitor drugs approved in China, such as fulzerasib and garsorasib, are undergoing clinical trials overseas. We assume that these drugs will have market potential both in China and globally.

3. *Urgent needs for KRAS G12C targeted therapy*

For a long time, KRAS G12C mutation positive patients lacked targeted drugs. There are approximately 300 thousands new cases of KRAS G12C mutant NSCLC globally each year, with 85-90% of them at locally advanced or metastatic stage, 90-95% of people receiving first-line treatment, and about 55% of patients entering second line treatment. For KRAS G12C mutant CRC, the number of new cases, late stage proportion, first line treatment rate and second line treatment rate are 70 thousands, 55-70%, 90-95% and 60-65% respectively. With the approval of effective targeted drugs for the mutation, we assume that the penetration rates of these KRAS G12C targeted drugs will mirror the previous development of EGFR-targeted drugs, i.e., reaching a high level.

The slowdown in the growth rate of the global KRAS G12C inhibitor market in 2023 is mainly due to the decline in revenue of Lumakras. According to Amgen’s financial report, this is mainly due to unfavorable changes to estimated sales deductions, including changes related to ongoing reimbursement negotiations in France. Full year sales were also impacted by lower net selling price and lower inventory levels, but noticeably, the annual sales volume increased by 16%. However, such reimbursement negotiations in France did not have material impact on the revenue of Lumakras in 2022 or 2024;

The main reasons for the accelerated growth in 2024 are:

- Kkrazati has been approved in EU and indication expansion in US. In 2023, krazati was only approved by the FDA for second-line and above treatment of locally advanced or meta static NSCLC adult patients with KRAS G12C mutation. In January 2024, the same indication was approved in Europe, and in June 2024, the FDA approved the extension of the indication to KRAS G12C mutated meta static CRC second-line treatment;
- Lumakras volume growth and favorable changes to estimated sales deductions; and
- The first KRAS G12C inhibitor was approved in China and quickly begins commercialization.

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Growth Drivers for KRAS G12C Inhibitor Drug Market

According to Frost & Sullivan, the growth of KRAS G12C inhibitor drug market has primarily been driven by the following factors:

- *Large number of addressable patients with Increasing Diagnostic Rates.* Globally, approximately 300 thousands new cases of KRAS G12C-mutated NSCLC and 70 thousands cases of KRAS G12C-mutated CRC annually. Current first-line treatment options for these patients—including chemotherapy, immunotherapy, and their combinations—demonstrate limited efficacy, highlighting significant unmet clinical needs. Concurrently, the rapid adoption of companion diagnostics has facilitated the advancement of precision medicine, establishing a solid foundation for the KRAS G12C inhibitor market.
- *Exploration of Combination Therapies and Indication Expansion.* Ongoing clinical researches are focusing on combination regimens involving KRAS G12C inhibitors with anti-EGFR, anti-VEGF, and SHP2 inhibitors, aiming to evaluate their potential in first-line treatment settings. Additionally, studies exploring the expansion of these therapies into other indications, such as pancreatic cancer (PC), are actively progressing, promising further market growth.
- *Policy Support Accelerating Approval and Improving Patient Access.* China’s first KRAS G12C inhibitor, Fuzuresib, has confirmed to enter the national reimbursement negotiation process with a 25% price reduction. If successfully included in the national reimbursement drug list (NRDL), it will substantially enhance patient accessibility. Furthermore, the “White Paper on Quality of Life for Chinese KRAS G12C Patients” project, initiated in April 2025 under the guidance of the Chinese Anti-Cancer Association, aims to comprehensively analyze patient survival status and drive the optimization of precision medicine models.

Alternate therapeutic options

NSCLC

For first line treatment of NSCLC: Chemotherapy, immunotherapy, and chemotherapy combined with immunotherapy;

For second and subsequent lines treatment of NSCLC:

- **China:** other approved KRAS G12C inhibitor, including garsorasib (安方寧), Glecirasib (艾瑞凱)
- **Global:** other approved KRAS G12C inhibitor, including Krazati, Lumakras

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CRC

for second line treatment

- **China:** Chemotherapy, targeted drugs (cetuximab/bevacizumab), PD-(L)1 immunotherapy, irinotecan and other drugs used alone or in combination
- **Global:** Krazati, Lumakras

The impact on the market potential and acceptance of GFH925

At present, the impact of other alternative treatment options on GFH925 in the target indications mainly comes from other approved KRAS G12C inhibitors. There are currently single drug efficacy data of competitors in China that are close to or even partially better than GFH925, which may affect doctors’ preferences and divert some market share. However, overall, GFH925 has significant advantages in multiple aspects, including impressive data in combination with cetuximab, a first mover advantage in China, and the potential for the first medical insurance coverage to accelerate commercial penetration. It has also been included in guidelines to further consolidate its position as a second-line treatment. Therefore, the current alternative treatment options have little impact on the potential and acceptance of GFH925.

From a global market perspective, due to the strong commercial foundation of competitors, BMS and Amgen have mature KOL relationships, medical insurance negotiation experience, and market education capabilities overseas, making it difficult to convert doctors’ prescription preferences in the short term. Also, GFH925, as a KRAS G12C inhibitor, is not designed or expected to eliminate drug resistance or certain side effects, such as gastrointestinal toxicity, associated with other approved KRAS G12C inhibitor drugs. If GFH925 is approved overseas, its commercialization challenges will be significant. However, GFH925 has efficacy and price advantages. Its efficacy data is comparable or superior to the other two products based on the published clinical trial data (though no head to head clinical trial has been conducted for efficacy comparison), which may become a key driving force for physicians to try dressing changes.

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The following chart represents comparison of GFH925 with other approved KRAS G12C inhibitors.

	GFH925	Other KRAS G12C Inhibitors	
		Domestic	Imported
MoA	Highly comparable, each targeting the cysteine residue of the KRAS G12C protein to disable its activity		
Approved Indication.	NSCLC	NSCLC, CRC	
Pricing . . .	Similar, significantly lower than imported products		High
Efficacy* . . .	The optimal DCR and mPFS data for monotherapy of NSCLC, with outstanding control of brain metastasis	The ORR data for the monotherapy of NSCLC with glecirasib is optimal, and the OS may be longer	The main safety data in NSCLC are inferior to domestic drugs, and the effectiveness data in CRC is determined
Safety* . . .	Common TRAEs include anemia, elevated alanine aminotransferase, etc. Most of them can be controlled by interrupting treatment or reducing dosage, and overall safety is controllable	Glecirasib TRAEs mainly include liver and gastrointestinal events, while Garsorasib TRAEs include anemia, elevated blood bilirubin, and elevated alanine aminotransferase, all of which are overall safe and controllable	The most common TRAEs are gastrointestinal and liver related events, mostly of low severity, and overall safety is controllable

All of the above approved products encounter the issue of drug resistance that is commonly observed across the KRAS G12C inhibitor class.

Note:

* Based on the published clinical trial data, not head-to-head clinical trials.

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Competitive Landscape of KRAS G12C Inhibitors

As of Latest Practicable Date, there were more than 20 KRAS G12C inhibitor candidates being clinically developed globally. The following table sets forth the KRAS G12C inhibitor candidates with at least a Phase III clinical trial globally as well as commercialized G12C inhibitors.

Pipeline of KRAS G12C Inhibitor Candidates with Phase III Clinical Trial and Beyond Globally

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country /region	First posted date
達伯特 (Fulzerasib)	advanced NSCLC	Approved	Innovent/Genfleet	mono	2L+	oral	600mg, BID	ORR 49.1% DCR 90.5% mPFS 9.7 months OS 13.3 months SAE 14.0%, TRAEs led to dose reduction 18.3%, drug interruption 32.6%, permanent discontinuation 2.7%	China	2024-08-21 (NMPA)
	advanced non-sq NSCLC	Phase 1b/3		combo with sintilimab±chem otherapy	1L		GFH925 recommended dose ± sintilimab 200mg Q3W ± cetuximab 500mg/m ² Q2W ± chemotherapy	ORR 45.5% mPFS 9.6 months TRAE 95.5% TRAE (grade ≥3) 36.4%	China	2022-09-14
	metastatic CRC	Phase 1b/3		combo with Cetuximab	NA		GFH925 recommended dose + cetuximab 500mg/m ² Q2W	ORR 45.8% DCR 89.6% TRAE (grade 3) 23.2% TRAE (dose reduction) 10.7% TRAE (interruption) 21.4%	China	2022-08-09
	advanced NSCLC	Phase 1b/2		combo with cetuximab	1L		GFH925 600mg BID with cetuximab 500mg/m ² Q2W, 28-day cycle	ORR 80.0% mPFS 12.5 months TRAE (dose reduction) 29.8%	EU	2023-03-06
	advanced solid tumors	Phase 1/2		mono	NA		700mg QD or 450/600/750mg BID	NSCLC: ORR 61.2%, DCR 92.5%, TRAE (any grade) 94.0%, TRAE (grade ≥3) 31.3% 600mg BID dose group: ORR 66.7%, DCR 96.7%, mPFS 8.2 months	China	2021-08-12
安方寧 (Garsorasib)	advanced NSCLC	Approved	Chia Tai Tianqing/ Inventisbio	mono	2L+	oral	600mg, BID	ORR 52.0% DCR 88.6% mPFS 9.1 months OS 14.1 months TRAEs 95.9% TRAEs led to dose reduction 30.1%, drug interruption 41.5%, permanent discontinuation 0%	China	2024-11-08 (NMPA)
	advanced or metastatic NSCLC, CRC, and other solid tumors	Phase 1/2		combo with pembrolizumab/cetuximab/afatinib	1L		600mg BID + cetuximab 400mg/m ² at the first day and 250mg/m ² after	-	China	2021-12-01
	advanced or metastatic solid tumors	Phase 1/2		mono or combo with pembrolizumab/Cetuximab/other	NA		150, 300, 600, 800, and 1200 mg QD, 400, 600, and 800 mg BID	PC: ORR 50.0%, mPFS 8.54 months, DCR 80.0%, TRAE (any grade) 70%, TRAE (grade 3) 20% CRC: ORR 20.8%, DCR 95.8%, mPFS 7.62 months, TRAE (any grade) 50%, TRAE (grade ≥3) 2pts NSCLC: ORR 54.5%, DCR 81.8%, TRAE (any grade) 93.8%	US, Australia, Korea, Taiwan	2020-10-14
	locally advanced or metastatic NSCLC	Phase 1b/2		combo with pembrolizumab/cetuximab/afatinib	1L		400mg BID or 600mg QD Pembrolizumab 200mg Q3W, Afatinib 30mg QD or QOD, Cetuximab 400mg/m ² at the first day or 250mg/m ² Q1W, 21-day cycle	-	China	2022-07-14

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Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country /region	First posted date
Krazati (Adagrasib)	locally advanced or metastatic NSCLC	Approved	BMS	mono	2L+	oral		ORR 42.9% mPFS 6.5 months OS 12.6 months TRAEs led to dose reduction 28%, drug interruption 77%, permanent discontinuation 13%	Europe, US	2022-12-12 (FDA) 2024-01-05 (EMA)
							600mg, BID	ORR 34% DCR 85.1% mPFS 6.9 months mOS 15.9 months TRAEs led to dose reduction 35%, drug interruption 62%, permanent discontinuation 2 patients (about 0.02%)	US	2024-06-21 (FDA)
	locally advanced or metastatic non-sq NSCLC	Phase 3		combo with pembrolizumab and chemotherapy	1L		Specified dose on specified days	-	Global	2025-03-13
	NSCLC	Phase 3		Combination with pembrolizumab	1L		Krazati 400mg BID + pembrolizumab 200mg Q3W	-	China	2024-03-27
	Advanced NSCLC	Phase 2/3		Mono or combo with pembrolizumab	1L		Krazati 400mg BID + pembrolizumab 200mg Q3W or Krazati 600mg BID or Pembrolizumab 200mg Q3W	ORR 44.3%, mDOR 26.3 months, mPFS 11.0 months, mOS 18.3 months, TRAE 94.6%, TRAE (grade 3/4) 68.4%	US, Europe, Canada, etc	2020-11-03
	Advanced solid tumors	Phase 1/2		Mono or combination therapy	NA		Krazati QD or BID ± pembrolizumab Q3W ± cetuximab Q2W ± Afatinib	CRC: ORR 43% DCR 86%, mPFS 6.9 months, mOS 16 months, TRAE (grade 3/4) 28%, TRAE (discontinuation) 10% NSCLC: ORR 30.3%, mPFS 4.8 months, mOS 12.3 months, TRAE (dose reduction) 51.4%, TRAE (discontinuation) 5.7%	Puerto Rico, US	2018-12-24
	Advanced solid tumors/NSCLC	Phase 1		Combo with nab-sirolimus	NA		Dose escalation of Krazati and nab-Sirolimus	-	US	2023-05-03
	Advanced solid tumors malignancies with KRAS G12C mutation			Combo with palbociclib	NA		Dose escalation of Krazati and palbociclib	-	US	2022-01-05
	Advanced solid tumors			Combo with TNO155	NA		Krazati 600mg BID + TNO155	-	US	2020-04-01
	Advanced NSCLC and CRC			Combo with BMS-986488	NA		Specified dose on specified days		US, Canada, Australia	2025-01-08

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Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country /region	First posted date
Lumakras (Sotorasib)	locally advanced or metastatic NSCLC	Approved	Amgen	mono	2L+	oral	960mg, QD	ORR 37.1% DCR 80.6% mPFS 6.3 months mOS 12.5 months SAE 14.0%, TRAEs led to dose reduction 5%, drug interruption 34%, permanent discontinuation 9%	Europe, US, Japan	2021-05-28 (FDA) 2022-01-06 (EMA) 2022-01-20 (PMDA)
	metastatic CRC			Combo with Panitumumab and FOLFIRI	1L		Lumakras QD ± Panitumumab and FOLFIRI Q2W	–	US, Argentina, Australia, Korea, etc	2024-02-12
	Stage IV or advanced stage IIIB/C non-sq NSCLC			Combo with platinum doublet	1L		Lumakras 960mg QD + carboplatin and pemetrexed	–	US, Europe, Japan, etc	2023-06-27
		Phase 3						Lumakras 960mg: ORR 30.2%, DCR 71.7%, mPFS 5.8 months Lumakras 240mg: mOS 11.9 months, ORR 7.5%, DCR 69.8%, mPFS 4.0 months	US, Spain, Korea, etc	2022-01-20
	metastatic CRC			Combo with panitumumab	2L+		Lumakras 960/240mg QD + panitumumab			
	Advanced PC	Phase 2		combo with chemo	1L		lumakras 960mg QD ± chemotherapy	–	Spain, France	2025-03-18
	Advanced solid tumors, advanced NSCLC	Phase 1/2		Mono and combined therapy	NA		Lumakras 960mg QD ± chemotherapy	NSCLC: mPFS 5.6 months, mOS 11.6 months, ORR 33.6%, TRAE (grade 3/4) 26.8% PC: ORR 21.1%, DCR 84.2%, mPFS 3.98 months, mOS 6.87 months CRC: ORR 9.7%, TRAE (grade 3) 10%	US, Europe, Japan, etc	2018-07-26
	Advanced solid tumors with KRAS p.G12C mutation	Phase 1		Mono or combo with other anti-cancer therapies	NA		Lumakras 960mg QD ± panitumumab 6mg/kg Q2W ± FOLFIRI ± other anti-cancer drugs	CRC: ORR 75%, DCR 95% NSCLC: mPFS 5.6 months, mOS 11.6 months, ORR 33.6%, TRAE (grade 3/4) 26.8%	US, Europe, Australia, etc	2019-12-04

INDUSTRY OVERVIEW

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country /region	First posted date
Glecirasib (JAB-21822)	advanced or metastatic NSCLC	Approved	Jacobio/Allist	Mono	2L+	oral	800mg QD	cORR 49.6% DCR 86.3% mPFS 8.2 months mDOR 14.5 months mOS 17.5 months	China	2025-05-20 (NMPA)
	Locally advanced or metastatic NSCLC	Phase 3		Combo with JAB-3312	1L		JAB-21822+JAB-3312, 21-days cycle	ORR 64.7%, mPFS 12.2 months	China	2024-05-16
	Locally advanced or metastatic PC	Phase 2		mono	2L+		800mg QD	–	China	2023-08-18
	advanced CRC, small intestinal cancer, appendiceal cancer	Phase 1b/2		combo with cetuximab	NA		JAB-21822+ cetuximab 21-days cycle	With cetuximab group: mDOR 5.1 months, mPFS 6.1 months, mOS 19.3 months, ORR 50%, DCR 87%, TRAEs (all grade) 97.7%, Grade 3–4 TRAEs 19.1%	China	2022-01-19
	advanced solid tumors	Phase 1/2		mono	NA		QD, 21-days cycle	PDAC: ORR 46.4%, DCR 96.4%, mDoR 4.1 months, mPFS 5.5 months	China	2021-06-29
JMKX001899	advanced or metastatic NSCLC	NDA	Jemincare	Mono	2L+	oral	JMKX001899 500mg QD + Docetaxel 75mg/m ² , 3-week cycle	–	China	2025-06-05
MK-1084	metastatic NSCLC with confirmed PD-L1 TPS ≥50%	Phase 3	MSD	Combo with pembrolizumab	1L	oral	MK-1084 QD + pembrolizumab 200mg on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles	–	US, South Korea, Ukraine, Chile	2024-04-03
	locally advanced or metastatic CRC	Phase 3		combo with cetuximab, chemo ± Bevacizumab	1L		MK-1084 QD, cetuximab Q2W, chemo Q2W	–	Global	2025-05-30
Olmorasib	advanced NSCLC with confirmed PD-L1 TPS ≥50%	Phase 3	Eli Lilly	Combo with pembrolizumab ± chemotherapy	1L	oral	olomorasib 50mg or 100mg BID + pembrolizumab plus	–	China, US, Europe, etc	2023-11-07
	NSCLC	Phase 3		Combo with pembrolizumab or Durvalumab	adjuvant		Olmorasib + Pembrolizumab up to 1 year followed by olomorasib alone for up to 3 years	–	Global	2025-03-24
Divarasib (RG6330)	advanced or metastatic NSCLC	Phase 3	Roche	Mono	2L+	oral	Divarasib QD	–	China, Korea	2022-10-11
	Advanced or Metastatic non-sq NSCLC	Phase 3		Combo with pembrolizumab ± chemotherapy	1L		Divarasib QD + Pembrolizumab Q3W ± chemotherapy Q3W	–	Global	2025-01-27
JDQ443	Locally advanced or metastatic NSCLC	Phase 3	Novartis	Mono	2L+	Oral	–	–	Global	2021-11-24

Note: Ongoing Clinical trials with first posted date up to Latest Practicable Date, initiated by companies are included.

* A Phase Ib/III clinical trial is typically designed to investigate the efficacy, safety and clinical benefits of the test drug(s), with a potentially more streamlined flow to reach the Phase III registrational trial stage, especially in the context of cancer treatment. Phase Ib/III clinical trial is a two-part trial. The first part is for determining a recommended Phase 3 dose (RP3D) for the second part, which is a normal Phase 3 clinical trial.

** The KRAS G12C inhibitors in the table have demonstrated remarkable clinical benefits in the second-line treatment of NSCLC, achieving an ORR of over 40% in patients with malignant NSCLC when used as monotherapy. Additionally, the combination of KRAS G12C inhibitors with antibody or chemotherapy drugs is being actively explored for first-line treatment, with initial results showing a promising ORR of up to 80%. Meanwhile, the application of KRAS G12C inhibitors is also expanding, with good efficacy demonstrated in other solid tumors such as CRC and pancreatic cancer, bringing new hope to more cancer patients.

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

INDUSTRY OVERVIEW

The selling price of ERBITUX (cetuximab) is approximately US\$330.0 for a 20 mL vial at a concentration of 2 mg/mL in the United States, €339.39 (equivalent to US\$367) for a 20 mL vial at a concentration of 5 mg/mL in Germany, and £178.1 (equivalent to US\$228) for a 20 mL vial at a concentration of 5 mg/mL in the United Kingdom.

Overview of KRAS G12D Drugs

The KRAS G12D mutation accounts for approximately 29% of all KRAS mutations, making it the most prevalent variant in human cancers. The KRAS G12D mutation is particularly frequent in pancreatic cancer (approximately 35%), CRC (approximately 12%) and NSCLC (approximately 4%). Compared to the KRAS G12C mutation, the KRAS G12D mutation causes more significant disruption of intrinsic GTPase activity, resulting in a higher proportion of active GTP-bound KRAS in tumor cells.

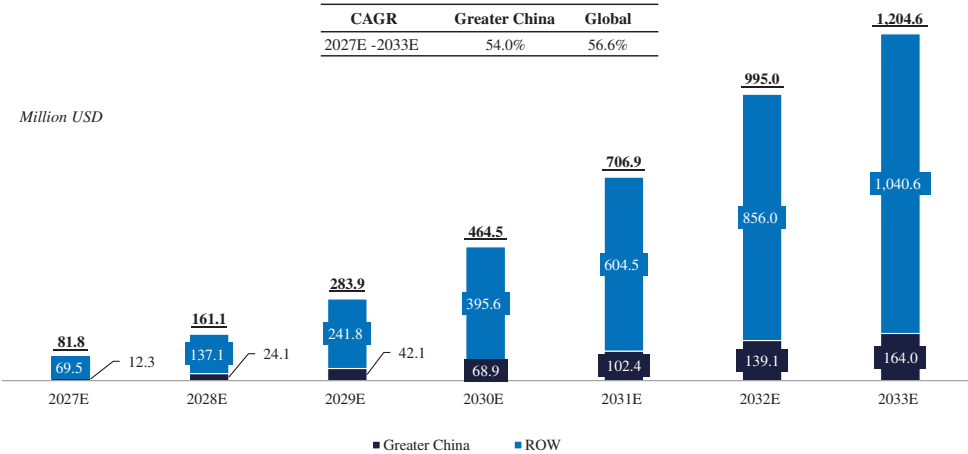
With the future commercialization of relevant drug pipelines, the global KRAS G12D inhibitor drug market is expected to grow from US\$81.8 million in 2027 to US\$1,204.6 million in 2033 with a CAGR of 56.6%. The Greater China KRAS G12D inhibitor drug market is expected to grow from US\$12.3 million in 2027 to US\$164.0 million in 2033 with a CAGR of 54.0%.

The Global KRAS G12D inhibitor drug market for pancreatic cancer is expected to rise from US\$81.8 million in 2027 to US\$1,023.9 million in 2033 with a CAGR of 52.4% during the period.

The Greater China KRAS G12D inhibitor drug market for pancreatic cancer is expected to rise from US\$12.3 million in 2027 to US\$139.4 million in 2033 with a CAGR of 49.9% during the period.

The diagram below sets forth the projected global market size of KRAS G12D inhibitor drugs from 2027 to 2033.

Global KRAS G12D Inhibitor Drug Market, 2027E-2033E



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

INDUSTRY OVERVIEW

The assumptions for the future market forecast of KRAS G12D inhibitor drugs globally are as follows.

1. Expected first market approval in 2027

We expect that the first KRAS G12D inhibitor drug will be approved for marketing and generate revenue in 2027, and the indication is likely to be second-line treatment of pancreatic cancer.

2. Large size of target patient population

The main indications for the clinical development of KRAS G12D inhibitors are pancreatic cancer, NSCLC, and CRC. It is expected that by 2027, there will be 212.4 thousand, 95.2 thousand, and 258.2 thousand KRAS G12D mutation positive pancreatic cancer, NSCLC, and CRC patients worldwide, respectively. Over 90% of pancreatic cancer patients are at advanced or metastatic stage, 90-95% of people receiving first-line treatment, and about 80-85% of patients entering second line treatment. For NSCLC patients, 85-90% of them at locally advanced or metastatic stage, 90-95% of people receiving first-line treatment, and about 55% of patients entering second line treatment. For CRC patients, the late stage proportion, first line treatment rate and second line treatment rate are 55-70%, 90-95% and 60-65% respectively.

3. Growth of penetration rate

Currently, there is no targeted drug for the KRAS G12D mutation. We believe that the launch of new KRAS G12D inhibitor drugs will quickly penetrate the target patient population, like the KRAS G12C inhibitor drugs, in light of the market performance of China's first KRAS G12C inhibitor after its launch. In the first year of marketing, the approved KRAS G12D inhibitor drug is expected to be used as a second-line treatment of about 1000 pancreatic cancer patients, which is equivalent to a penetration rate of about 2% (calculated only for the Chinese and American pancreatic cancer patients who can accept second-line treatment). By 2033, the penetration rate is expected to reach about 10% (calculated only for the Chinese and American pancreatic cancer, NSCLC, CRC patients who can accept second-line treatment). By 2033, the penetration rate is expected to reach about 10% (calculated only for the Chinese and American pancreatic cancer, NSCLC, CRC patients who can accept second-line treatment).

4. Other growth factors

The expected rapid growth of the future market of KRAS G12D inhibitor drugs is also based on factors such as the expected increase in the number of approved KRAS G12D inhibitor drugs, the strong commercialization capabilities of companies with current product layouts, and the expected expansion of indications of approved KRAS G12D inhibitor drugs. For example, on August 12, 2025, Bayer and Kumquat Biosciences announced an exclusive global license and collaboration to develop and commercialize Kumquat's KRAS G12D inhibitor. Collaborations between large pharmaceutical corporations and biotechnology firms have become a mainstream global model and are expected to continue driving the development of KRAS G12D drug market.

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Competitive Landscape of KRAS G12D Inhibitors

As of the Latest Practicable Date, there was no approved KRAS G12D inhibitor drug globally. GFH375 is one of the most advanced orally bioavailable inhibitors of KRAS G12D in terms of development status as of the same date.

The following chart represents comparison of GFH375 with other approved KRAS G12G inhibitor drugs.

	GFH375	Other KRAS G12D Inhibitor Candidates
MoA	Targeting both the “on” GTP-bound and “off” GDP-bound states of KRAS protein with G12D mutation	Mostly targeting “on” GTP-bound states of KRAS protein with G12D mutation
Route of administration .	Oral daily	Infusion or oral
Pricing	Expected to be priced lower than overseas products	While domestic prices are expected to be broadly comparable, overseas products are generally priced at higher levels
Safety*	Special attention should be paid to the incidence of TRAEs of grade ≥ 3	Safety profile is similar among the products with disclosed clinical data, subject to further clinical confirmation
Efficacy*	Superior efficacy profile in PDAC and comparable or superior efficacy profile in NSCLC	Products with comparable data for NSCLC treatment

Note:

* Based on the published clinical trial data, not head-to-head clinical trials.

There were 16 KRAS G12D inhibitor candidates being clinically developed globally as of Latest Practicable Date. The following table sets forth the clinical-stage KRAS G12D inhibitor candidates globally.

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Pipeline of Clinical-stage KRAS G12D Inhibitor Candidates Globally

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
AZD0022	Advanced solid tumors, NSCLC, PDAC, CRC	Phase 1/2a	AZ	Mono or combo with Cetuximab	2L+	oral	AZD0022 ± cetuximab at the assigned dose level, dose level not disclosed	–	US, China	2024-09-19
DN022150	Advanced solid tumors	Phase 1/2a	DE NOVO	Mono	2L+	Infusion	20/50/100/200/300 mg QW/Q2W/Q3W	–	China	2024-08-02
RNK08954	Advanced solid tumors	Phase 1/2	Ranok Therapeutics	Mono	2L+	oral	RNK08954 QD, 21-day cycle	–	US, China	2024-10-08
GDC-7035	Advanced or metastatic solid tumors	Phase 1/2	Genentech	Mono or combo with other drugs	NA	NA	administered at the assigned dose level, dose level not disclosed	–	NA	2024-10-01
	Metastatic pancreatic cancer	Phase 2		Mono	2L+		administered at the assigned dose level, dose level not disclosed	–	China	2025-05-30
GFH375/VS-7375	Advanced solid tumors	Phase 1/2	GenFleet/Verastem	Mono	NA	oral	GFH375 100/200/400/600/750/900 mg QD and 300mg BID	All pts: ORR 38%, DCR 90%, TRAE (grade ≥3) 29%, SAE 15.6%, TEAE (interruption) 21% PDAC: ORR 52%, DCR 100% NSCLC:) RR 42%, DCR 83%	China	2024-07-01
	Advanced solid tumors	Phase 1/2a		Mono	NA		administered at the assigned dose level, dose level not disclosed	–	US	2025-06-13
	PDAC	Phase 2		Combo with chemotherapy	NA		administered at the assigned dose level, dose level not disclosed	–		2024-09-19
HRS-4642	Advanced solid tumors	Phase 1/2	HengRui	Combo with Adebrelimab or SHR-A1921	NA	Infusion	HRS-4642 + Adebrelimab/SHR-9839/HRS-4642, dose level not disclosed	–	China	2024-04-26
		Phase 1		Mono	NA		15/50/100/200/300 mg QW, 21-day cycle	NSCLC: DCR 90.0% All patients: DCR 77.8%, TRAE (grade ≥3) 33.3%		2022-09-06
TSN1611	Advanced solid tumors	Phase 1/2	Tyligand	Mono	1L+	oral	administered at the assigned dose level, dose level not disclosed	ORR 25%, DCR 67% (600-800mg, BID)	US	2024-04-26
HBW-012336	Advanced solid tumors	Phase 1/2	Hyperway	Mono	2L+	oral	administered at the assigned dose level, dose level not disclosed	–	China	2025-06-18
HS-10529	Advanced solid tumors	Phase 1	Hansoh	Mono	NA	oral	HS-10529, 21-day cycle	–	China	2023-05-06
LY3962673	Advanced solid tumors	Phase 1	Eli Lilly	Mono or combo with Cetuximab and chemotherapy	2L+	oral	LY3962673 ± chemotherapy at the assigned dose level, dose level not disclosed	–	US	2024-9-19
QTX3046	Advanced solid tumors	Phase 1	Quanta Therapeutics	Mono, or combo with cetuximab	2L+	oral	QTX3046 ± cetuximab, dose level not disclosed	–	US	2024-05-24
QLC1101	Advanced solid tumors	Phase 1	Qilu Pharmaceutical	Mono	1L+	oral	QLC1101 BID, 21-day cycle	–	China	2024-05-08
	Unresectable or metastatic solid tumors	Phase 1/2b		Combo with QL1203/QL2107/QL1706/ docetaxel	NA		QLC1101 600-1200mg BID, 14-day cycle	–	China	2025-05-21
AST2169	Advanced solid tumors	Phase 1	Allist Pharmaceuticals	Mono	1L+	Infusion	42/150/300/400/500/600 mg at the 1, 8 and 15 day of one 21-day cycle	–	China	2024-04-02
INCB161734	Advanced or metastatic solid tumors	Phase 1	Incyte Corporation	Mono, or combo with other anti-cancer therapies	1L+	oral	INCB161734 ± protocol-defined dose strength based on cohort assignment	–	Australia, US, Belgium, Canada, France, Italy, Spain	2023-12-21
INCB186748	Advanced or Metastatic Solid Tumors, PDAC, CRC	Phase 1		Combo with cetuximab/ GEMNabP/ mFOLFIRINOX	2L+	NA	administered at the assigned dose level, dose level not disclosed	–	US	2025-02-10
RMC-9805	Advanced solid tumors	Phase 1	Revolution Medicines	Mono, and combo with RMC-6236	2L+	oral	600 mg BID or 1200 mg QD	NSCLC: ORR 61%, DCR 89%	US	2023-09-15

Note: Ongoing Clinical trials with first posted date up to Latest Practicable Date, initiated by companies are included.

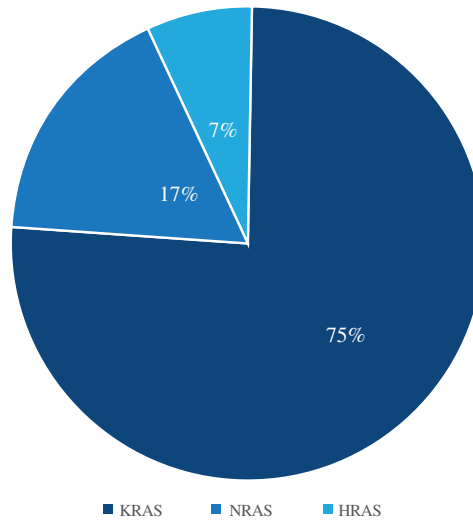
Source: CDE, ClinicalTrials.gov, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

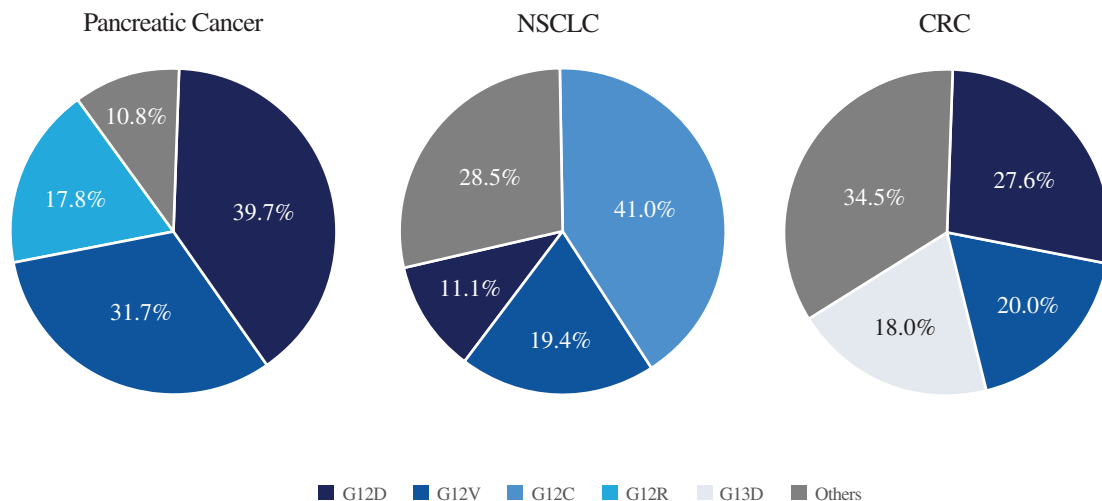
Overview of Pan-RAS Drugs

RAS proteins are frequently mutated proto-oncogenes in human cancers, which are encoded by three commonly expressed genes: HRAS, KRAS, and NRAS. Three RAS oncogene mutations are present in approximately 30% of all human cancers, and they drive tumor growth and metastasis through aberrant activation of RAS-mediated signaling.

Percentage Distribution of RAS Isoforms Contributing to Cancer



KRAS mutations are detected in approximately 90% of pancreatic cancer, 30-40% of CRC, and 15-20% of lung cancer patients. According to the U.S. data, the five most common KRAS mutant isoforms, KRAS G12D (29%), G12V (23%), G12C (15%), G13D (7%), and G12R (5%), collectively accounted for about 80% of all KRAS alterations. According to a landscape analysis of Chinese tumor samples, KRAS G12C accounted for 14.5% of all KRAS mutations. The top three cancers with the highest KRAS mutation rates are pancreatic cancer, NSCLC, and CRC. The percentages of incidence of different types of KRAS mutation in these cancers are shown below.



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The prevalence of different types of KRAS mutations in cancer patients vary by ethnicity. The incidence of KRAS mutations is different between the East and the West. KRAS mutations are found in approximately 20%–25% of lung cancer cases in the Western countries and 10%–15% of lung cancer cases in Asian countries. There are at least nine different KRAS mutational subtypes. Among the subtypes of KRAS mutations, KRAS G12C is the subtype most often found in the West. The patterns reported in Asia are somewhat different: whereas some studies similarly report G12C as the most common subtype, others report that G12D is most often identified. GFH925 targets the G12C mutation, whereas GFH375 targets the G12D mutation. The varying prevalence of the two types of KRAS mutation affect the size of potential markets for KRAS G12C and G12D inhibitor drugs at different geographical locations.

Pan-RAS inhibitors are theoretically advantageous over mutation-specific products in addressing a broader range of oncogenic RAS mutants and wild-type RAS isoforms. Pan-targeting approaches have the potential to block compensatory activation of wild-type RAS proteins and prevent the emergence of acquired resistance to mutant-specific inhibitors. Pan-RAS may also have potentially broad applications and long-lasting therapeutic benefits across various cancer types. Drug candidates that dampen excessive activities of RAS proteins in a pan-RAS manner could potentially enable sequential therapies to overcome resistance to mutant-specific treatments.

Pan-RAS inhibitors, regardless of the specific mutation sites of RAS oncogenes, act as multi-selective, triple-complex inhibitors designed to comprehensively block RAS proteins. Pan-RAS inhibitors can be categorized as direct-binding and indirect-binding pan-RAS inhibitors. Direct-binding inhibitors target common binding sites across all RAS isozymes, allowing them to suppress the entire RAS signaling network, independent of any specific isozyme or mutation. Indirect-binding inhibitors function by targeting RAS-interacting proteins, thereby inhibiting RAS protein-protein interactions and reducing RAS signaling. Examples of indirect-binding inhibitors include inhibitors that block RAS-activating proteins to suppress RAS activity. In addition, innovative modalities, such as functional antibody-molecular drug conjugates, are also being explored to achieve pan-RAS signaling inhibition. On the other hand, available clinical results suggest that some pan-RAS inhibitors may be associated with adverse effects that are related to their comprehensive blockage of RAS proteins. Therefore, pan-RAS inhibitor drug candidates with improved safety profiles may have enhanced therapeutic potentials.

Pan-RAS approaches are differentiated from pan-KRAS approaches that aim to address multiple KRAS mutations at the same time. Pan-KRAS “off” state inhibitors are vulnerable to adaptive resistance caused by mitogen-activated protein kinase (“**MAPK**”) reactivation via upstream receptor tyrosine kinase signaling. Moreover, pan-KRAS “off” state inhibitors have been found ineffective against certain KRAS mutants, such as KRAS G12R or KRAS Q61X, which exhibit nearly complete impairment of GTPase activity in tumor cells. Therefore, a pan-RAS “on” state inhibitor would potentially encompass a larger patient population and yield better clinical outcomes compared to existing pan-KRAS “off” state inhibitors.

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Competitive Landscape of Pan-RAS Drugs

As of the Latest Practicable Date, there was no approved pan-RAS drug worldwide. There were six pan-RAS and 15 pan-KRAS inhibitor candidates being clinically developed globally as of Latest Practicable Date. The following table sets forth the clinical-stage pan-RAS inhibitor and pan-KRAS inhibitor candidates globally.

INDUSTRY OVERVIEW

Pipeline of Clinical-stage Pan-RAS Inhibitor Drug Candidates Globally

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date				
RMC-6236	metastatic PDAC	Phase 3	Revolution Medicines	mono	2L+	oral	administered at the assigned dose level, dose level not disclosed	–	US, Europe, Japan, Puerto Rico	2024-10-03				
	Locally Advanced or Metastatic RAS mutant NSCLC	Phase 3		mono	2L+		administered at the assigned dose level, dose level not disclosed	–	US, Puerto Rico	2025-03-18				
	Gastrointestinal solid tumors	Phase 1/2		combo with SOC or novel agents	NA		RMC-6236 + 5-fluorouracil-based regimens	RMC-6236 + cetuximab with or without mFOLFOX6	RMC-6236 + gemcitabine + nab-paclitaxel	RMC-9805 with or without RMC-6236 + 5-fluorouracil-based regimens	RMC-6236 + cetuximab with or without mFOLFOX6	RMC-6236 + gemcitabine + nab-paclitaxel	US, Europe	2024-06-06
RMC-6236	RAS-mutated NSCLC	Phase 1/2	Revolution Medicines	Combo with pembrolizumab, with or without chemotherapy	2L+	oral	RMC-6291 BID/RMC-9805 QD or BID ± RMC-6236 QD + pembrolizumab Q3W ± chemotherapy (Q3W-Q4W)	–	US, Europe	2023-12-08				
	Advanced KRAS G12C Mutant Solid Tumors	Phase 1		Combo with RMC-6291	2L+		RMC-6291 + RMC-6236 administered at the assigned dose level, dose level not disclosed	–	US, Europe, Puerto Rico	2023-11-13				

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Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
RMC-6236	RAS mutant advanced solid tumors	Phase 1		Mono	2L+	oral	doses ranging from 160mg to 300mg QD	KRAS G12X mutation in the PDAC 2L treatment (300mg daily): mPFS 8.8 months, OS 100%	US	2022-05-18
								KRAS G12X mutation in the NSCLC 2L treatment (120-220mg daily): mPFS 9.8 months, mOS 17.7 months any RAS mutation in the 2L treatment (300mg daily): mPFS 8.5 months, OS 97%		
JYP0015/E RAS-0015	RAS mutant advanced or metastatic solid tumors	Phase 1/2	JOYO Pharma/ Erasca	Mono or in combination with pembrolizumab or panitumumab	NA	oral	4/8/16mg QD, 21-day cycle, 4 cycles	–	China	2025-03-07
LUNA18	Locally Advanced or Metastatic Solid Tumors	Phase 1	Chugai Pharma	Mono or in combination with other anti-cancer drugs	NA	oral	LUNA18 ± cetuximab administered at the assigned dose level, dose level not disclosed	–	US, Japan	2021-08-19

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Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
RO7673396	Advanced solid tumors with RAS mutation	Phase 1	Roche	Mono	NA	NA	administered at the assigned dose level, dose level not disclosed	-	Australia, New Zealand	2025-03-19
VVD-159642	Advanced solid tumors, PDAC, CRC, NSCLC	Phase 1	Vividion Therapeutics	Mono or combination with sotorasib/trametinib	NA	oral	administered at the assigned dose level, dose level not disclosed	-	US, Australia	2025-02-03
HRS-7172	Advanced solid tumors with RAS mutation	Phase 1	HengRui	Mono	NA	NA	administered at the assigned dose level, dose level not disclosed	-	China	2025-08-21

Note: Ongoing Clinical trials with first posted date up to Latest Practicable Date, initiated by companies are included.

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

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Pipeline of Clinical-stage Pan-KRAS Inhibitor Drug Candidates Globally

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
PF-07985045	advanced solid tumors, NSCLC, CRC, PDAC	Phase 1	Pfizer	mono or combo with other anti-cancer therapies	part I: 2-3L part II: PDAC 1L, CRC 1L+, NSCLC 1L	oral	PF-07985045 administered at the assigned dose level ± cetuximab/ pembrolizumab/ sasanlimab/SHP2 ± chemotherapy, 21/28-day cycle	–	US, Japan, Puerto Rico	2024-11-26
PF-07934040	Advanced Solid Tumors Harboring Mutations in the KRAS Gene	Phase 1	Pfizer	Combo with other Targeted Agents	part I: 2-3L part II: PDAC 1L, CRC 1L+, NSCLC 1L	oral	PF-07934040 administered at the assigned dose level ± cetuximab/ pembrolizumab/ sasanlimab/SHP2 ± chemotherapy, 21/28-day cycle	–	China, US, Puerto Rico	2024-06-07
QTX3544	advanced solid tumors	Phase 1	Quanta Therapeutics	mono or combo with cetuximab	2L+	oral	QTX3544 administered at the assigned dose level ± cetuximab	–	US	2024-12-04
QTX3034	Solid tumors with KRASG12D mutation	Phase 1	Quanta Therapeutics	Mono, or combined with cetuximab	2L+	oral	QTX3034 administered at the assigned dose level ± cetuximab	–	US	2024-01-26

INDUSTRY OVERVIEW

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
JAB-23E73	advanced solid tumors	Phase 1/2a	Jacobio	mono	NA	oral	5/10/40mg QD, 21-day cycle	-	China, US	2024-11-11
LY4066434	locally advanced or metastatic solid tumors	Phase 1	Eli Lilly	mono or combo with other treatments	NA	oral	LY4066434 administered at the assigned dose level ± cetuximab ± chemotherapy	-	China, US, Belgium, Japan, Spain, Taiwan	2024-09-23
BGB-53038	advanced or metastatic solid tumors	Phase 1	BeiGene	mono or combo with tislelizumab	NA	oral	BGB-53038 administered at the assigned dose level ± Tislelizumab and cetuximab	-	China, US, Australia, Korea, New Zealand, Spain	2024-09-05
YL-17231	Advanced solid tumors	Phase 1	Yingli Pharmaceutical	Mono	NSCLC: 2L CRC: 3L others: 2L+	oral	0.25-10mg BID, 21-day cycle	-	China	2023-10-12
BI 3706674	Unresectable Metastatic KRAS Wild Type Amplified GAC, EAC and AGEJ	Phase 1	Boehringer Ingelheim	Mono	NA	oral	administered at the assigned dose level, dose level not disclosed	-	US, Japan, Korea, Taiwan	2023-09-28
BI 1701963	KRAS Mutated Advanced or Metastatic Solid Tumours	Phase 1		Mono and Combined With Trametinib	2L+	oral	BI 1701963 50/100/200/400/800 mg, QD ± Trametinib	TRAE 64%	Germany, Netherlands, US	2019-10-01

INDUSTRY OVERVIEW

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
BBO-11818	locally advanced and unresectable or metastatic NSCLC, PDAC, CRC, or other solid tumor with KRAS mutation	Phase 1	TheRas/BridgeBio Oncology Therapeutics	Mono and combined with pembrolizumab, pembrolizumab +/- cis/carboplatin + pemetrexed, or cetuximab	NA	oral	administered at the assigned dose level, dose level not disclosed	-	US	2025-04-08
	Advanced solid tumors with KRAS mutations, PDAC, NSCLC, CRC	Phase 1	Alterome Therapeutics	Mono	NA	oral	administered at the assigned dose level, dose level not disclosed	-	US	2025-02-19
ERAS-4001	Advanced Solid Tumors	Phase 1	Erasca	Mono and combined with pembrolizumab/panitumumab	NA	oral	administered at the assigned dose level, dose level not disclosed	-	NA	2025-06-15
KQB-365	Advanced Solid Tumors with either a KRAS G12C or KRAS G12S mutation	Phase 1	Kumquat Biosciences	mono or combined with cetuximab	NA	Intravenous	administered at the assigned dose level, dose level not disclosed	-	US	2024-12-06
	KRAS-altered advanced or metastatic solid tumors	Phase 1	Amgen	mono or combined with Pembrolizumab or Panitumumab	NA	oral	administered at the assigned dose level, dose level not disclosed	-	US, Australia	2025-07-30

INDUSTRY OVERVIEW

Note: Ongoing Clinical trials with first posted date up to Latest Practicable Date, initiated by companies are included.

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

INDUSTRY OVERVIEW

Entry Barriers of RAS Drug Market

There are considerable entry barriers for the development of RAS drugs:

- *Challenging Druggability.* RAS proteins have been well-established to be challenging drug targets. Primarily, it is difficult to design selective RAS inhibitors because of the unique smooth surface of RAS proteins. Additionally, the high affinity for GTP/GDP of RAS proteins and the absence of known allosteric regulatory sites also make it difficult to develop targeted therapies. Furthermore, not only it is difficult to identify effective therapeutics for each mutant RAS protein, it is also challenging to enhance their ability to selectively inhibit mutated RAS proteins in order to reduce toxicity and side effects. These factors combined pose considerable challenges to the development of RAS-targeted drugs.
- *Considerable Development Uncertainty.* In the past, the successful rate of conducting preclinical and/or clinical studies of RAS-targeted drugs was relatively low, mainly due to unsatisfying efficacy and/or inherited toxicity. The high risk of development failure has discouraged pharmaceutical companies from investing in this particular domain. Moreover, since RAS mutations are present in a wide range of cancers, the response to RAS-targeted therapies can vary significantly across different patient populations, which further increases the uncertainty of developing RAS-targeted drugs.
- *Significant R&D Cost.* Developing RAS inhibitors requires extensive preclinical studies to understand their effects on multiple signaling pathways and to optimize drug candidates for potency and selectivity. For instance, the mechanism of RAS drugs resistance is complex, including primary resistance, acquired resistance due to mutation escape, and adaptive resistance, all of which require considerable research efforts. The monetary and time investment required for these studies are significant and could be an entry barrier especially for emerging pharmaceutical companies.

Growth Drivers and Future Trends of RAS Drug Market

According to Frost & Sullivan, the RAS drug market growth has primarily been driven by the following factors:

- *Development Beyond KRAS Targets.* As of the Latest Practicable Date, all RAS-targeted drugs approved globally were KRAS G12C inhibitors. Nonetheless, ongoing research has expanded to additional KRAS mutations, such as G12D, G12V and G13D, as well as NRAS and HRAS mutations, thereby broadening therapeutic options across a wider range of cancers. A key area of interest is the development of pan-RAS inhibitors, which target multiple RAS isoforms or mutations simultaneously. These inhibitors are designed to treat a broader spectrum of RAS-driven cancers by inhibiting various RAS variants and to overcome the limitations of mutation-specific therapies.

INDUSTRY OVERVIEW

- *Exploration of Combination Therapies.* A promising trend in cancer treatment is the development of combination therapies that integrate RAS inhibitors with other targeted agents, immunotherapies, or chemotherapy. These combinations aim to improve treatment efficacy, minimize the emergence of drug resistance, and effectively address the complexities of cancer signaling pathways.
- *Extending the Breadth of RAS Inhibitors.* Recent research has focused on designing novel modalities, including bioconjugates, RAS degraders, toxins, immunotherapy, and siRNA-based approaches, each offering distinct advantages. For instance, FAScon, a class of bioconjugates featuring a combination of antibody and small molecule drug targeting separate components of the same signaling pathway, has the potential to realize both precise targeting and synergistic effects of the large and small molecules, and to prevent premature release of payload in the blood and enables conjugation of hydrophobic small molecules at a high drug-to-antibody ratio.

The Company stays at the forefront of the industry by expanding its RAS pipelines, developing various combination therapies and exploring novel modalities.

Major Indications of RAS Inhibitors

NSCLC

NSCLC is any type of epithelial lung cancer other than small cell lung cancer (SCLC), which accounts for approximately 85% of all lung cancer incidence. The three main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma. All types can occur in unusual histologic variants and develop as mixed cell-type combinations. The subtypes of NSCLC can be categorized based on the presence or absence of driver gene mutations. Among the common driver genes identified in NSCLC, KRAS mutations are one of the most prevalent mutations, accounting for approximately 20% of cases, and KRAS G12C mutation alone is present in approximately 13% of all NSCLC cases. The following table sets forth the percentages of NSCLC incidence with different oncogene mutations.

Percentages of NSCLC Incidence with Oncogenes Mutations

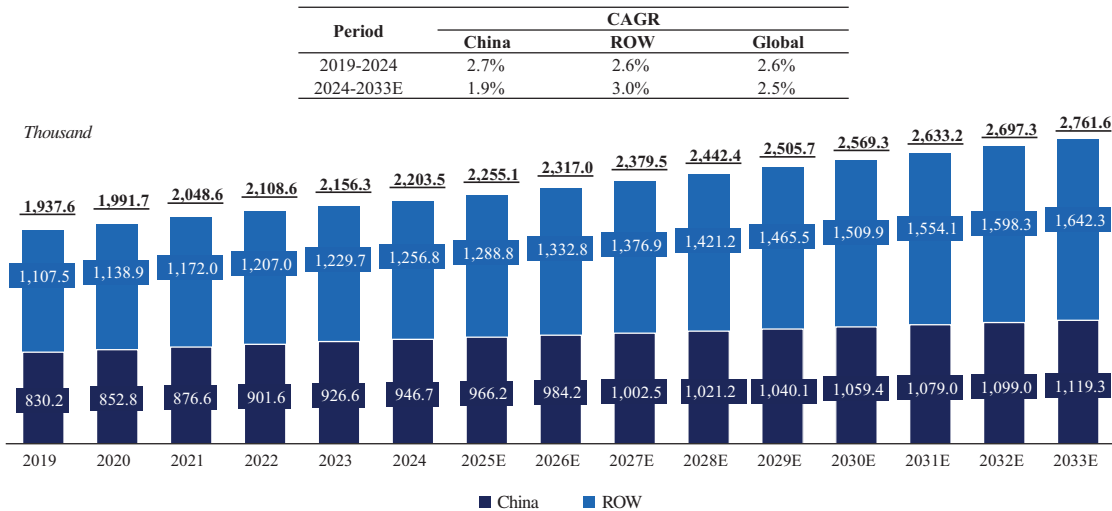
Gene Mutation	Percentage
EGFR mutation	45-50% (Asian), ~20% (Western Countries)
ALK fusion	3-5%
ROS1 fusion	~2%
BRAF V600E	1-2%
NTRK fusion	Less than 1%
KRAS G12C mutation	~4% (Asian), ~13% (Western Countries)
MET14 exon skipping mutation	~3%
RET fusion	1-2%
ERBB2 mutation	1-6%

Source: Literature review, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

The global incidence of NSCLC increased from 1,937.6 thousand in 2019 to 2,203.5 thousand in 2024, and is expected to further increase to 2,761.6 thousand in 2033. In China, the incidence of NSCLC increased from 830.2 thousand in 2019 to 946.7 thousand in 2024, and is expected to further increase to 1,119.3 thousand in 2033. The diagram below sets forth the historical and projected incidence of NSCLC from 2019 to 2033.

Global and China Incidence of NSCLC, 2019-2033E

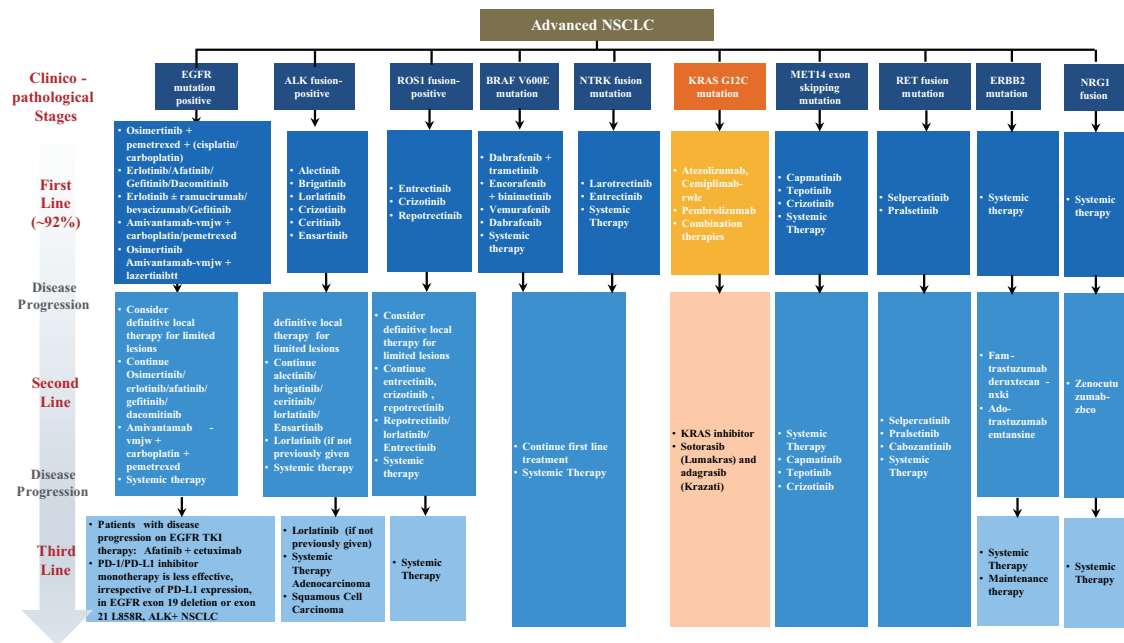


Source: WHO, NCC, IARC, Frost & Sullivan Analysis

NSCLC treatment options mainly depend on the disease stage and specific gene mutation. The following charts set forth the treatment regimen of advanced NSCLC (stage IV with metastasis) according to NCCN 2025 and CSCO 2024, respectively.

INDUSTRY OVERVIEW

Treatment Paradigm of Advanced NSCLC in U.S. (NCCN 2025)

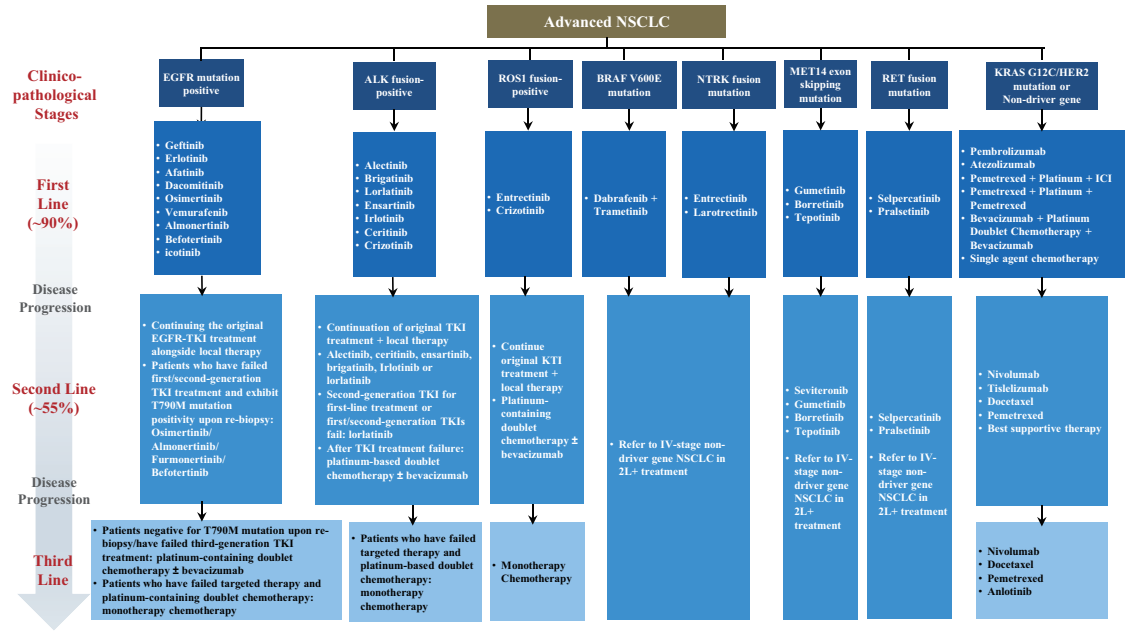


Source: NCCN2025v3, Frost & Sullivan Analysis

In summary, for advanced NSCLC patients without specific gene mutations, first-line treatment mainly includes immunotherapy, chemotherapy, or combination therapy. If there are targeted gene mutations, targeted drugs (such as osimertinib and alectinib) are preferred as first-line treatment. The second-line selection of advanced NSCLC patients is mainly adjusted based on the first-line medication. If immunotherapy is used as first-line treatment, chemotherapy or targeted drugs (if there are newly discovered mutations) should be switched. If targeted drugs are used as first-line treatment, another targeted drug should be switched, or chemotherapy combined with immunotherapy should be used. According to NCCN, for NSCLC patients with the KRAS G12C mutation, the first-line treatment is PD-(L)1 as a monotherapy or in combination with chemotherapy, and the second-line treatment is sotorasib or adagrasib.

INDUSTRY OVERVIEW

Treatment Paradigm of Advanced NSCLC in China (CSCO 2024)



Source: CSCO 2024, Frost & Sullivan Analysis

Abbreviations: PCBA=Paclitaxel + Carboplatin + Bevacizumab in combination with Atezolizumab; PCBT=Paclitaxel + Carboplatin + Bevacizumab combined with Trastuzumab; PCBR=Paclitaxel + carboplatin + bevacizumab combined with ramucirumab; APCA=Albumin-bound Paclitaxel + Carboplatin in combination with Atezolizumab; NIP=Nivolumab and Ipilimumab in combination with Pembrolizumab; PP=Pemetrexed in combination with platinum agents; BP=Bevacizumab in combination with platinum-based doublet chemotherapy; PC=PD-L1 inhibitors as monotherapy or in combination with chemotherapy

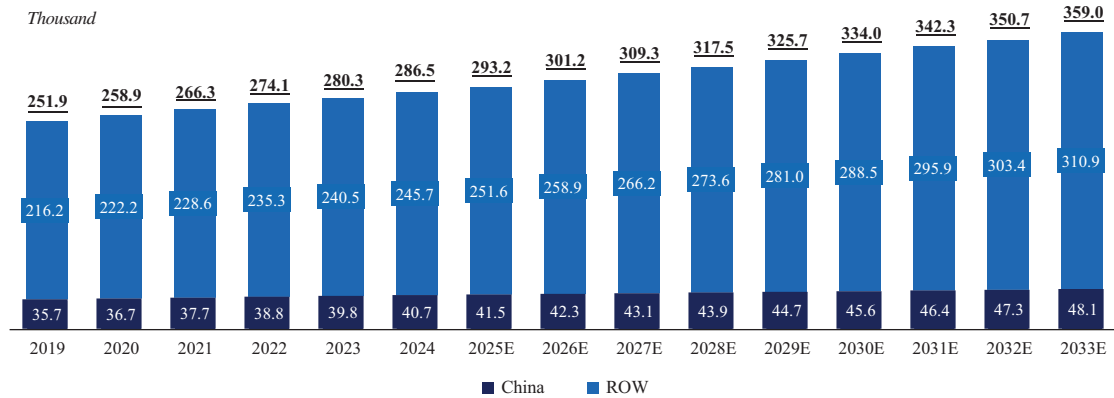
In China, the overall principles for the first-line and second-line treatments for advanced NSCLC are similar to those in the United States, but there is a gap in the availability of new targeted drugs. For some disease causing specific gene mutations, there are no marketed drugs that target these gene mutations. In China, for NSCLC patients with the KRAS G12C mutation in the 2024 version of the diagnosis and treatment guidelines, the I/II grade recommendations for first-line and second-line treatments refer to the treatment plan for NSCLC patients without driver gene mutations (i.e., without gene mutations that promote the development and progression of the cancer), and the III grade recommendations for second-line treatment are sotorasib and adagrasib (not yet approved in China).

The KRAS G12C and G12D mutations are among the most common oncogene mutations in NSCLC incidence. The diagrams below set forth the historical and projected incidences of G12C and G12D mutated NSCLC from 2019 to 2033, respectively.

INDUSTRY OVERVIEW

Incidence of KRAS G12C mutated NSCLC, 2019-2033E

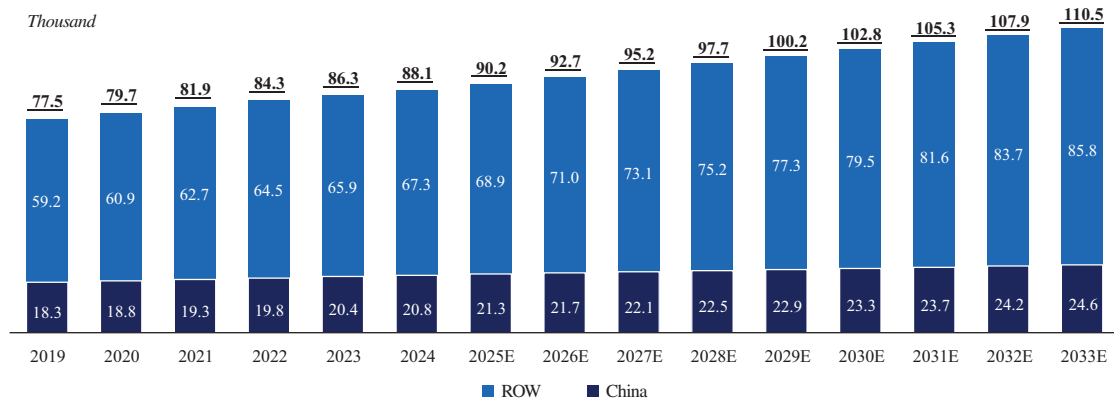
CAGR	China	Global
2019-2024	2.7%	2.6%
2024-2033E	1.9%	2.5%



Source: IARC, NCCN, Frost & Sullivan Analysis

Incidence of KRAS G12D mutated NSCLC, 2019-2033E

CAGR	China	Global
2019-2024	2.7%	2.6%
2024-2033E	1.9%	2.5%



Source: IARC, NCCN, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

The 5-year survival rate for lung cancer in China is comparable to that in the United States, both standing at approximately 20%, which is significantly lower than that of other major cancers. The low survival rate is primarily attributed to a lack of early detection tools and the limited number of early-stage diagnoses. In China, the majority of NSCLC patients are diagnosed at an advanced stage, with approximately 60% to 70% being diagnosed at Stage IV. For patients with unresectable locally advanced NSCLC, the prognosis remains poor despite standardized treatment, which typically involves concurrent radiotherapy. Despite following these treatment protocols, many patients experience rapid disease progression and unsatisfied outcomes, leading to a 5-year overall survival rate of only 15% to 25%. The low survival rate and deficient treatment underscore the critical need for improved therapeutic options.

There is also a lack of effective targeted therapies for KRAS mutations in NSCLC. About 90% advanced NSCLC patients received first-line treatment, and about 55% of them entered the second-line treatment in China. Research has shown that KRAS-mutant NSCLC patients in the past were considered insensitive to chemotherapy and had poor prognoses. The efficacy of PD-1 combined with chemotherapy has also been reported with mixed results. Additionally, primary and acquired resistance in EGFR-mutant patients is also associated with KRAS mutations. In August 2024, GFH925 (fulzerasib) became the first commercially available KRAS G12C inhibitor drug in China, which offers a novel solution for patients with KRAS G12C mutations, and potentially addresses the gap in targeted therapies for this mutation.

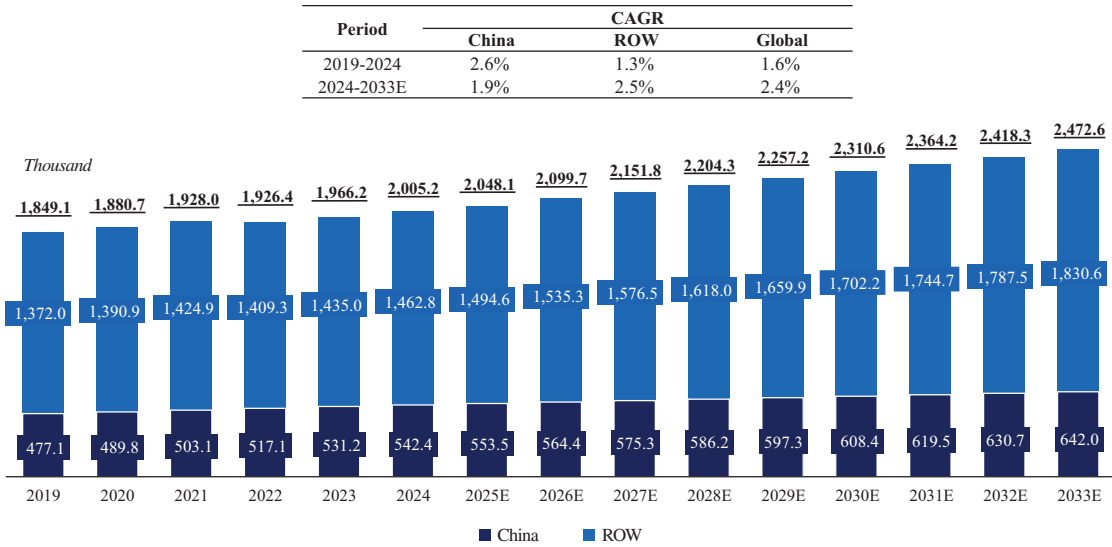
CRC

CRC, also known as bowel cancer, colon cancer, or rectal cancer, is a type of cancer that develops from the colon or rectum. Most colorectal cancers develop first as polyps, which are abnormal growths inside the colon or rectum that may later become cancerous if they are not removed. KRAS mutations are also prevalent mutations for CRC. RAS is one of the most frequently mutated oncogenes in CRC, and KRAS G12C mutation alone appears in approximately 3-4% of the CRC incidence.

The global incidence of CRC increased from 1,849.1 thousand in 2019 to 2,005.2 thousand in 2024, and is expected to further increase to 2,472.6 thousand in 2033. In China, the incidence of CRC increased from 477.1 thousand in 2019 to 542.4 thousand in 2024, and is expected to further increase to 642.0 thousand in 2033. The diagram below sets forth the historical and projected incidence of CRC from 2019 to 2033.

INDUSTRY OVERVIEW

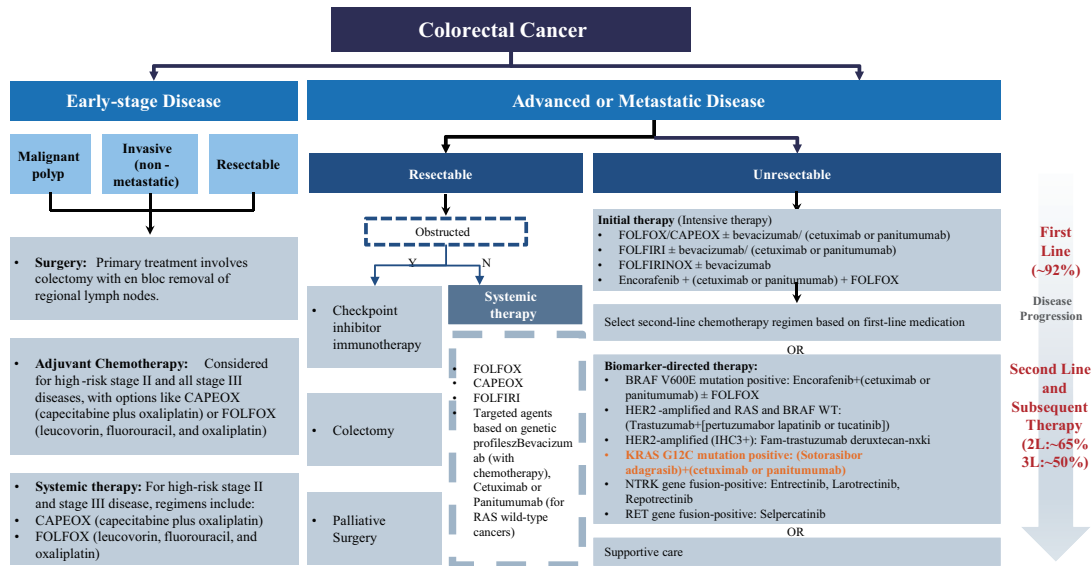
Global and China Incidence of CRC, 2019-2033E



Source: WHO, IARC, NCC, Frost & Sullivan Analysis

Treatment options for CRC mainly depend on the disease stage. Advanced CRC refers to CRC at stage IV with metastasis. The following charts set forth the treatment regimen of CRC according to NCCN 2025 and CSCO 2024, respectively.

Treatment Paradigm of CRC in the U.S. (NCCN 2025)

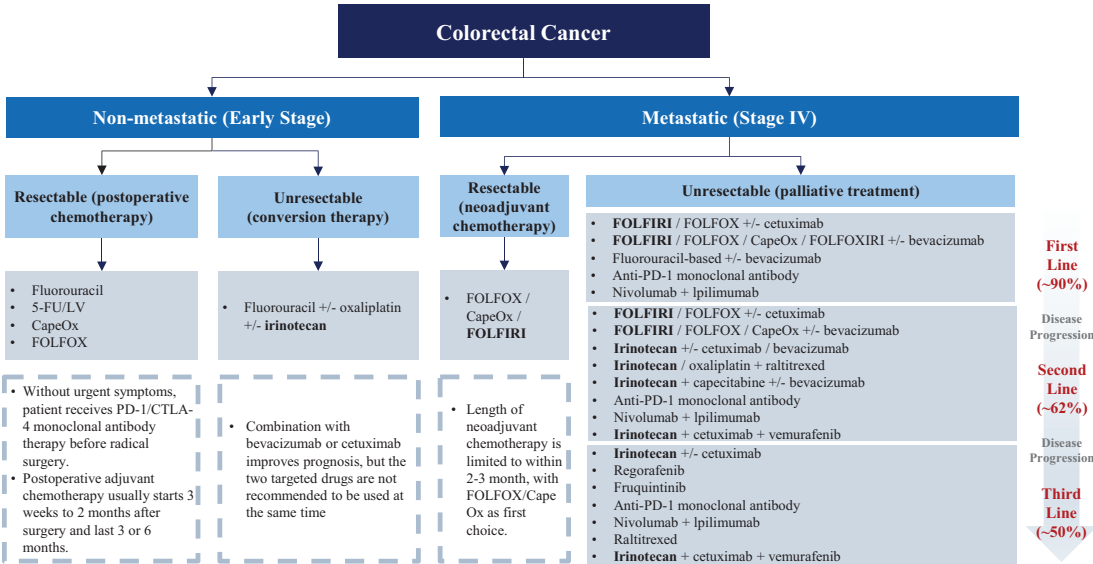


Source: NCCN 2025, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

The first-line treatment is based on chemotherapy, and targeted drugs can be used in combination after genetic testing (cetuximab or panitumumab can be used for patients with EGFR mutations, and bevacizumab can be used for non mutations). Second line and subsequent treatments are adjusted to different chemotherapy regimens and targeted drugs based on first-line medication choice. Patients with special gene mutation can use corresponding targeted drugs.

Treatment Paradigm of CRC in China (CSCO 2024)



Note:

1. FOLFOX=oxaliplatin + leucovorin + 5-FU; FOLFIRI=irinotecan + leucovorin+ 5-FU; CapeOx=oxaliplatin + capecitabine.

Source: CSCO 2024, Frost & Sullivan Analysis

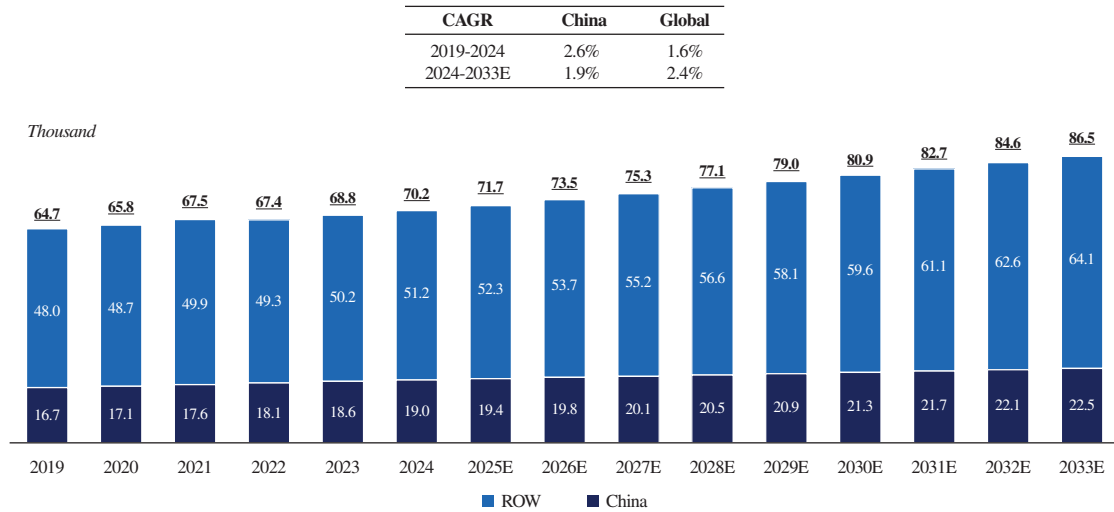
Abbreviations: FOLFOX = oxaliplatin + leucovorin + 5-FU; FOLFIRI = irinotecan + leucovorin + 5-FU; CapeOx = oxaliplatin + capecitabine

Similarly, the principles for selecting first-line and second-line drugs for advanced CRC in China are similar to those in the United States, but lack targeted drugs for specific genes, such as KRAS G12C.

The KRAS G12C and G12D mutations are among the most common oncogene mutations in CRC incidence. The diagrams below set forth the historical and projected incidences of G12C and G12D mutated CRC from 2019 to 2033, respectively.

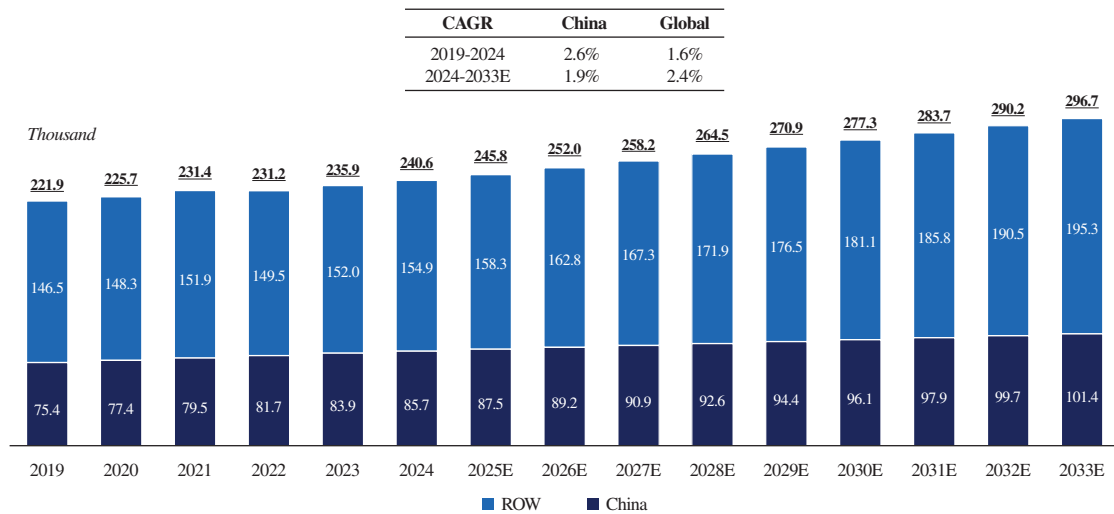
INDUSTRY OVERVIEW

Incidence of KRAS G12C mutated CRC, 2019-2033E



Source: IARC, NCCN, Frost & Sullivan Analysis

Incidence of KRAS G12D mutated CRC, 2019-2033E



Source: IARC, NCCN, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

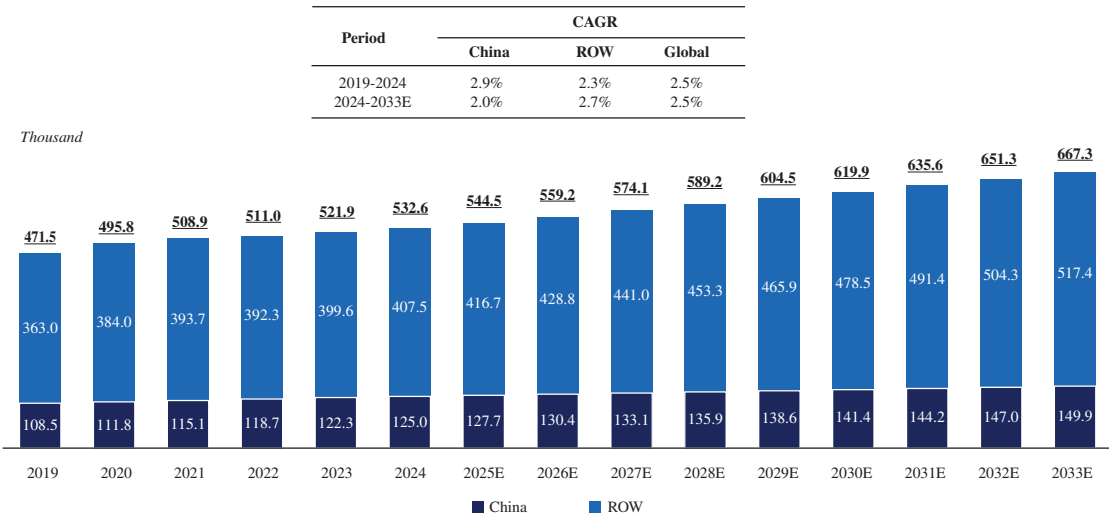
CRC ranks as the second most lethal and the third most commonly-diagnosed cancer globally. The incidence of CRC among the younger population has also been rising, a trend expected to continue over the next decade, and such trend is especially pronounced in Asian and African populations. Additionally, metastatic CRC (“**mCRC**”), with its complex and heterogeneous nature, further contributes to poor outcomes for many patients, complicating the development of effective targeted treatments. While other cancers have seen significant advancements in targeted therapy availability, treatment options for mCRC remain limited. Despite extensive research, there is still a relative shortage of therapies that address the common genetic mutations found in mCRC patients.

Pancreatic cancer

Pancreatic cancer is an aggressive disease in which malignant cells originate in the pancreatic tissue. Pancreatic cancers have certain prevalent genetic mutations, the most commonly mutated genes being KRAS (approximately 85%) and loss-of-function mutations in tumor suppressors, such as TP53, CDNK2A, DPC4/SMAD4, and BRCA2.

The global incidence of pancreatic cancer rose from 471.5 thousand to 532.6 thousand between 2019 and 2024, with a CAGR of 2.5% and is expected to continue increasing to 667.3 thousand by 2033. In China, the incidence of pancreatic cancer increased from 108.5 thousand in 2019 to 125.0 thousand in 2024, with a CAGR of 2.9% and is expected to further increase to 149.9 thousand in 2033. The diagram below sets forth the historical and projected incidence of pancreatic cancer from 2019 to 2033.

Global and China Incidence of Pancreatic Cancer, 2019-2033E

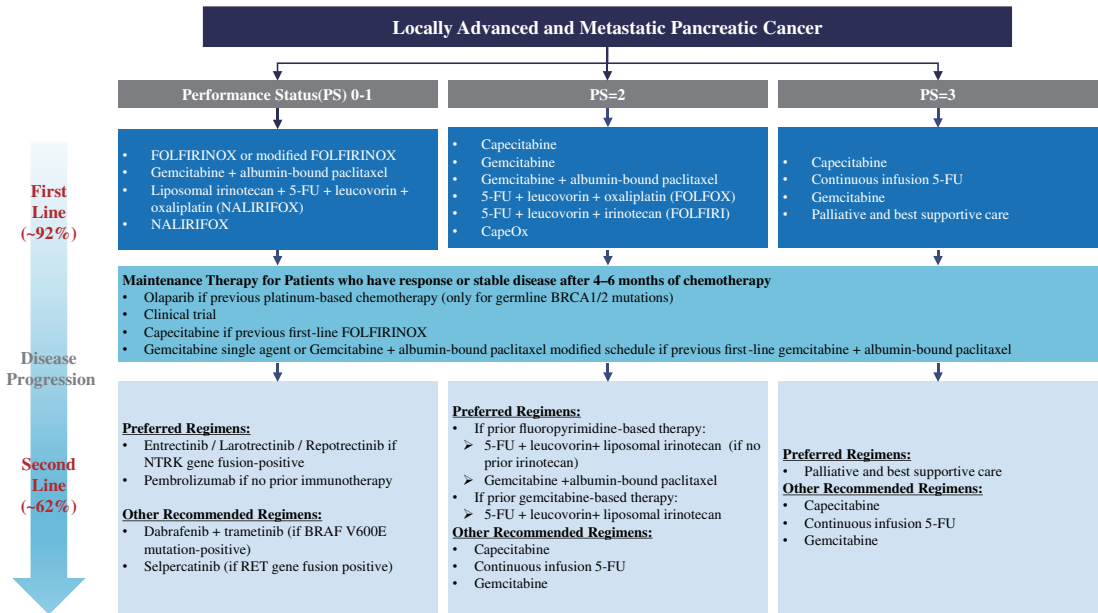


Source: WHO, NCC, IARC, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Treatment options for pancreatic cancer mainly depend on the disease stage. The following charts set forth the treatment regimen of pancreatic cancer according to NCCN 2025 and CSCO 2024, respectively.

Treatment Regimen of Advanced and Metastatic Pancreatic Cancer (NCCN 2025)

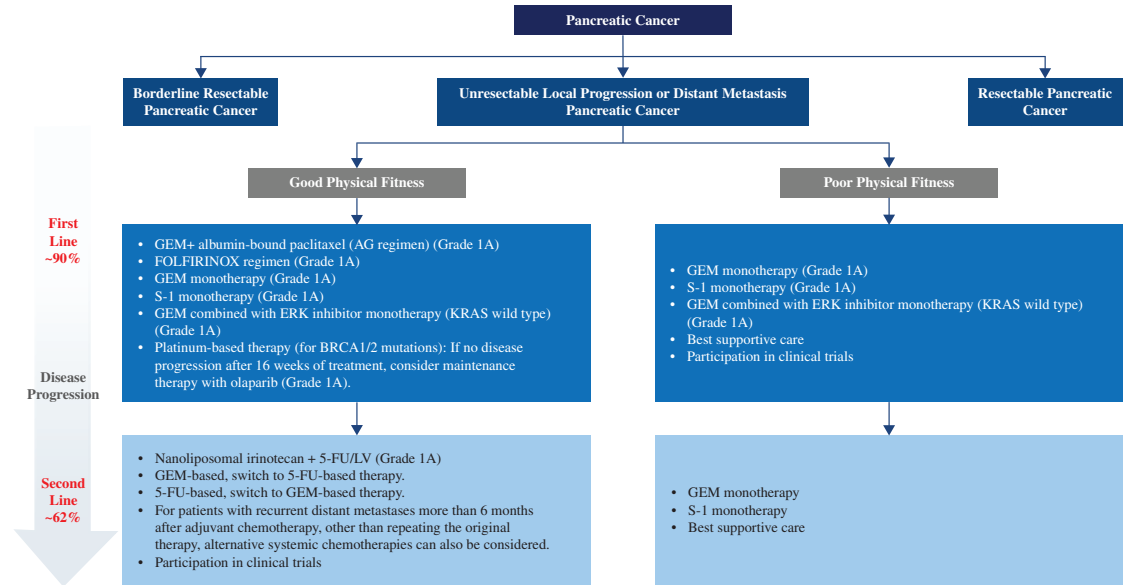


Source: NCCN2025v2, Frost & Sullivan Analysis

The standard first-line treatment for locally advanced and metastatic pancreatic cancer is FOLFIRINOX chemotherapy (suitable for patients in good condition), or gemcitabine combined with albumin paclitaxel. If there is a BRCA mutation, targeted drug olaparib can be added. Second line treatment involves switching to another chemotherapy regimen based on first-line treatment, as well as targeting drugs specific to mutated genes, including NTRK, BRAF V600E and RET.

INDUSTRY OVERVIEW

Treatment Regimen of Pancreatic Cancer (CSCO 2024)

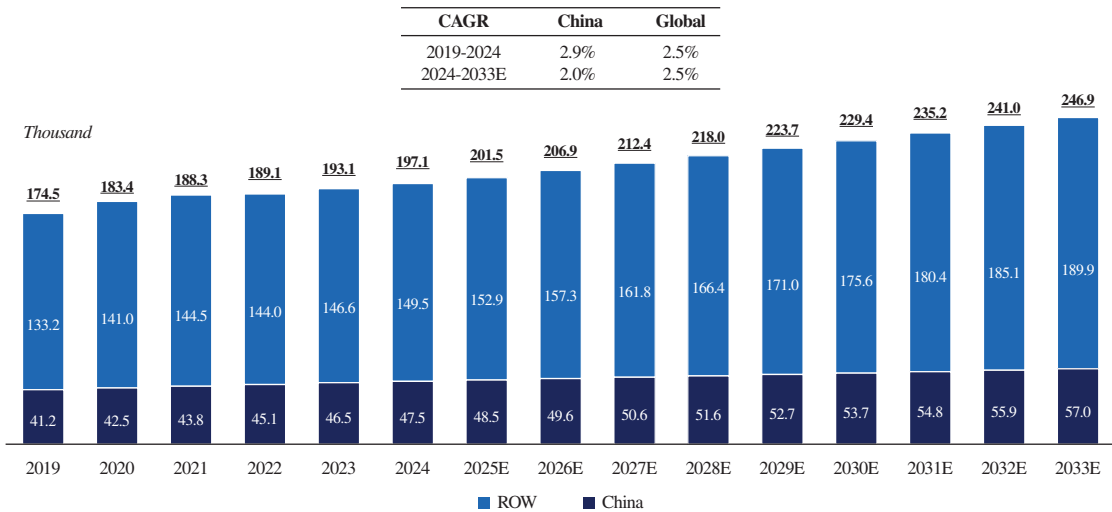


Source: CSCO 2024, Frost & Sullivan Analysis

The first-line chemotherapy regimens between China and the U.S. are similar, but second-line treatment relies more on basic chemotherapy in China.

The KRAS G12D mutation is among the most common oncogene mutations in pancreatic cancer incidence. The diagram below sets forth the historical and projected incidences of G12D mutated pancreatic cancer from 2019 to 2033.

Incidence of KRAS G12D Mutated Pancreatic Cancer, 2019-2033E



Source: IARC, NCCN, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Pancreatic cancer has a rising incidence and is one of the most lethal human malignancies. The 5-year survival rate of pancreatic cancer is approximately 13% and two factors mainly contributed to the low survival rate. First, early diagnosis at a curable stage is difficult because patients with early-stage pancreatic cancer rarely exhibit symptoms. The second factor is the lack of effective treatment options. The treatment of pancreatic cancer mainly includes surgical treatment, radiotherapy, chemotherapy, interventional therapy, endoscopic retrograde cholangiopancreatography related treatment and traditional Chinese medicine treatment. Currently, the option of targeted therapies is quite limited. Several targeted therapies have been assessed in combination with gemcitabine, but none has been shown to significantly impact outcomes. As pancreatic cancer is mainly driven by mutations in the KRAS oncogene, we believe that our KRAS-targeted inhibitors have the potential to become a promising therapeutic solution to pancreatic cancer, one of the most lethal forms of cancer.

OVERVIEW OF RIPK1 DRUG MARKET

Receptor-interacting serine/threonine-protein kinase 1 (“**RIPK1**”) is a master regulator of cellular fate, balancing pro-survival nuclear factor kappa B (“**NF-κB**”) signaling and cell death in response to a wide range of inflammatory processes, apoptosis, necroptosis and pro-death stimuli in human diseases. Activation of RIPK1 kinase has been observed in pathological samples from autoimmune, inflammatory and neurodegenerative conditions. Additionally, both monogenic and polygenic variants of known RIPK1 regulators contribute to inflammatory and neurodegenerative diseases. Furthermore, RIPK1 kinase activation plays a central role in mediating cell necroptosis following the activation of tumor necrosis factor receptor 1 (“**TNFR1**”) by TNF-α, particularly in apoptosis-deficient conditions.

RIPK1 inhibitors downregulate RIPK1 kinase activity and effectively suppress cell death induced by TNF-α and caspase inhibitors. Inhibition of RIPK1 has demonstrated efficacy across a wide range of human diseases*, including autoimmune diseases such as psoriasis, ulcerative colitis, lupus, and rheumatoid arthritis, as well as neurodegenerative conditions such as amyotrophic lateral sclerosis, multiple sclerosis and Alzheimer’s disease.

* Degterev A, Ofengeim D, Yuan J. Targeting RIPK1 for the treatment of human diseases. *Proc Natl Acad Sci U S A*. 2019;116(20):9714-9722.

Bai Y, Qiao Y, Li M, Yang W, Chen H, Wu Y, Zhang H. RIPK1 inhibitors: A key to unlocking the potential of necroptosis in drug development. *European Journal of Medicinal Chemistry*. 2024; 265(5):116-123.

Mifflin L, Ofengeim D, Yuan J. Receptor-interacting protein kinase 1 (RIPK1) as a therapeutic target. *Nat Rev Drug Discov*. 2020;19(8):553-571.

INDUSTRY OVERVIEW

Competitive Landscape of RIPK1 Drug Market

The prevalence of PAD globally rose from 271.6 million in 2019 to 322.3 million in 2024, with a CAGR of 3.5%. It is expected to continue increasing to 378.1 million by 2033, reflecting a CAGR of 1.8% from 2024. The prevalence of PBC globally rose from 1,115.8 thousand in 2019 to 1,206.2 thousand in 2024, with a CAGR of 1.6%. It is expected to continue increasing to 1,353.9 thousand by 2033, reflecting a CAGR of 1.3% from 2024.

As of the Latest Practicable Date, there was no approved RIPK1 inhibitor drug globally. There were seven RIPK1 inhibitor candidates under clinical development globally, and GFH312 was the only one developed for the treatment of PAD and PBC as of Latest Practicable Date. The following table sets forth the clinical-stage RIPK1 inhibitor candidates globally.

INDUSTRY OVERVIEW

Pipeline of Clinical-stage RIPK1 Inhibitor Drug Candidates Globally

Drug names	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
GDC-8264	Cardiac Surgery-Associated Acute	Phase 2	Genentech	mono	Not applicable	oral	single- (5–225 mg) and multiple- (50 and 100 mg) once daily, up to 14 days	–	US, Australia, Europe, Canada, etc.	2024-09-19
	Kidney Injury and Major Adverse Kidney Events prevention									
ABBV-668	Moderate to severe UC	Phase 2	AbbVie	Mono	Not applicable	oral	BID, for 52 weeks	–	US, Belgium, France, etc	2022-10-06
Eclitasertib	Adult with moderate to severe UC	Phase 2	Sanofi & Denali Therapeutics	Mono	Not applicable	oral	administered at 3 assigned dose levels, dose level not disclosed	no study drug-related severe or serious AEs reported, At doses of 100 mg and above, > 90% inhibition of RIPK1 phosphorylation in human peripheral blood mononuclear cells was observed with eclitasertib at 12 h post-dose	US, China, Europe, etc.	2022-10-20

INDUSTRY OVERVIEW

Drug names	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
LY3871801	Moderately-to-severely active RA	Phase 2	Eli Lilly & Rigel Pharmaceuticals	Mono	Not applicable	oral	administered at the assigned dose level, dose level not disclosed	No TEAEs	US, United Kingdom, France, etc.	2023-05-08
AC-003	aGVHD	Phase 1b	Accro Bioscience	Combo with glucocorticoid	Not applicable	oral	BID or QD, 28-day cycle	–	China	2023-12-12
GFH312	Inflammatory conditions (healthy volunteer)	Phase 1	GenFleet	Mono	Not applicable	oral	a single ascending dose up to 500 mg (part I) or once-daily repeated doses up to 200 mg for 14 days (part II)	TEAE: part I 42.1%, part II 63.2%	Australia, China	2020/12/21
SIR9900	Systemic Inflammatory Response Syndrome (healthy volunteer)	Phase 1	SIRONAX	Mono	Not applicable	oral	30mg QD, 10-day cycle or 200mg for one day	–	China	2025/4/16

INDUSTRY OVERVIEW

Note: Ongoing Clinical trials with first posted date up to Latest Practicable Date, initiated by companies are included.

Source: CDE, Clinical Trials, Frost & Sullivan Analysis

Abbreviations: UC: urothelial carcinoma; MS: multiple sclerosis; RA: rheumatoid arthritis; aGVHD: acute graft-versus-host disease

Entry Barriers of RIPK1 Drug Market

The RIPK1 drug market has the following entry barriers:

- *Development Obstacles.* The complex structure of RIPK1 necessitates comprehensive studies in structural biology to elucidate its active site and mechanism of action. RIPK1 participates in complex signaling pathways, and it requires a thorough understanding of molecular biology and cellular signaling to develop RIPK1-targeted drugs. This complexity presents significant barriers for pharmaceutical companies lacking the requisite expertise or technology to enter the market. Moreover, the current RIPK1 inhibitors are constrained to specific chemotypes, and the optimization of RIPK1 inhibitors to enhance their activity and selectivity remains a substantial challenge.
- *Safety Concern.* Developing effective RIPK1 inhibitors with an acceptable safety profile presents a significant challenge. Although the targeting of RIPK1 itself appears to be relatively safe at least in short-term studies, the clinical development of some of compounds has been discontinued due to potential safety signal. Adverse events tend to be drug-specific and related to off-target effects, among which, headache and gastrointestinal events are the most common. Elevated liver enzymes were also observed with some drugs. Therefore, ensuring drug safety remains a major concern in the development of RIPK1 inhibitors.
- *Blood-brain Barrier Crossing.* Studies have shown that elevated RIPK1 activity in the brain drives neuroinflammation and cell necrosis, and it is believed to be associated with various CNS and autoimmune diseases. Therefore, designing RIPK1 inhibitors capable of penetrating the blood-brain barrier will be key to achieving breakthroughs. However, developing compounds that can safely and effectively penetrate the blood-brain barrier without causing toxicity poses considerable difficulties.

INDUSTRY OVERVIEW

Growth Drivers and Future Trends of RIPK1 Drug Market

According to Frost & Sullivan, the RIPK1 drug market growth has primarily been driven by the following factors:

- *Viable Drug Target with Considerable Potential.* The critical regulatory role of RIPK1 in mediating the interactions between inflammatory responses, apoptosis, and necroptotic signaling pathways, combined with its kinase structure that is well-suited for the development of pharmacologically specific small-molecule inhibitors, has established RIPK1 as an attractive drug target for pharmaceutical companies.
- *Broad Therapeutic Applications.* RIPK1 inhibitors are being studied in clinical trials for a diverse array of therapeutic applications, including autoimmune disorders, neurodegenerative diseases, and beyond. For instance, recent findings indicate that RIPK1 degradation mediated through PROTAC can induce immune cell death and improve the efficacy of antitumor therapies. Additionally, RIPK1 has also shown promising potential in the treatment of atherosclerosis-related conditions.
- *Combination Therapies.* The therapeutic efficacy of RIPK1 inhibitors could be potentially enhanced with reduced side effects if developed in combination with other drugs. These combination therapies can target multiple pathways in conditions such as neurodegeneration and autoimmune disorders, and they could potentially yield improved patient outcomes and reduced drug resistance.

Major Indications of RIPK1 Drug

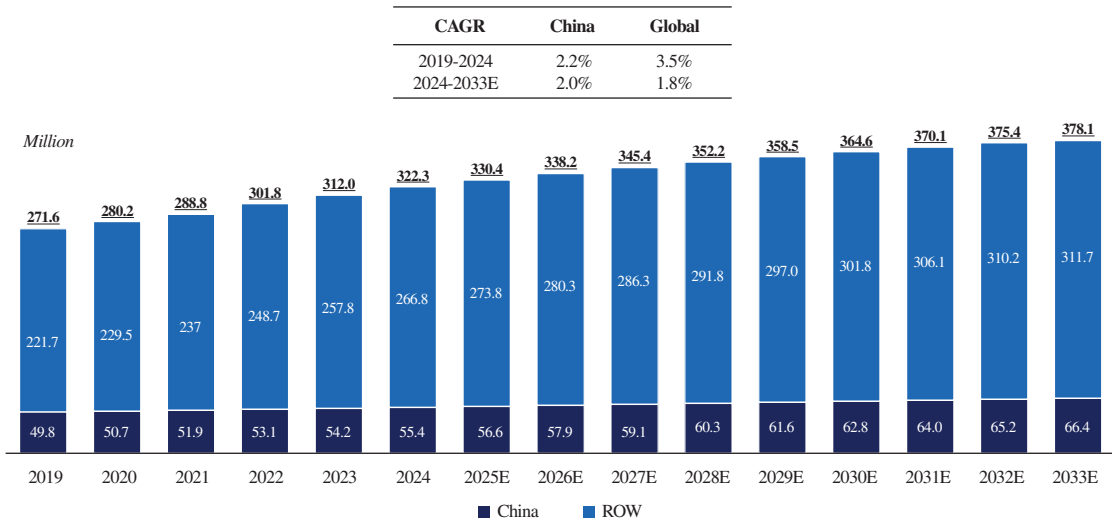
PAD

Peripheral Arterial Disease (“**PAD**”) is a condition in which narrowed arteries reduce blood flow to the limbs. Arteries are responsible for transporting oxygen-rich blood from the heart to various parts of the body. However, the accumulation of cholesterol and scar tissue can create plaque, which obstructs the arteries and limits the flow of blood, oxygen, and essential nutrients to the arms and legs, leading to PAD. PAD is mainly caused by atherosclerosis, as well as other factors including inflammation, trauma or injury, structural abnormalities in ligaments or muscles, and radiation exposure. Major risk factors for PAD include smoking, diabetes, hypertension, high cholesterol, obesity, advancing age, and a family history of the condition, with atherosclerosis being the most prevalent cause.

The global prevalence of PAD increased from 271.6 million in 2019 to 322.3 million in 2024, and is expected to further increase to 378.1 million in 2033. In China, the prevalence of PAD increased from 49.8 million in 2019 to 55.4 million in 2024, and is expected to further increase to 66.4 million in 2033. The diagram below sets forth the historical and projected prevalence of PAD from 2019 to 2033.

INDUSTRY OVERVIEW

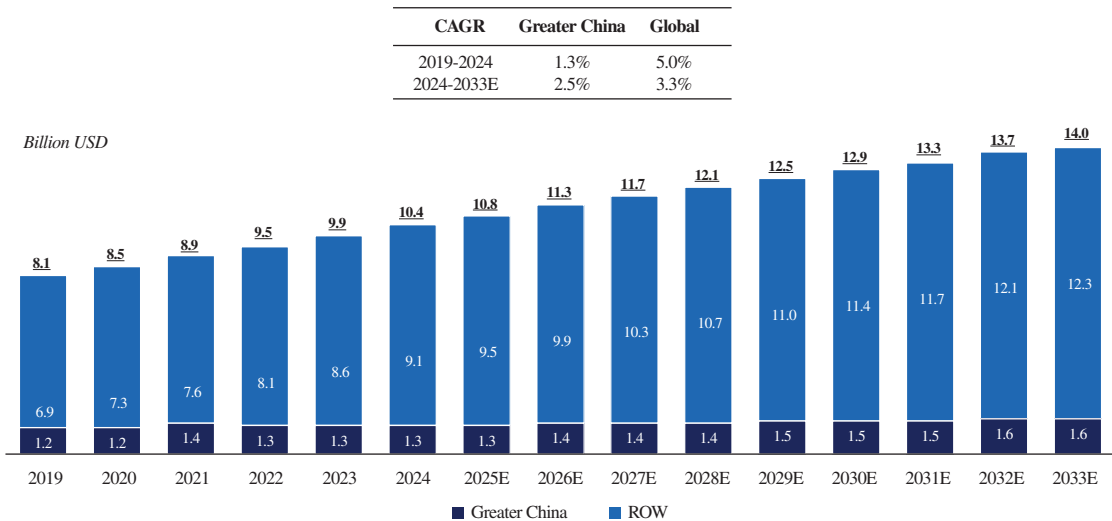
Global and China Prevalence of PAD, 2019-2033E



Source: Research review, Frost & Sullivan Analysis

The global PAD drug market grew from US\$8.1 billion in 2019 to US\$10.4 billion in 2024, and is expected to further grow to US\$14.0 billion in 2033. Greater China’s PAD drug market grew from US\$1.2 billion in 2019 to US\$1.3 billion in 2024, and is expected to further grow to US\$1.6 billion in 2033. The diagram below sets forth the historical and projected global and Greater China’s market sizes of PAD drugs from 2019 to 2033.

Global and Greater China PAD Drug Market, 2019-2033E



Source: Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Current Treatment Options and Limitations

The current treatment regimen of PAD mainly constitutes medical and exercise therapies, preventive foot care and revascularization. However, these treatment options have notable limitations. For instance, revascularization, such as percutaneous endovascular balloon dilation or stenting, remains the primary intervention for patients with severe claudication, yet there is a lack of pharmacological therapies specifically targeting the inflammatory mechanisms underlying PAD. Moreover, many patients remain asymptomatic until the disease progresses to a critical stage, at which point invasive surgical and pharmacological interventions become necessary, yet these treatments often come with critical risks. The limitations of existing treatment options call for more effective and less invasive treatment strategies with better clinical outcome, lower risks and less complications. Given the observed elevation of RIPK1 expression in human atherosclerotic lesions, RIPK1 has been viewed as a potential therapeutic target for reducing residual inflammation in patients at high risk of developing coronary artery disease and subsequently PAD.

PBC

Primary biliary cholangitis (“**PBC**”) is a chronic, progressive autoimmune cholestatic disease that primarily affects the liver. It is characterized by non-suppurative inflammation of the small intrahepatic bile ducts, which eventually leads to liver fibrosis and cirrhosis.

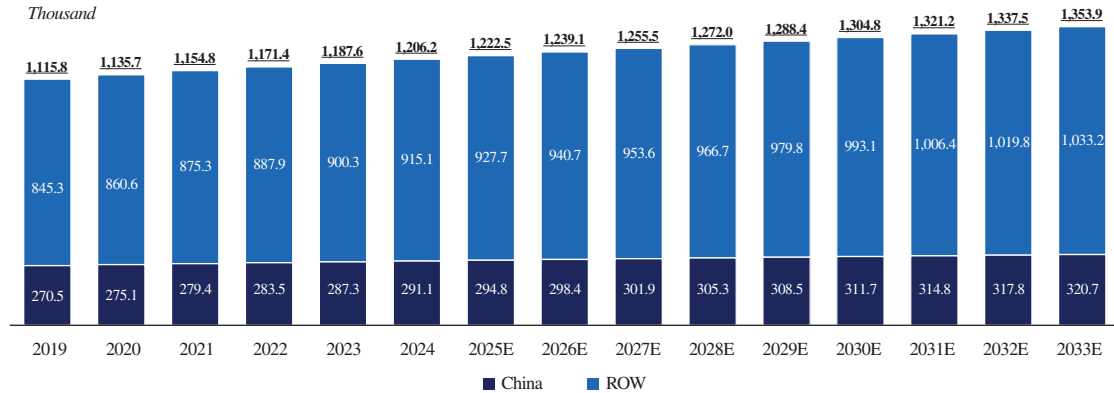
PBC predominantly affects middle-aged and older female patients and is diagnosed in patients with high serum titres of antimitochondrial antibodies, elevated bile enzymes, and distinctive liver pathology. A combination of genetic and environmental factors likely causes PBC, although its precise pathogenesis remains unclear. The onset of PBC is often insidious, with some patients presenting with cirrhosis at the time of diagnosis. Due to improved understanding of the disease in recent years that has led to earlier detection, there are more patients being diagnosed at the stage of small bile duct inflammation, where treatment response tends to be more favorable.

The global prevalence of PBC increased from 1,115.8 thousand in 2019 to 1,206.2 thousand in 2024, and is expected to further increase to 1,353.9 thousand in 2033. In China, the prevalence of PBC increased from 270.5 thousand in 2019 to 291.1 thousand in 2024, and is expected to further increase to 320.7 thousand in 2033. The diagram below sets forth the historical and projected prevalence of PBC from 2019 to 2033.

INDUSTRY OVERVIEW

Global and China Prevalence of PBC, 2019-2033E

CAGR	China	Global
2019-2024	1.5%	1.6%
2024-2033E	1.1%	1.3%

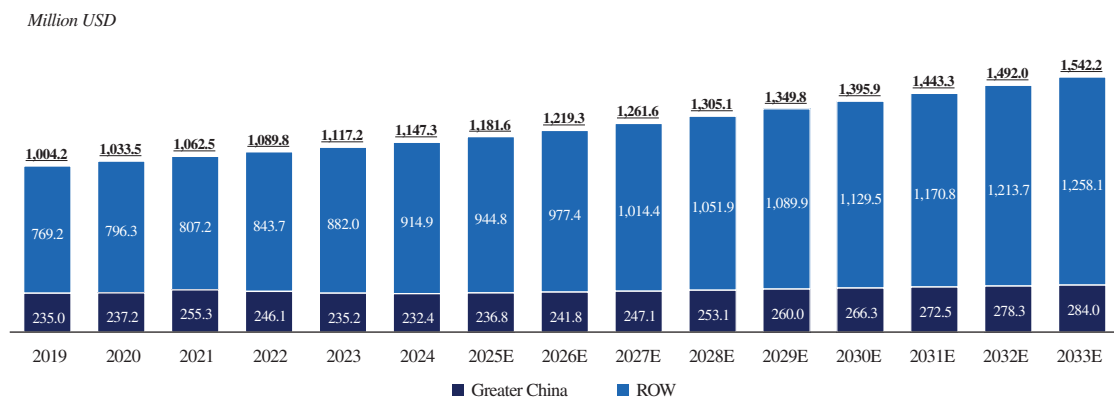


Source: Research review, Frost & Sullivan Analysis

The global PBC drug market grew from US\$1,004 million in 2019 to US\$1,147.3 million in 2024, and is expected to further grow to US\$1,542.2 million in 2033. Greater China’s PBC drug market grew from US\$235.0 million in 2019 to US\$232.4 million in 2024, and is expected to further grow to US\$284.0 million in 2033. The diagram below sets forth the historical and projected global and Greater China’s market sizes of PBC drugs from 2019 to 2033.

Global and Greater China PBC Drug Market, 2019-2032E

CAGR	Greater China	Global
2019-2024	-0.2%	2.7%
2024-2033E	2.3%	3.3%



Source: Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Current Treatment Options and Limitations

As of the Latest Practicable Date, there were four drugs approved by the FDA for the treatment of PBC. Current recommended treatments include first-line treatment of ursodeoxycholic acid (“UDCA”) and second-line treatment of obeticholic acid (“OCA”). Similarly in China, UDCA is generally the first-line treatment option to PBC. However, approximately 40% of patients with PBC exhibit incomplete response to UDCA, leaving considerable medical need for novel treatments of PBC.

When a patient is diagnosed with PBC, UDCA is used as a first-line medication. Currently, for the treatment of PBC, both in China and globally, the recommended dosage is 13-15mg/kg/day, and it usually does not require discontinuation of medication. According to the median bid price of UDCA in China in 2025, the annual cost of medication for Chinese patients is approximately RMB3,558.8 (calculated based on an average weight of 60kg for Chinese patients). The annual cost of medication for U.S. patients is approximately \$80,088 (calculated based on an average weight of 80kg).

For patients with poor biochemical response to UDCA, their long-term prognosis is poor and survival rate is low. In that case, second line treatment may be considered, such as UDCA in combination with OCA or fibrate drugs (e.g., bezafibrate and fenofibrate). However, OCA and fibrate drugs (including bezafibrate and fenofibrate) have not been approved in China for the treatment of PBC. The recommended dosage for OCA is 5-10mg/day, and the annual cost for U.S. patients using this medication is approximately \$129,730.

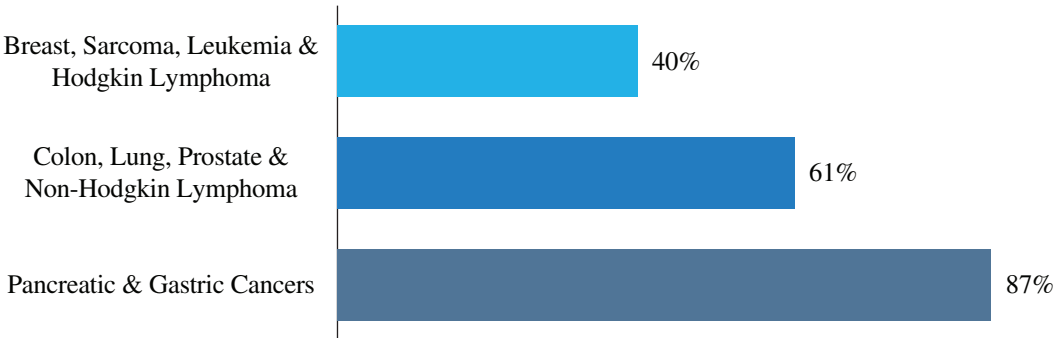
If PBC only progresses to decompensated cirrhosis, liver transplantation may be considered.

OVERVIEW OF CACHEXIA DRUG MARKET

Overview of Cachexia

Cachexia, including cancer cachexia, is a common and severe condition characterized by appetite loss, accelerated breakdown of muscle and fat tissue, subsequent weight loss and decreased physical function. These symptoms not only impact patient tolerability to treatment but also significantly deteriorate their quality of life. Overall, cachexia is responsible for 20% of all cancer-related deaths and is an indicator of poor prognosis.

Prevalence of Cachexia in Different Cancer Types



INDUSTRY OVERVIEW

Competitive Landscape of Cachexia Drugs

As of the Latest Practicable Date, there was only one approved drug specifically for the treatment of cancer cachexia globally, being Adlumiz, a ghrelin receptor agonist co-developed by Helsinn Group and Ono Pharmaceutical Co., Ltd. which was approved by the Pharmaceuticals and Devices Agency of Japan in 2021 for the treatment of cancer cachexia in malignant tumors of NSCLC, gastric cancer, pancreatic cancer or CRC. There were 10 cachexia drug candidates under clinical development globally as of the Latest Practicable Date. The following table sets forth the clinical-stage cachexia drug candidates globally.

Pipeline of Clinical-stage Cachexia Drug Candidates Globally

Drug	Target	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country	First posted date
Ponsegromab	GDF15	cancer, cachexia, and elevated GDF 15	Phase 2	Pfizer	Mono	NA	subcutaneous	100/200/400mg every 4 weeks for 12 weeks	100mg group: body weight +2.02%, TRAE 7.7% 200mg group: body weight +3.48%, TRAE 8.9% 400mg group: body weight +5.61%, FAACT-ACS (12-week) 4.11, FAACT-SIASS (12-week) 2.30	US, Europe, China, Japan	2022-09-19
		cachexia and metastatic PDAC	Phase 2b/3		Combo with standard of care chemotherapy	1L		200/400mg Q4W	–		
Anamorelin Hydrochloride	GHSR	Cancer Induced-Weight Loss and Anorexia in Advanced PC	Phase 2	Helsinn	Combo with standard of care chemotherapy	1L	oral	100mg QD, 24-week cycle	–	US	2021-04-14
		Cachexia/anorexia in NSCLC	Phase 1		Combo with standard of care chemotherapy	1L		100mg QD, 24-week cycle	body weight change from baseline: 1.938kg (Placebo: 0.594kg)		
TCMCB07	MC4R, MC3R	Cachexia of CRC	Phase 2	Endevica Bio	Combo with standard of care chemotherapy	1L	subcutaneous	12.5/25/50mg QD, 28-day cycle	–	US, Canada	2025-04-22
Visugromab	GDF15	Cachexia	Phase 2/3	CatalYm	Mono	NA	intravenous	NA	–	NA	2025-08-08
NGM120	GFRAL	Colorectal Cancer with Cachexia	Phase 2	NGM Biopharmaceuticals	Mono	NA	subcutaneous	Q4W/Q8W	–	US	2025-06-24
STC008	GHSR	Cachexia of NSCLC, C, PC, CRC and other advanced solid tumors	Phase 1a	Sintanovo	Mono	NA	subcutaneous	10/30/100/300/500/750µg or 1/1.25/1.5mg, single dose	–	China	2024-09-29
JMT203	GFRAL	Cachexia	Phase 1	JMT-Bio	Mono	NA	subcutaneous	5-300mg, Q3W	–	China	2024-01-04
AV-380	GDF15	Metastatic Cancer Patients With Cachexia	Phase 1	AVEO Pharmaceuticals	Combo with standard of care chemotherapy	1L	intravenous	7 doses in total, the 2nd dose will be 28 days after the 1st, the remaining 5 doses will be given every 2 weeks	–	US	2023-05-19
DS010	–	Cachexia	Phase 1	Dartshio	Mono	NA	intravenous	15-400mg, single dose	–	China	2025-04-28
GFS202A	GDF15, IL6	Cachexia	Phase 1	GenFleet	Mono	NA	intravenous	240mg, Q3W, 12 weeks	–	China	2025-03-19

Note: Ongoing Clinical trials with first posted date up to the Latest Practicable Date, initiated by companies are included.

Source: CDE, Clinical Trials, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Current Treatment Options and Limitations

As of the Latest Practicable Date, progesterone and glucocorticoids were the major drugs used to alleviate the symptoms of cachexia in clinical practice. However, such treatment options primarily increase fat instead of muscle mass of patients. Nutritional interventions may also improve quality of life for patients suffering from cachexia, although in the refractory stage of cachexia, nutritional interventions may not fully reverse weight loss and metabolic abnormalities. Given the limited existing treatment options, there are considerable unmet medical needs for effective treatments for cachexia, such as targeted therapies for important cytokines including GDF15 and IL-6. In particular, GDF15 has been recently recognized as a key driver target in various diseases, including cachexia, and reported positive data from clinical study of ponesimab, a monoclonal antibody directed against GDF15 developed by Pfizer, underscored its therapeutic potential.

Entry Barriers and Future Trends of Cachexia Drug Market

There are considerable entry barriers for the development of cachexia drugs:

- *Complex Disease Mechanisms.* The pathogenesis of cachexia is complex and involves multiple factors, including tumor burden, chronic inflammation, and other contributing elements. This complexity makes drug development challenging and necessitates targeted drug design for specific underlying causes. Due to the complexity of cachexia, effective methods for reversing it remain unclear, and therapeutic options are still in the exploratory stage.
- *Lack of Clinical Evidence.* The first drug globally for cancer cachexia, Adlumiz, was approved in Japan. However, its effects on physical functioning, quality of life, and overall survival of patients with cancer have not been well established. Other drugs for the treatment of cachexia remain in the early stages of clinical research, and there is limited clinical evidence to guide the further development of cachexia drugs.
- *Difficulty to Conduct Clinical Trials.* Clinical trials for cachexia drugs demand considerable time and resources due to the relatively complex patient population and their poor health conditions. Additionally, these trials face challenges in both design and execution, with a critical need to ensure the safety and efficacy of such treatments.

According to Frost & Sullivan, future cachexia drug market may observe the following trends:

- *Increasing Clinical Needs.* The global cancer incidence is projected to continue its upward trend, having reached 21.3 million cases in 2024 and is estimated to further reach 26.0 million by 2033. This trend is likely to result in a higher number of patients affected by cachexia, driving an anticipated increase in demand for effective cachexia treatments in the coming years.

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- *Advancements in Targeted Drug Development.* Currently, the primary therapeutic options for treating cachexia are appetite stimulants and various symptom-management medications, while numerous targeted therapies are actively being researched or developed preclinically. Pharmaceutical companies are investing in innovative drug candidates that can intervene at different stages of cachexia progression, and R&D investment in targeted therapies for cachexia is expected to continue to grow.
- *Personalized and Comprehensive Treatment.* Given the complex causes of cachexia, personalized treatment strategies are expected to evolve and tailored for different patient populations. A comprehensive approach, involving multi-pathway and multi-target combination drug therapy alongside multidisciplinary collaboration, offers a promising strategy to enhance treatment efficacy. This approach integrates medications, dietary and nutritional support, psychological care, and physical exercise for a holistic intervention.
- *Increasing Awareness.* In the future, ongoing research into the causes of cachexia, along with increased awareness among healthcare professionals and patients, is expected to lead to improved diagnosis and more proactive treatment strategies of cachexia.

OVERVIEW OF CDK9-TARGETED AND TGF- β R1-TARGETED DRUG MARKET

Overview of CDK9-targeted Drug

Cyclin-dependent kinases (“CDKs”) are a group of serine/threonine kinases that regulate major steps throughout the cell cycle. As a transcriptional regulator, CDK9 plays crucial roles in tumorigenesis and tumor growth. CDK9, when associated with cyclin T, forms the positive transcription elongation factor b (“P-TEFb”) complex. This complex regulates gene transcription elongation and mRNA maturation of super enhancer-regulated genes, including the myelocytomatosis oncogene (“MYC”) (a proto-oncogene involved in cell growth and cell-cycle progression) and myeloid cell leukemia 1 (“MCL1”) (an anti-apoptosis gene). Together, these genes modulate proliferation and survival of cancer cells. Notably, deregulation in the CDK9-related pathway has been reported in several human malignancies, such as lymphomas, leukemia, neuroblastoma, primary neuroectodermal tumors, rhabdomyosarcoma, and prostate cancer. These findings suggest that CDK9 could be a promising therapeutic target for cancer therapy. CDK9 inhibitors have emerged as promising therapeutic agents for various hematologic cancers due to their ability to reduce the levels of short-lived oncogenic proteins, induce apoptosis, and inhibit tumor growth.

INDUSTRY OVERVIEW

Major Indication of CDK9-targeted Drug

AML

Acute myeloid leukemia (“**AML**”) and diffuse large B-cell lymphoma (“**DLBCL**”) are two hematologic cancers that CDK9 inhibitors could potentially target. AML is characterized by a rapid increase in the number of immature blood cells, whose genetic damage impairs their abilities to function as normal blood cells. AML typically originates in the blood and bone marrow — the spongy, red tissue within large bones — and can sometimes spread to other parts of the body. It progresses rapidly and aggressively, necessitating immediate treatment. The global incidence of AML increased from 86.1 thousand in 2019 to 97.1 thousand in 2024, and is expected to further increase to 112.9 thousand in 2033. In China, the incidence of AML increased from 29.4 thousand in 2019 to 31.5 thousand in 2024, and is expected to further increase to 34.3 thousand in 2033.

Chemotherapy, particularly cytarabine-based therapies, remains the primary treatment for AML. However, intensive chemotherapy may not be suitable for patients in poor health condition and advanced age. Even with chemotherapy being an available treatment, over 50% of patients eventually experience disease progression due to relapsed/refractory AML. A potential treatment option arises recently as CDK9 inhibitors have shown promise in preclinical models, especially in AML, where they have demonstrated the ability to reduce key oncogenic proteins and improve survival in both animal models and clinical trials.

Competitive Landscape of CDK9-targeted Drugs

As of the Latest Practicable Date, there was no approved CDK9 inhibitor globally, and there were 8 CDK9 inhibitor candidates under clinical development globally as of Latest Practicable Date. The following table sets forth the clinical-stage CDK9 inhibitor candidates globally.

INDUSTRY OVERVIEW

Pipeline of Clinical-stage CDK9 Inhibitor Drug Candidates Globally

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
QHRD107	R/R AML	Phase 2	Qianhong Biopharma	Combo with venetoclax and azacitidine	3L+	oral	40/60/80mg BID + venetoclax	ORR 41.3%	China	2023-8-18
							QD according to a ramp-up schedule to a maximum dose of 400 mg, 28-day cycle	mOS 12.8 months, ORR 60.9%		
GFH009/ SLS009	R/R DLBCL			Combo with zanubrutinib	3L+		GFH009 60/75/100mg QW + Zanubrutinib 160mg BID, 28-day cycle	All pts: ORR 67%, AE (grade ≥3) 55.6%; non-GCB DLBCL: DCR 83%	China	2024-2-18
							GFH009 QW, 21-day cycle	–		
	R/R hematologic malignancies	Phase 1/2	GenFleet/ SELLAS	Mono and combo with venetoclax and azacitidine	3L+ 2L	infusion	45/60mg QW or 30mg BIW + venetoclax + azacitidine	ORR: 44% (AML-MR), 50% (AML MR with Myelomonocytic/Myelo monoblastic (M4/M5) Subtype) mOS: 8.9 months (AML-MR), 8.8 months (all r/r to venetoclax-based regimens pts)	US, China	2020-10-19
SYHX 1903	R/R hematologic malignancies	Phase 1/2	CSPC	Mono	NA	oral	SYHX 1903 QD	–	–	2021-09-24

INDUSTRY OVERVIEW

Drug	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
AZD4573	R/R haematological malignancies	Phase 1/2	AstraZeneca	Combo with anti-cancer agents	2L+	infusion	AZD4573 6/9/12mg QW ± acalabrutinib 100mg BID	ORR 50%, CR 25%	Australia US, Europe	2020-11-16
PRT2527	R/R hematologic malignancies	Phase 1	Prelude Therapeutics	Mono and combo with zanubrutinib or venetoclax	1L+	infusion	PRT2527 9/15/18mg/m2 QW ± Zanubrutinib QD/BID	ORR: 17.4% (mono), 38.5% (combo with zanubrutinib)	US Canada, Europe	2022-12-27
Voruciclib	R/R B cell malignancies or AML	Phase 1	MEI Pharma	Mono or Combo with venetoclax	3L+	oral	Voruciclib 7 dose levels between 50 mg and 300 mg on days 1-14 of 28-day cycles, Venetoclax was administered at 200 mg on days 1-21 and 400 mg on days 22-28	death 17.1%	US	2018-06-06
TG02	R/R HGG	Phase 1	CothraBio	Mono	2L+	oral	100/150/200/250mg BIW	mPFS 1.77 months, TRAE (grade 3/4) 50%	China	2019-1-18
YK-2168	Histologically or cytologically confirmed advanced or unresectable solid tumors, and R/R NHL	Phase 1	YOKO Pharmaceutical	Mono	1L+	infusion	5mg QW ramp-up to a maximum dose of 30 mg, 21-day cycle	-	China	2021-11-17

Note: Ongoing Clinical trials with first posted date up to Latest Practicable Date, initiated by companies are included.

Source: CDE, Clinical Trials, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Overview of TGF- β R1-targeted Drug

TGF- β is a multifunctional cytokine that binds and activates TGF- β receptor II (“TGF- β R2”) on the cell membrane. In turn, TGF- β R2 phosphorylates and activates TGF- β R1, which subsequently phosphorylates and activates the downstream Smad binding element, which directly regulates gene expression and facilitates various biological functions. In cancer cells, the activation of the TGF- β signaling pathway promotes epithelial-to-mesenchymal transition and metastasis, inhibits antitumor immune responses, and enhances angiogenesis and tissue fibrosis within the tumor microenvironment, thereby driving tumor progression. Furthermore, elevated expression of TGF- β signaling pathway genes in blood and tumors has been observed in patients with various solid tumors, including hepatocellular carcinoma, glioma, CRC, lung cancer, pancreatic cancer, and urothelial cancer. Higher levels of TGF- β expression are also positively correlated with poorer differentiation, advanced tumor stages, and worse prognosis.

There are several possible mechanisms to inhibit the TGF- β R1 signaling pathway, including small molecule receptor kinase inhibitors, antibodies that bind to TGF- β R1, ligand traps that bind to TGF- β R1, and latent TGF- β R1. The inhibition of the TGF- β signaling pathway could potentially slow the tumor progression.

Competitive Landscape of TGF- β R1-targeted Drug

As of the Latest Practicable Date, there was no approved TGF- β R1 inhibitor globally, and there were eight TGF- β R1 inhibitor candidates under clinical development globally as of Latest Practicable Date. The following table sets forth the clinical-stage TGF- β R1 inhibitor candidates globally.

INDUSTRY OVERVIEW

Pipeline of Clinical-stage TGF-βR1 Inhibitor Drug Candidates Globally

Drug names	Indication	Latest status	Company	Therapeutic strategy	Treatment Line	Route of Administration	Treatment Schedules	Efficacy & Safety	Country/region	First posted date
AGMB-129	Fibrotenotic Crohn's disease	Phase 2	Agomab Therapeutics	Mono	Not Applicable	oral	200mg twice-daily or 100mg QD	–	US, Italy, Canada, etc.	2023-05-06
AGMB-447	Idiopathic pulmonary fibrosis	Phase 1		Mono	Not Applicable	inhaled	a single dose of AGMB-447, multiple doses of AGMB-447 over 7 days or multiple doses of AGMB-447 over 14 days	–	United Kingdom	2023-12-26
	Unresectable, locally advanced stage III NSCLC	Phase 2	Genfleet Therapeutics	Combo with toripalimab and concurrent chemoradiotherapy	1L	oral	80mg QD 7days-on/7day-off + Toripalimab 240mg Q3W + chemotherapy	–	China	2022-05-23
GFH018	Advanced solid tumor	Phase 1/2		Combo with toripalimab	2L+		GFH018 40/80mg BID for 14day-on/14day-off + Toripalimab 3mg/kg Q2W	All r/m NPC pts: ORR 36.1%, mPFS 2.0 months, DCR 43.5% r/m NPC pts without prior treatment of ICIs: ORR 40%, mPFS 9.0 months, DCR 60%	China, Australia	2021-06-04
	Advanced solid tumor	Phase 1		Mono	NA		5/10/20/30/40/50/65/85 mg BID, 14day-on/14day-off, 28-day cycle or 85mg BID, 7day-on/7day-off	DCR 25.0%, TRAE 86.0%, TRAE (grade ≥3) 6%	China	2021-09-21
LY2157299	Metastatic castration-resistant PC	Phase 2	Eli Lilly	Combo with enzalutamide	NA	oral	LY2157299 150mg BID on 1-14 days of each cycle + Enzalutamide 160mg QD on 1-28 days of each cycle	–	US	2015-05-22
	advanced liver cancer			mono or combo with Sorafenib	NA		150mg BID for 14 days	CR 32%	China	2015-07-10
	Metastatic castration-resistant PC			Combo with enzalutamide	1L		150mg BID for 14 days	ORR 5%, SAE 30%	US	2015-05-22
LY3200882	Solid Tumor	Phase 1	MedPacto	Mono and combo with LY3300054, Gemcitabine + nab-Paclitaxel or Cisplatin + Radiation	NA	oral	50 mg BID 2-weeks-on/2-weeks-off and 35 mg BID 3-weeks-on/1-week-off	DCR 75%, TEAE 93.5%, TEAE (LY3200882-related) 39.6%	US, Italy, Canada, etc.	2016-10-18
Vactosertib	Adolescents and adults with recurrent, refractory or progressive osteosarcoma	Phase 1/2		Mono	2L+		150/200/250mg BID, 5day-on/2day-off, 4-week cycle	–	US, Korea	2022-10-20
SH3051	Advanced malignant solid tumor	Phase 1		Mono	1L+		20/40/60/80/100mg BID, 28-day cycle	–	China	2020-03-27
YL-13027	Metastatic PC	Phase 1b/2	YingLi Pharmaceutical	combo with chemotherapy, with or without HY-0102	NA	oral	YL-13027 180mg BID + Nab-paclitaxel 125mg/m ² , D1, D8, D15 Q4W + Gemcitabine 1000mg/m ² , D1, D8, D15 Q4W ± HY-0102 10mg.D1, D15 Q4W	–	China	2024-10-29
	Advanced solid tumors	Phase 1/2		Combo with sintilimab	1L+		YL-13027 240/360mg BID + sintilimab 200mg Q3W, 21-day cycle	–	China	2022-07-14
	Solid tumors	Phase 1		Mono	1L+		start with initial dose 60mg BID, 28-day cycle	TEAE (grade ≥3): gamma-glutamyltransferase increased (7.7%), haemoglobin decreased (0%), blood alkaline phosphatase increased (7.7%), aspartate aminotransferase increased (0%) and blood phosphorus decreased (0%)	China	2019-06-14

Note: Ongoing Clinical trials with first posted date up to Latest Practicable Date, initiated by companies are included.

Source: CDE, Clinical Trials, Frost & Sullivan Analysis

The following table represents toripalimab approval timeline in China.

Approval Time	Indication
2018/12	Unresectable or metastatic melanoma that has failed previous systemic therapy
2021/02	Recurrent/metastatic nasopharyngeal carcinoma that has failed second-line or above systemic treatment in the past

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Approval Time	Indication
2021/04	Failure of platinum-based chemotherapy, includes locally advanced or metastatic urothelial carcinoma that progresses within 12 months of neoadjuvant or adjuvant chemotherapy
2021/11	First-line treatment for recurrent/metastatic nasopharyngeal carcinoma that has not received systemic therapy before
2022/05	In combination with platinum chemotherapy as first-line treatment for locally advanced or metastatic esophageal squamous cell
2022/09	In combination with pemetrexed and platinum for first-line treatment of EGFR gene mutation negative and ALK negative, unresectable locally advanced or metastatic non squamous NSCLC
2024/01	In combination with chemotherapy perioperative and monotherapy adjuvant therapy for resectable stage III NSCLC patients
2024/04	In combination with axitinib for first-line treatment of intermediate to high-risk unresectable or metastatic renal cell carcinoma patients
2024/06	In combination with etoposide and platinum for first-line treatment of extensive stage small cell lung cancer (ES-SCLC)
2024/06	In combination with paclitaxel for injection (albumin binding type) for first-line treatment of recurrent or metastatic triple negative breast cancer (TNBC) with fully verified PD-L1 positive (CPS $\geq$ 1) detection
2025/03	In combination with bevacizumab for first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) patients
2024/04	First-line treatment for unresectable or metastatic melanoma

Source: Frost & Sullivan analysis.

In China, toripalimab is priced at RMB812.88 for a 2 mL vial containing 80 mg.

INDUSTRY OVERVIEW

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the major markets for which our drug candidates are positioned. Frost & Sullivan is an independent global market research and consulting company founded in 1961 and is based in the United States. We have agreed to pay Frost & Sullivan a total fee of approximately RMB0.7 million for the preparation of the Frost & Sullivan Report, and we believe that such fee is consistent with the market rate. The payment of such amount was not contingent upon our successful [REDACTED] or on the content of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED].

The market projections in the Frost & Sullivan Report were based on the following key assumptions: (i) the overall social, economic and political environment globally and in China is expected to remain stable during the forecast period; (ii) the economic and industrial development globally and in China is likely to maintain a steady growth trend over the next decade; (iii) related key industry drivers are likely to continue driving the growth of the market during the forecast period; and (iv) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally. The reliability of the Frost & Sullivan Report may be affected by the accuracy of the foregoing key assumptions., including those used to make future projections, are factual, correct and not misleading.

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OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

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

Pharmaceutical Regulatory System

Principal Regulatory Authorities

The major regulatory authorities of pharmaceutical industry in the PRC include the National Medical Products Administration (the “**NMPA**”, formerly known as the China Food and Drug Administration (“**CFDA**”)), the National Health Commission (“**NHC**”, formerly known as the National Health and Family Planning Commission), and the National Healthcare Security Administration.

The NMPA carries on responsibilities for pharmaceutical supervision of CFDA, its predecessor, as the principal pharmaceutical regulatory authority in charge of the pharmaceutical registration and supervision, including non-clinical research, clinical trial, marketing approval, production and circulation.

The NHC is the chief healthcare regulator of the PRC, which is primarily responsible for drafting national healthcare policies, regulating public health, medical services and health contingency system, coordinating the implementation of healthcare reform and overseeing the operation of medical institutions and practice of medical personnel.

The National Healthcare Security Administration (a new authority established in May, 2018 in accordance with the Institutional Reform Program of the State Council) is responsible for drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; administering healthcare fund; formulating a uniform medical insurance catalogue and payment standards on drugs, medical consumables and healthcare services; formulating and administering the bidding and tendering policies for drugs and medical consumables.

Laws and Regulations Relating to Drugs

Drug Administration Laws and Regulations

The PRC Drug Administration Law (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) promulgated by the Standing Committee of the National People’s Congress (the “**NPCSC**”) on September 20, 1984, and amended on February 28, 2001, December 28, 2013, April 24, 2015, and August 26, 2019, as well as the Implementing Rules for the PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) (the “**Implementing Rules for the Drug Administration Law**”) issued by the State Council on August 4, 2002, and amended on February 6, 2016 and March 2, 2019 have together laid down the legal framework for the administration of drugs, including the research, development,

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manufacturing and business operation for new drugs, and administer the pharmaceutical manufacturing enterprises, pharmaceutical operating enterprises, and medicinal preparations of medical institutions, along with the development, research, production, distribution, packaging, pricing and advertisements of drugs.

Non-Clinical Research and Animal Testing

The SAMR requires preclinical data to support registration applications for imported and domestic drugs. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), issued by the SAMR on January 22, 2020, and became effective on July 1, 2020, non-clinical drug safety evaluation studies shall comply with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) (the “GLP”). The latest GLP has been implemented by the CFDA since September 1, 2017, to improve the quality of non-clinical research.

Pursuant to the Measures for Administration of Certification of the 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》) promulgated on January 19, 2023 and implemented since July 1, 2023 by the NMPA, applying for the GLP certification is required for institutions that intend to conduct non-clinical safety evaluation studies in the PRC used for drug registration applications. The NMPA is in charge of the administration of the GLP certification nationwide, while the provincial medical products administrative authorities are responsible for the daily supervision and administration of non-clinical safety evaluation studies institutions within the administrative region. The GLP Certificate will be issued by the NMPA with its approval if the relevant requirements for the GLP are satisfied by the applicant. The valid period for the GLP certificate lasts for 5 years. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

Pursuant to the Administrative Regulations on Experimental Animals (《實驗動物管理條例》) issued by the State Science and Technology Commission on November 14, 1988, and latest amended on March 1, 2017 by the State Council, the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly issued by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) issued by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and implemented since January 1, 2002, using and breeding experimental animals shall be subject to certain rules, and performing experiments on animals requires a Certificate for Use of Experimental Animals. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

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Approval of Clinical Trials

Pursuant to the Administrative Measures for Drug Registration, an applicant that applies for a drug clinical trial after completion of the pharmaceutical, pharmacological and toxicological research, etc., which support the drug clinical trial, shall submit relevant research materials according to the requirements for application materials. The application materials shall be accepted if they are deemed acceptable upon formal examination. The Center for Drug Evaluation of the National Medical Products Administration (the “CDE”) shall organize pharmaceutical, medical and other technicians to review the accepted application for the drug clinical trial. A decision on approval or non-approval of the application for clinical trials of drugs shall be made within 60 days from acceptance of application, and the applicant shall be notified of the examination and approval outcome through the CDE website; where the applicant is not notified within the stipulated period, the application shall be deemed approved, and the applicant may conduct clinical trial of drugs in accordance with the submitted scheme.

According to the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) issued by the CFDA on September 6, 2013, all clinical trials approved by the NMPA and conducted in the PRC shall complete clinical trial registration and publish trial information through the Drug Clinical Trial Public Information Platform. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of the drug clinical trial to obtain an exclusive trial registration number and complete the subsequent information registration before the first participant is enrolled in the trial.

Phases of Clinical Trials and Communication with the CDE

Pursuant to the Drug Administration Law (《藥品管理法》), drug clinical trials shall be carried out in a clinical trial institution with corresponding conditions. The conditions that clinical trial institution should satisfy shall mainly comply with the relevant requirements of Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The NMPA is responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

According to the Administrative Measures for Drug Registration, based on the drug’s characteristics and the purpose of research, clinical trials of drugs consist of Phase I, II, III and IV clinical trials, as well as the bioequivalence trials, contents of which include clinical pharmacology research, exploratory clinical trials, confirmatory clinical trials and post-marketing research. Clinical trials shall be conducted in accordance with the provisions of the PRC GCP, including the preparation for clinical trials, clinical trial protocols, responsibilities of sponsors and investigators, and protection of subjects, etc.

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Pursuant to the Administrative Measures for Communication on Drug Development and Technical Reviews (《藥物研發與技術審評溝通交流管理辦法》) issued by the CDE on December 10, 2020, during the research and development, and application for registration stages of innovative drugs, the applicant may propose communication sessions with the CDE. The forms of communication can be face-to-face conference, video conference, telephone conference or written replies. The communication sessions are classified into three types. Type I sessions are held to address the material safety issues encountered in the clinical trials of drugs and the significant technical issues in the research and development process of breakthrough therapeutic drugs. Type II sessions are held during the key research and development stages of drugs, mainly including the sessions held prior to the application of IND, the sessions held upon completion of Phase II clinical trials and prior to commencement of Phase III clinical trials of new drugs, the sessions held prior to application for marketing approvals of new drugs, and the risk evaluation and control sessions. Type III sessions are those sessions not falling into the categories of Type I or II sessions.

International Multi-Center Clinical Trial

Pursuant to the International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》) issued by the CFDA on January 30, 2015 and effective from March 1, 2015, applicants may simultaneously conduct clinical trials in different centers of multiple regions using the same clinical trial protocol, or conduct regional clinical trials simultaneously in multiple centers in different countries within a certain region using the same protocol. Where the data derived from the international multi-center clinical trials are to be used for application for a drug registration in the PRC, it shall satisfy the requirements for clinical trials set forth in the Administrative Measures for Drug Registration. Where the applicant plans to conduct the international multi-center clinical trials in the PRC, it shall comply with the Drug Administration Law, the Implementing Rules for the Drug Administration Law and the Administrative Measures for Drug Registration and other relevant laws and regulations, to carry out the PRC GCP with reference to internationally recognized principles such as the ICH-GCP, and to meet the requirements of the laws and regulations of the relevant countries at the same time.

The NMPA issued the Technical Guiding Principles for the Acceptance of 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》) on July 6, 2018, to guide work related to the acceptance of overseas clinical trial data as clinical evaluation reference by the applicant applying for the registration of drugs in the PRC.

Registration and Application of New Drugs

According to the Administrative Measures for Drug Registration, the drug registration administration shall be categorized into traditional Chinese drugs, chemical drugs and biological products; among them, the registration of chemical drugs shall be categorized into innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

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Pursuant to the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by the CFDA on March 4, 2016, new registration of chemical drugs are divided into 5 categories: (i) Category 1: innovative drugs that have not been marketed in the PRC or abroad which shall contain new compounds with clear structure and pharmacological effects and clinical value; (ii) Category 2: improved new drugs that have not been marketed in the PRC or abroad with optimization in structure, dosage form, prescription technology, route of drug administration and indications on the basis of known active ingredients as well as obvious clinical advantages; (iii) Category 3: drugs imitated by domestic applicants which are marketed overseas while originator’s drugs are not marketed in the PRC. Such drugs should possess quality and efficacy in line with that of the originator’s drugs (i.e. the first drugs approved to be marketed in the PRC or overseas with complete and sufficient safety and efficacy data to serve as the basis for its launch); (iv) Category 4: drugs imitated by domestic applicants while originator’s drugs have been marketed in the PRC. The quality and efficacy of such drugs should be consistent with that of the originator’s drugs; and (v) Category 5: drugs which have been marketed abroad with the applications to be marketed in the PRC. Among them, the reporting procedure for Category 1 and 2 shall comply with those for new drugs and for Category 3 and 4 it shall be in accordance with those for generic drugs, while Category 5 shall be reported pursuant to the procedures for imported drugs.

According to the Registration Classification of Chemical Drugs and the Reporting Information Requirements (《化學藥品註冊分類及申報資料要求》) issued by the NMPA on June 29, 2020 with implementation of the Registration Classification of Chemical Drugs from July 1, 2020, the registration of chemical drugs is categorized into innovative drugs, improved new drugs, generic drugs, and chemical drugs marketed abroad only. The Registration Classification of Chemical Drugs and the Reporting Information Requirements reaffirmed the classification principles for chemical drugs set forth by the Reform Plan for Registration Classification of Chemical Drugs (《化學藥品註冊分類改革工作方案》) and made further adjustments to the chemical drugs subclassifications of Category 2 and 5 among which as well as elaboration regarding the quality and efficacy requirements for generic drugs in Category 3 and 4; in addition, it is also proposed the registration requirements and reporting information requirements for various types of chemical drugs.

According to the Administrative Measures for Drug Registration, the applicant may submit an application for permission of the drugs registration for marketing (“**New Drug Application**”) upon determining quality standards after completion of researches on pharmacy, pharmacology, toxicology, and clinical trials of drugs that support the registration of drugs for marketing and completing the commercial-scale production process verification and preparations for receiving on-site inspections. The New Drug Application shall be evaluated by the NMPA in accordance with applicable laws and regulations.

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Accelerated Approval for Clinical Trial and New Drug Registration

The Opinions of the State Council on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》) issued by the State Council on August 9, 2015, established a reform framework of the evaluation and approval system for drugs and medical devices, and specified the tasks of enhancing the standards of approval for, among others, drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs.

The Announcement on 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》) issued by the CFDA on November 11, 2015, provided fast-track clinical trial approvals and drug registration pathways for the following new drug applications: (i) registration of innovative new drugs treating HIV, malignant tumors (cancers), severe infectious diseases and rare diseases; (ii) registration of pediatric drugs; (iii) registration of geriatric drugs and drugs treating diseases specially or commonly contracted by the senior population; (iv) registration of drugs listed in national major science and technology projects or national key research and development plan; (v) registration of innovative drugs using advanced technology or innovative treatment methods, or having distinctive clinical benefits; (vi) registration of foreign innovative drugs to be manufactured locally in China; (vii) concurrent applications for new drug clinical trials which are already approved in the United States or the European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (viii) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

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 jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging 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》), aiming to simplify the clinical trial procedures and shorten the time. For new drugs and medical devices urgently needed in clinical practice and drugs and medical devices used for the treatment of rare diseases, the evaluation and approval procedures for marketing shall be accelerated.

Furthermore, according to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC on May 17, 2018, the drug approval process shall be further streamlined and expedited.

Pursuant to the provisions of the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》) issued by the NMPA on July 7, 2020, during the clinical drug trials, the applicant is allowed to apply for the breakthrough therapeutic drug procedure during Phase I and Phase II clinical trials and normally no later than the commencement of Phase III clinical trials for the innovative or

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improved drugs etc. which are used for the prevention and treatment of diseases that seriously endanger life or seriously affect quality of life and there is no effective means of prevention and treatment or there is sufficient evidence to show a significant clinical advantage over existing treatment approach.

The Administrative Measures for Drug Registration has integrated the previous reform in respect of the accelerated approval for clinical trial and drug marketing registration and introduced four procedures for expedited marketing registration of drugs, which are procedures for breakthrough therapeutic drugs, procedures for conditional approval, procedures for prioritized review and approval, and procedures for special examination and approval:

Procedures for breakthrough therapeutic drugs: during the drug clinical trials, for an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or there is adequate evidence to prove that the said innovative drug or improved new drug has obvious clinical advantages over existing treatment approach, the applicant may request for application of procedures for breakthrough therapeutic drugs.

Procedures for conditional approval: during the drug clinical trials, for drugs which fall under the following circumstances, an application for conditional approval of marketing registration may be submitted (i) for drugs for treatment of life-threatening illnesses for which there is no effective treatment approach, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; (ii) for drugs urgently needed for public health, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; and (iii) for other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed, its benefits outweigh the risks according to the evaluation.

Procedures for prioritized review and approval: at the time of the drug marketing registration, drugs have obvious clinical value may apply for application of procedures for prioritized review and approval, including (i) clinically and urgently needed but insufficient drug, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drugs included in the procedures for breakthrough therapeutic drug; (v) drugs which comply with conditional approval criteria; and (vi) other circumstances of prioritized review promulgated by the NMPA.

Procedures for special examination and approval: at the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for urgently needed drug required for the prevention and treatment during the public health emergency.

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Marketing Authorization Holder System

Pursuant to Drug Administration Law, the drug marketing authorization holder system has been implemented for drug management in the PRC. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate, which is responsible for the safety, efficacy and controlled quality of medicine during the whole process of drug development, production, operation and utilization processes in accordance with laws. The marketing authorization holders shall be liable for non-clinical study, clinical trial, manufacturing and business operation, post-market launch study, monitoring, reporting and handling of adverse reactions of the pharmaceuticals. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs.

The drug marketing authorization holders may produce drugs by themselves or entrust drug manufacturers with the production of such drugs; they may sell drugs with a drug registration permit on their own or through entrusting qualified drug operating enterprises. Blood products, anesthetics, psychotropic drugs, toxic drugs for medical use and pharmaceutical precursor chemicals are in principle not allowed to be produced through entrustment.

The drug marketing authorization holders shall establish a pharmaceutical quality assurance system, equipped with specialized staff solely responsible for the management of drug quality; the drug marketing authorization holders shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise their continuous quality assurance and control capabilities. The drug marketing authorization holders, drug manufacturers, drug distributors and medical institutions shall establish and implement a drug traceability system, provide traceability information in accordance with regulations and ensure that drugs are traceable.

Pharmacovigilance

Pursuant to the Pharmacovigilance Quality Control Specifications (《藥物警戒質量管理規範》) issued by the NMPA on May 7, 2021, and implemented from December 1, 2021, drug marketing authorization holders and drug registration applicants who are permitted to implement drug clinical trials shall establish the pharmacovigilance system to monitor, identify, evaluate and control adverse drug reactions and other drug-related harmful reactions through the effective operation and maintenance of the system. The drug marketing authorization holders shall initiate quality objectives for pharmacovigilance and establish quality assurance system for quality management on pharmacovigilance system and activities with an aim to consistently improve the efficiency of the system and ensure the compliance of the activities with the relevant laws and regulations. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the pharmacovigilance activities. The drug marketing authorization holders shall complete the information registration in the National Adverse Drug Reaction Monitoring System within 30 days upon the date of obtaining the first drug approval document.

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Filing for Gathering and Collection of Human Genetic Resources

Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human Genetic Resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology on July 2, 2015, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. The Ministry of Science and Technology promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) on October 26, 2017, which became effective on December 1, 2017, simplifying the approval of sampling and collecting human genetic resources for the purpose of marketing a drug in the PRC.

According to the Regulation of the People’s Republic of China on the Management of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), as promulgated by the State Council on May 28, 2019, effective on July 1, 2019, and revised on March 10, 2024, 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 human genetic resources at clinical institutions without export of human genetic resources materials. However, the two parties should file the type, quantity and usage of the human genetic resources to be used with the competent health department under the State Council before clinical trials. On May 26, 2023, the Ministry of Science and Technology issued the Implementing Rules of the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), which became effective from July 1, 2023, further specifying the requirements for the collection, preservation, use, and outbound offering of the human genetic resources in the PRC.

On October 17, 2020, the NPCSC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”) which became effective on April 15, 2021 and was revised on April 26, 2024, establishing a comprehensive legislative framework on the current regulations in the areas including epidemic control of human, animal and plant infectious diseases, security of biotechnology research, development and application, biosafety management of pathogenic microbiology laboratories, security management of human genetic resources and biological resources, countermeasures against microbial resistance and prevention of bioterrorism and threat of biological weapons. According to the Biosecurity Law, the high-risk and medium-risk biotechnology research and development activities shall be carried out by legal entities lawfully established in the PRC, and shall be approved or filed; the establishment of a pathogenic microbiology laboratory shall be lawfully approved or filed; the approval from the competent health department under the State Council is required for the following activities: (i) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent health department under the State Council, (ii) preserving human genetic resources of the PRC, (iii) using human genetic resources of the PRC to carry out international scientific research cooperation, or (iv) transporting, mailing or exiting human genetic resource materials of the PRC.

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Drug Manufacturing License

According to the Drug Administration Law and the Implementing Rules for the Drug Administration Law, when engaging in pharmaceutical manufacturing activities, an enterprise must obtain a Drug Manufacturing License (藥品生產許可證) granted by the drug regulatory authority of the people’s government of the province, autonomous region, or municipality directly under the central government at the place where the enterprise is located. No medicinal products shall be manufactured without a Drug Manufacturing License. The drug regulatory authority of the people’s government of the province, autonomous region, or municipality directly under the central government shall organize acceptance inspection for an enterprise subject to the following conditions, and issue a drug manufacturing license if the acceptance inspection is passed: (i) it shall be staffed with legally certified pharmaceutical technical personnel, engineering technical personnel, as well as corresponding skilled workers; (ii) it shall have factory premises, facilities and a sanitary environment suitable for the drugs produced; (iii) it shall have institutions and personnel capable of managing and inspecting the quality of the drugs produced, as well as necessary instruments and equipment; and (iv) it shall have rules and regulations to ensure the quality of drugs. Each Drug Manufacturing License is valid for a period of five years. If an enterprise holding the Drug Manufacturing License needs to continue the manufacturing of drugs upon the expiration of the license, the enterprise should apply for renewal in compliance with the regulation of the drug regulatory authority under the State Council six months prior to the expiration of the license.

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The Good Manufacturing Practices (《藥品生產質量管理規範》) (GMP) was first promulgated on March 17, 1988, subsequently revised on December 28, 1992, by the Ministry of Health. After the establishment of the NMPA, the GMP was amended on June 18, 1999 and became effective on August 1, 1999. The GMP, which was amended by the Ministry of Health on January 17, 2011 and became effective on March 1, 2011, stipulates the basic standards for pharmaceutical production which cover various areas including production plants and facilities, qualification of management personnel, documentation, material packaging and labeling, testing, production management, sales and return of products, and complaints of customers.

On August 2, 2011, the CFDA issued the Circular on Printing and Distributing the Administrative Measures for the Certification of Good Manufacturing Practice (《關於印發藥品生產質量管理規範認證管理辦法的通知》), which provided that newly established drug manufacturers, or existing drug manufacturers that wish to expand manufacturing scope or build new workshops shall apply for the GMP certification in accordance with the Implementing Rules for the Drug Administration Law. Those drug manufacturers that have already obtained the GMP certificates shall re-apply for the GMP certification within six months prior to the expiration date of the GMP certificates. On December 30, 2015, the CFDA issued the Notice on Effectively Implementing the Good Manufacturing Practice (《關於切實做好實施藥品生產質量管理規範有關工作的通知》), which provided that those drug manufacturers that failed to obtain the GMP certificates shall not be granted the drug manufacturing license.

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On November 29, 2019, the NMPA issued the Announcement on Matters relating to the Implementation of the Drug Administration Law of the PRC (《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》), which confirmed that the GMP certification would be canceled from December 1, 2019, and no application for GMP certification would be accepted and no GMP certificate would be granted. However, according to the Drug Administrative Law, drug manufacturers shall still comply with the GMP, establish and improve the GMP system, and ensure the whole drug production process is consistently in compliance with statutory requirements.

The Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) issued by the NMPA on May 24, 2021, and revised on July 19, 2023, and the Administrative Measures for the Certification of Good Manufacturing Practice was repealed. The Administrative Measures for Drug Inspection (Trial) provided that onsite inspections shall be conducted pursuant to the GMP on a drug manufacturer applying for the Drug Manufacturing License for the first time, while for the drug manufacturers applying for the renewal of Drug Manufacturing License, the review shall be conducted based on the risk management principles, in combination with the drug manufacturers’ compliance with the laws and regulations of drug administration, and the operation of the GMP and quality management system, and inspections on the drug manufacturers’ conformity to the GMP may be conducted where necessary.

Entrusted Manufacturing of Drugs

Pursuant to the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》), promulgated by the State Administration for Market Regulation on December 11, 2002, with latest amendments on January 22, 2020 effective from July 1, 2020, the drug marketing authorization holders may entrust qualified drug manufacturing enterprises with drug production, provided that they shall evaluate the entrusted party’s quality assurance capabilities and risk management capabilities. They shall also sign the quality agreement and the entrustment agreement with the entrusted party in accordance with the requirements of the guidelines for entrusted drug production promulgated by the NMPA and supervise the fulfillment of the obligations agreed by the entrusted party in the agreement; the entrusted party shall not re-commission the production of the drugs it agreed to be entrusted to another third party. The drug marketing authorization holders shall establish a pharmaceutical quality assurance system, equipped with specialized staff solely responsible for the quality of medicines management. They shall regularly review the quality management system of the drug manufacturer and the drug distributor and supervise its continuous quality assurance and control capabilities.

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Drug Operation License

According to the Drug Administration Law, the Measures for the Supervision and Administration of Drug Quality in Operation and Usage (《藥品經營和使用質量監督管理辦法》), which was issued by the SAMR on September 27, 2023 and came into effect on January 1, 2024, whoever engages in the wholesale or retail of drugs shall be subject to the approval of the drug regulatory authority, obtain a Drug Operation License in accordance with the law. The drug marketing authorization holders may sell the drugs for which they have obtained drug registration certificate on their own or entrust a drug operating enterprise with the sale of such drugs. However, the drug marketing authorization holders engaged in retail activities of drugs shall obtain a Drug Operation License. Each Drug Operation License is valid for five years. Where it is necessary to continue the operation of drugs upon the expiration of the period of validity of the Drug Operation License, a drug operating enterprise shall file an application with the license-issuing organ for re-examination and issuance of license in 6 to 2 months before the expiration of the period of validity.

Other Relevant Regulations in the PRC Pharmaceutical Industry

Coverage of the National Medical Insurance Program

The national medical insurance program was first adopted according to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. On July 10, 2007, the State Council issued the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》), further enlarged the coverage of the basic medical insurance program, under which urban residents of the pilot district, rather than urban employees, may voluntarily join the Urban Resident Basic Medical Insurance. In addition, on January 3, 2016, the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) issued by the State Council required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees.

Pursuant to Interim Measures for the Administration of Drug Use in Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) issued by the National Healthcare Security Administration on July 30, 2020, and became effective on September 1, 2020, the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue (《基本醫療保險藥品目錄》), the cost of drugs falls under which shall be paid by the Basic Medical Insurance Fund in accordance with regulations in the PRC. The pharmaceutical products listed in the PRC Medical Insurance

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Catalogue shall be chemical drugs, biological products, traditional Chinese drugs (including ethnic drugs) and Chinese medicine decoction pieces prepared according to national standards, all of which shall be clinically needed, safe and effective, and reasonably priced, with approval from the drug administration department in the PRC and obtainment of drug registration certificates. The administrative department of medical insurance under the State Council established and improved the dynamic adjustment mechanism so that the Medical Insurance Catalogue shall be adjusted once a year in principle. On the premise of meeting clinical needs, the medical insurance designated medical institutions are required to prioritize the preparation and utilization of drugs listed in the Medical Insurance Catalogue.

Pursuant to Interim Measures for the Administration of Drug Use in Basic Medical Insurance, expenses incurred by insured persons using drugs listed in the Medical Insurance Catalogue may be paid by the Basic Medical Insurance Fund with satisfaction of the following: (i) they are for the purpose of diagnosis or treatment of diseases; (ii) the diagnosis and treatment are in line with their conditions, the legal indications of the drugs, and the limited payment scope of the medical insurance; (iii) they are supplied by the designated medical institutions in compliance with the regulations, except for emergency and rescue medicines; (iv) the drug expenses paid by the unified fund shall be based on prescriptions from physicians or hospitalization instructions; (v) they are examined by pharmacists or licensed pharmacists through the prescribed procedures. Western medicines and traditional Chinese drugs are divided into “Class A drugs” and “Class B drugs”. The use of “Class A drugs” is paid for by the insured according to the payment standards and sharing methods stipulated by the basic medical insurance; the use of “Class B drugs” is paid for according to the payment standards stipulated by the basic medical insurance, with a certain percentage paid out of pocket by the insured first, and then paid for according to the sharing methods stipulated by the basic medical insurance. The proportion of out-of-pocket payments for “Class B drugs” is determined by the administrative department of medical insurance in provinces or regions subject to its overall planning.

National Essential Drug List

According to the Circular on the Printing and Distribution of the Administrative Measures for the National Essential Drug List (《關於印發國家基本藥物目錄管理辦法的通知》) issued on February 13, 2015, the Opinions of the General Office of the State Council on Improving the National Essential Drugs System (《國務院辦公廳關於完善國家基本藥物制度的意見》) issued on September 13, 2018 and the National Essential Drug List (2018 version) (《國家基本藥物目錄(2018年版)》) (the “**National Essential Drug List**”) issued by the NHC on September 30, 2018 and effective from November 1, 2018, basic healthcare institutions funded by the government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the National Essential Drug List. The drugs listed in the National Essential Drug List shall be purchased by centralized tender process and shall be subject to the price control by the National Development and Reform Commission (the “**NDRC**”). Remedial drugs listed in the National Essential Drug List are all listed in the Medical Insurance Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

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Centralized Procurement of Drugs

According to the Certain Regulations on the Trial Implementation of Centralized Tender Procurement of Drug by Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定》) jointly issued by authorities including the MOH on July 7, 2000, and the Notice on Further Improvement on the Implementation of Centralized Tender Procurement of Drugs by Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) jointly issued by authorities including the MOH on July 23, 2001, non-profit medical institutions run by the people’s governments at county level and above are required to implement centralized tender procurement of drugs. Drugs included in the drug catalogue of basic medical insurance for urban employees (or publicly-funded medical care) and those with relatively high clinical usage in medical institutions are, in principle, subject to centralized tender procurement.

The Opinions on Further Regulating Centralized Procurement of Drugs by Medical Institutions (《關於進一步規範醫療機構藥品集中採購工作的意見》) was jointly issued by authorities including the MOH on January 17, 2009, according to which, the centralized procurement of drugs for medical institutions shall be organized on a provincial (regional and municipal) basis. Non-profit medical institutions owned by the people’s governments at county level and above or owned by state-owned enterprises (including state-controlled enterprises) must purchase pharmaceutical products by centralized procurement; other medical institutions are encouraged to participate in the centralized procurement of drugs. The centralized procurement of drugs should give full consideration to the characteristics of the clinical demand for drugs at all levels and in all types of medical institutions, and the centralized procurement cycle should be once a year in principle. Each provincial (regional and municipal) government shall formulate its catalogue of drugs subject to centralized procurement. Drugs included in the National Essential Drug List are implemented in accordance with the provisions of the national essential drugs system. A few varieties of drugs under special management by the State, such as Class II psychotropic drugs, toxic drugs for medical use and radiopharmaceuticals, as well as Chinese herbal drugs and Chinese medicine decoction pieces, are not be included in the catalogue for the centralized procurement of drugs, and narcotic drugs and Class I psychotropic drugs are not included in the catalogue for the centralized procurement of drugs. Except for the above drugs, all other drugs used by medical institutions must, in principle, be included in the centralized procurement catalogue.

According to the Guiding Opinions on Enhancing Centralized Procurement of Pharmaceutical Products by Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) issued by the General Office of the State Council on February 9, 2015, the centralized procurement of drugs is carried out by categories: (i) for essential drugs and non-patented drugs with large clinical usage, high procurement amounts and produced by multiple enterprises, the advantages of provincial centralized bulk procurement are brought into play, and the provincial drug procurement agency adopts the two-envelope system of open tendering and procurement, and hospitals, as the main procurement body, purchase the drugs according to the winning bid prices; (ii) for some patented drugs and exclusively produced drugs, an open and transparent price negotiation mechanism with multi-party participation will be established, and the results of the negotiation will be announced on the National Drug Supply Security Comprehensive Management Information Platform, and the hospitals will purchase the drugs according to the results of the negotiation; (iii) for generic drugs for women and children, emergency (rescue) drugs, basic infusion, drugs with small clinical usage (the

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specific scope of the above drugs is determined by provinces, autonomous regions and municipalities) and commonly used low-priced drugs, centralized online bidding is implemented and hospitals can directly procure them; (iv) for drugs that are clinically necessary, in small quantities and in short supply in the market, the State will invite tenders for designated production and purchase at negotiated prices; (v) for narcotic medicines, psychotropic medicines, free medicines for the prevention and treatment of infectious and parasitic diseases, vaccines under the National Immunization Program, medicines for planned parenthood, and Chinese medicinal tablets, they shall be purchased in accordance with the existing state regulations.

According to the Opinions of the General Office of the State Council on Further Reform and Improvement of Policy on Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) promulgated by the General Office of the State Council on January 24, 2017, cross-regional and specialized hospitals are encouraged to make joint purchases; in areas where the reform of the payment method of health insurance is comprehensively implemented or where the payment standard for drugs under health insurance has already been formulated, public hospitals are allowed to jointly carry out volume- and budget-based procurement on the provincial centralized drug procurement platform (the provincial public resources trading platform).

According to the Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State (《國家組織藥品集中採購和使用試點方案》) issued by the General Office of the State Council on January 1, 2019, eleven pilot cities including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an, are selected to launch pilot programs of the centralized procurement and use of drugs under the organization of the State. According to the Implementation Opinions on Expanding the Regional Scope in the Pilot Program of Centralized Drug Procurement and Use Organized by the State (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) issued by the National Healthcare Security Administration and other departments on September 25, 2019, the regional scope in the pilot program of centralized procurement and use of drugs organized by the State is being expanded and the volume-based procurement model of the pilot program for conducting the centralized procurement and use of drugs organized by the State is being promoted throughout the country.

The Opinions of the General Office of the State Council on Promoting the Centralized Volume-based Procurement of Drugs in a Normalized and Institutionalized Manner (《國務院辦公廳關於推動藥品集中帶量採購工作常態化制度化開展的意見》), which was promulgated by the General Office of the State Council on January 22, 2021, set out the promotion of the normalization and institutionalization of the centralized procurement of drugs. All public medical institutions (including military medical institutions, hereinafter referred to as the same) shall participate in the centralized procurement of drugs, with reference to the requirements of the management of designated social medical institutions and designated pharmacies in accordance with the management of designated agreements for medical insurance. In accordance with the principles of preserving the basics and the clinical care, emphasis shall be placed on including drugs that are listed in the Drug Catalogue of Basic Medical Insurance with large consumption and high procurement price in the procurement scope, and gradually covering various drugs which are clinically necessary and reliable, so as to achieve the procurement of all medicines as much as possible.

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Drug Price Management

Pursuant to the Opinions on Promoting Drug Pricing Reform (《推進藥品價格改革的意見》), which was jointly promulgated by the authorities including the NDRC on May 4, 2015, from June 1, 2015, the original prices of the drugs formulated by the government will be canceled, except for narcotic drugs and Class I psychotropic drugs. The prices of narcotic drugs and Class I psychotropic drugs are still temporarily managed by the NDRC through the implementation of maximum factory prices and maximum retail prices. The drugs other than the narcotic drugs and Class I psychotropic drugs no longer adopted government-designated pricing. Such notice aimed to improve the mechanism of the drug purchase, give play to the role of health care insurance in drug fees controlling, and actual transaction prices of the drugs are mainly determined by the market competition.

Two-invoice System

Pursuant to the 2016 Key Tasks for Deepening the Reform of the Pharmaceutical and Healthcare System (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, in order to optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, the implementation of the “two-invoice system” shall be constructed throughout the pilot provinces for comprehensive healthcare reform and actively encouraged in the public hospitals of the pilot cities therefor.

According to the Opinions on the Implementation of the “Two Invoice System” in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)》) issued by Deepen Medical and Healthcare System Reform Leading Group Office (深化醫藥衛生體制改革領導小組辦公室) of the State Council on December 26, 2016, the “Two Invoice System” refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. The wholly-owned or holding commercial company (only one commercial company is permitted in the whole country) with the sales of its own enterprise (group) drugs only and the domestic general agent for overseas drugs (only one domestic agent is permitted in the whole country) established by a pharmaceutical manufacturer or a group enterprise integrating science, industry and trade may be regarded as a manufacturer. The allocation of drugs between a pharmaceutical distribution group enterprise and its wholly-owned (holding) subsidiaries or among its wholly-owned (holding) subsidiaries may not be regarded as a process for which an invoice should be issued, but one invoice is allowed to be issued at most. The gradual implementation of the “Two Invoice System” in drug procurement by public medical institutions would be encouragement for its implementation in the drug procurement for other medical institutions.

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Other Significant PRC Regulations Affecting Our Business Activities in the PRC

Laws and Regulations relating to Company Law and Foreign Investment

The establishment, operation and management of enterprises in the PRC are governed by the Company Law of the PRC (《中華人民共和國公司法》) (the “**Company Law**”), which was promulgated by the NPCSC on December 29, 1993 and became effective on July 1, 1994. It was subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, October 26, 2018, and December 29, 2023, respectively. Pursuant to the Company Law, companies are classified into two categories, namely limited liability companies and limited companies by shares. The Company Law shall also apply to foreign-invested limited liability companies and companies limited by shares. According to the Company Law, the provisions otherwise prescribed by the laws on foreign investment shall prevail.

On March 15, 2019, the National People’s Congress (the “**NPC**”) issued the Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”), which came into effect on January 1, 2020 and the Sino-Foreign Equity Joint Venture Enterprise Law of the People’s Republic of China (《中華人民共和國中外合資經營企業法》), the Wholly Foreign-Invested Enterprise Law of the People’s Republic of China (《中華人民共和國外資企業法》), and the Cooperative Joint Venture Enterprise Law of the People’s Republic of China (《中華人民共和國合作經營企業法》) were simultaneously abolished. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. According to the Foreign Investment Law and the Implementation Regulations for the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) issued by the State Council on December 26, 2019, with effect from January 1, 2020, “foreign investment” refers to the investment activities in the PRC carried out directly or indirectly by foreign individuals, enterprises or other organizations (the “**Foreign Investors**”), including the following: (i) Foreign Investors establishing foreign-invested enterprises in the PRC alone or collectively with other investors; (ii) Foreign Investors obtaining shares, equities, shares of properties or other similar equities of Chinese domestic enterprises; (iii) Foreign Investors investing in new projects in the PRC alone or collectively with other investors; (iv) Foreign Investors investing through other ways prescribed by laws and regulations or the State Council. The provisions of the Company Law, the Partnership Enterprise Law of the People’s Republic of China (《中華人民共和國合夥企業法》) and other laws shall apply to the form of organization of a foreign-invested enterprise, its organizational structure and the rules governing its activities.

The PRC implements a pre-access national treatment plus negative list management system for foreign investment, which means that foreign investors and their investments are given treatment no less favorable than that accorded to domestic investors and their investments at the stage of investment access; while the “negative list” refers to special administrative measures for access of foreign investment in specific fields as stipulated by the PRC. The national treatment shall be granted to foreign investments outside of the negative list.

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The Measures on Reporting Foreign Investment Information (《外商投資信息報告辦法》) was issued by MOFCOM and State Administration for Market Regulation on December 30, 2019 and came into effect on January 1, 2020, pursuant to which, for foreign investors carrying out investment activities directly or indirectly in the PRC, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to such measures. When submitting an annual report, a foreign-invested enterprise shall submit the information such as basic enterprise information, the information on investor and actual controller thereof, enterprise business operation, assets and liability, as well as the relevant industry license information, if any special administrative measure for foreign investment access is involved.

Laws and Regulations on Outbound Investment

Pursuant to the Administrative Measures on Outbound Investments (《境外投資管理辦法》) issued by the MOFCOM on March 16, 2009, and amended on September 6, 2014, and the Administrative Measures for the Outbound Investments of Enterprises (《企業境外投資管理辦法》) issued by the NDRC on December 26, 2017, and effective from March 1, 2018, if an enterprise in the PRC intends to make outbound investments, it shall be subject to approval or filing for the project, report relevant information, and cooperate in the supervisory inspections. Non-sensitive projects directly conducted by domestic enterprise in China, involving direct contribution of assets or rights and interests or provision of financing or security, shall be subject to filing.

Laws and Regulations relating to Foreign Exchange

The principal law governing foreign currency exchange in the PRC is the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Administration Regulations**”). The Foreign Exchange Administration Regulations were enacted by the State Council on January 29, 1996 and implemented on April 1, 1996. On January 14, 1997 and August 5, 2008, the State Council amended the Foreign Exchange Administration Regulations. According to the Foreign Exchange Administration Regulations, international payments in foreign currencies and transfer of foreign currencies under current items shall not be restricted. Foreign currency transactions under the capital account are still subject to limitations and require approvals from, or registration with, the State Administration of Foreign Exchange of the PRC (中華人民共和國外匯管理總局) (the “SAFE”) or its local counterpart and other relevant PRC governmental authorities.

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 [REDACTED] issuance, register the overseas [REDACTED] with the local Foreign Exchange Administration at the place of its establishment. The [REDACTED] from an overseas [REDACTED] of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the [REDACTED] shall be consistent with the content of the document or company securities [REDACTED] documents, circulars of the shareholders, resolutions from the Board of Directors or at the shareholders’ meetings, and other disclosure documents.

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According to the Circular of SAFE on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts (《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》) (the “SAFE Circular 16”) promulgated on June 9, 2016, and revised on December 4, 2023, by the SAFE, the Discretionary Foreign Exchange Settlement shall be unified for all the domestic institutions, while the use of foreign exchange incomes of capital projects by domestic institutions shall follow the principles of authenticity and self-use within the business scope of enterprises. The SAFE Circular 16 stipulates that the foreign exchange [REDACTED] under the capital account of and the Renminbi funds obtained from foreign exchange settlement by a domestic institution may be used for expenditures under the current account within its business scope or the expenditures under the capital account permitted by the laws and regulations. The foreign exchange [REDACTED] under the capital account of and the Renminbi funds obtained from foreign exchange settlement by a domestic institution (i) shall not be used directly or indirectly for expenditures beyond the business scope of the domestic institution or as prohibited by the laws and regulations; (ii) unless otherwise provided, shall not be used directly or indirectly for securities investments or other investments (except for wealth management products and structured deposits with risk rating not higher than level 2); (iii) shall not be used for offering loans to non-affiliated enterprises, unless expressly permitted by the business scope; (iv) shall not be used for the purchase of residential real estate not for self-use (except for enterprises engaged in real estate development and real estate leasing).

According to the Circular of SAFE on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) promulgated by the SAFE on April 10, 2020, the reform of facilitating the payments of incomes under the capital projects shall be promoted nationwide. Under the prerequisite of ensuring true and compliant use of funds and complying with the prevailing administrative provisions on use of income from capital projects, enterprises which satisfy the criteria are allowed to use income under the capital account, including capital funds, foreign debt and overseas [REDACTED], for domestic payment, without the need to provide proof materials for veracity to the bank beforehand for each transaction.

Distribution of Dividends

Pursuant to the provisions of the Company Law, when distributing each year’s profits after taxation, the company shall set aside 10% of its profits for the company’s statutory common reserve fund until the fund has reached more than 50% of the company’s registered capital. When the company’s statutory common reserve fund is not sufficient to make up for the company’s losses for the previous years, the current year’s profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon the resolution at a shareholders’ general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its common reserve fund, the remaining profits after taxation shall be distributed to the shareholders.

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On January 26, 2017, the SAFE issued the Notice on Promoting the Reform of Foreign Exchange Administration and Improving the Review of Authenticity and Compliance (《關於進一步推進外匯管理改革完善真實合規性審核的通知》) which provided that when processing the outward remittance of profits of a domestic institution equivalent to more than 50,000 US dollars, the bank shall, in light of the principle of genuine transaction, review the profit distribution resolution made by the board of directors (or by the partners), original tax filing form and audited financial statements relating to the outward remittance of profits, and chop on the original tax filing form to endorse the amount and date of the outward remittance. The domestic institution shall make up for its losses during the previous years according to the laws before remitting the profits.

Laws and Regulations Related to Intellectual Property Rights

Patents

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) (the “**Patent Law**”) promulgated by the NPCSC on March 12, 1984, and amended on September 4, 1992, August 25, 2000 December 27, 2008, and October 17, 2020, respectively, with the latest amendments effective from June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) promulgated by the State Council on June 15, 2001, with the latest amendments on December 11, 2023, effective from January 20, 2024, the patents in the PRC refer to invention, utility model and design. An invention or a utility model to be granted as a patent shall have novelty, creativity and practicality. The Patent Office under the State Intellectual Property Office is responsible for receiving, examining, and approving patent applications. A patent is valid for a twenty-year term for an invention, a ten-year term for a utility model, or a fifteen-year term for a design, commencing from their respective application dates.

According to the provisions of the Patent Law and the Implementation Rules of the Patent Law of the PRC, for the purpose of compensating for the time taken to examine and approve a new drug to be marketed, the patent administrative department under the State Council shall grant compensation to the validity period of patent rights for the invention patents of new drugs approved to be marketed in the PRC upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights after a new drug is approved to be marketed shall not exceed fourteen years. During the validity compensation period of patent rights, the scope of protection of the invention patent of a new drug is limited to the new drug and its approved indications-related technical solutions; within the scope of protection, the patentee enjoys the same rights and undertakes the same obligations as those before the validity compensation period.

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On July 4, 2021, the NMPA and the National Intellectual Property Administration jointly issued the Implementation Measures for Early Resolution Mechanism of Pharmaceutical Patent Disputes (for Trial Implementation) (《藥品專利糾紛早期解決機制實施辦法(試行)》), which establishes an early resolution mechanism of pharmaceutical patent disputes; the pharmaceutical marketing authorization holder shall, within 30 days upon obtainment of pharmaceutical registration certificates, register the relevant pharmaceutical patent information on the PRC Marketing Pharmaceutical Product Patent Information Registration Platform (中國上市藥品專利信息登記平台). When an application is submitted by a chemical generic drug applicant for its marketing permit, he/she shall make declaration of each relevant pharmaceutical patent of the generic drugs in accordance with the disclosed patent information on the PRC Marketing Pharmaceutical Product Patent Information Registration Platform. Provided there are disputes from the patentee or interested party considering the patent declaration, he/she may, within 45 days from the disclosure date of the drug marketing authorization application by drug evaluation institutions in the PRC, initiate legal proceedings in the People’s Court or apply for an administrative ruling to the patent administration department of the State Council on whether the relevant technical solution of the drug under application falls within the scope of protection of the relevant patent right.

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the NPCSC on August 23, 1982, and amended on February 22, 1993, October 27, 2001 and August 30, 2013 respectively, and last amended on April 23, 2019 with the latest amendment effective on November 1, 2019 and the Implementation Regulations of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) promulgated by the State Council on August 3, 2002 which became effective on September 15, 2002 and was revised on April 29, 2014 and the latest amendment became effective on May 1, 2014, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within 12 months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled.

Copyright

Copyright is protected by the Copyright Law of the PRC (《中華人民共和國著作權法》) promulgated by the NPCSC on September 7, 1990 and last amended on November 11, 2020 with the latest amendment effective on June 1, 2021 and the Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》) issued by the State Council on August 2, 2002 and last amended on January 30, 2013 with the latest amendment effective on March 1, 2013, which provided provisions on the classification of works and the obtaining and protection of copyright and the related rights.

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Domain Names

Domain names are protected by the Administrative Measures of Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology (the “MIIT”) on August 24, 2017 and effective from November 1, 2017 and the Implementing Rules on Registration of China Country Code Top-level Domain Names (《國家頂級域名註冊實施細則》) issued by China Internet Network Information Center on June 18, 2019. The MIIT is the regulatory body responsible for the administration of PRC internet domain names. The China Internet Network Information Center is responsible for the administration of registration of China country code top-level domain names. Domain name registrations are processed by the domain name registration service agencies established pursuant to the relevant provisions. The applicants become domain name holders upon successful registration.

Trade Secrets

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by the NPCSC on September 2, 1993 and amended on November 4, 2017 and April 23, 2019 respectively and the Provisions of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Trade Secret Infringement (《最高人民法院關於審理侵犯商業秘密民事案件適用法律若干問題的規定》) issued by the Supreme People’s Court on September 10, 2020 and effective from September 12, 2020, the term “trade secrets” refers to technical, operational and other business information that is unknown to the public, has business value, may create business interests or profits for its legal owners or holders, and is maintained as a secret with relevant security measures taken by its right holders. According to the Anti-Unfair Competition Law of the PRC, business operators are prohibited from infringing others’ trade secrets by (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion or any other illicit means; (ii) disclosing, using or allowing other person to use a trade secret acquired from the right holder by any means as specified in the preceding subparagraph; (iii) disclosing, using or allowing other person to 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; (iv) abetting, tempting or aiding a person into or in acquiring, disclosing, using or allowing other person to use the trade secret of the right holder in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known the above mentioned illegal conducts but nevertheless acquires, uses or allows other persons to use such trade secrets, the third party shall be deemed to have infringed others’ trade secrets. The right holders whose trade secrets are infringed may apply for administrative corrections, and the regulatory authorities shall order to stop any illegal activities and impose fine penalties on the infringers.

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Regulations relating to Enterprise Income Tax and Value-added Tax

Enterprise Income Tax

Pursuant to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the “**EIT Law**”) promulgated by the NPCSC on March 16, 2007, which became effective from January 1, 2008, and last amended on December 29, 2018, enterprises shall be classified into resident enterprises and non-resident enterprises. The income tax rate of resident enterprises is 25%, while the income tax rate of non-resident enterprises is 20%. According to the EIT Law and the Implementation Regulations for the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) (the “**Implementation Regulations for EIT Law**”) issued by the State Council on December 6, 2007, which became effective from January 1, 2008, and last amended on April 23, 2019, enterprise income tax shall be payable by a resident enterprise for the income derived from or accruing in or outside the PRC. Enterprise income tax shall be payable by a non-resident enterprise with office or premises within the territory of the PRC for the income derived from or accruing in the PRC by its office or premises, and the income derived from or accruing outside the PRC for which its office or premises has a de facto relationship. Where the non-resident enterprise has no office or premises within the territory of the PRC or the income derived or accrued has no de facto relationship with its office or premises, enterprise income tax shall be payable by the non-resident enterprise for the income derived from or accruing in the PRC at a reduced rate of 10%.

Value-Added Tax

According to the Interim Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例》), which was promulgated by the State Council on December 13, 1993 and amended on November 10, 2008, February 6, 2016 and November 19, 2017 respectively, and the Detailed Rules for the Implementation of the Interim Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the Ministry of Finance on December 25, 1993 and last amended on October 28, 2011 with the last amendment effective on November 1, 2011, entities and individuals selling goods or processing, repair and fitting-out services, selling services, intangible assets, immovable property and importing goods within the territory of the PRC shall be subject to VAT. The applicable VAT rates, depending on the nature of the taxable acts of the general taxpayer, are 17%, 11%, 6% and 0%, respectively. According to the Circular of the MOF and the SAT on Adjusting Value-added Tax Rate (《財政部、稅務總局關於調整增值稅稅率的通知》), which was jointly issued by the MOF and the SAT on April 4, 2018 and took effective on May 1, 2018, the VAT rates of 17% and 11% originally applicable to general taxpayers’ relevant taxable acts are adjusted to 16% and 10%, respectively. According to the Circular of the MOF, the SAT and the General Administration of Customs on Policies in Relation to the Deepening of Value-added Tax Reforms (《財政部、稅務總局、海關總署關於深化增值稅改革有關政策的公告》), which was jointly issued by the MOF and other departments on March 20, 2019 and became effective on April 1 2019, the VAT rates of 16% and 10% originally applicable to general taxpayers’ relevant taxable acts are further adjusted to 13% and 9%, respectively.

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Laws and Regulations Relating to Product Quality

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated on February 22, 1993 by the NPCSC and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively, is the main law regulating the supervision and management of quality of products in China. According to the Product Quality Law of the PRC, producers shall be responsible for the quality of the products they produce, and sellers shall take measures to maintain the quality of the products they sell. If a defect in a product causes physical injury or damage to property other than the defective product, the producer shall bear the liability for compensation, unless the producer can prove any of the following circumstances: (i) the product has not been put into circulation; (ii) the defect causing the damage did not exist when the product was put into circulation; (iii) when the product was put into circulation, the level of science and technology at the time was not sufficient to detect the existence of the defect.

Pursuant to the Civil Code of the PRC (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effective on January 1, 2021, where a patient suffers damage due to defects in drugs, he/she may seek compensation from the drug marketing authorization holder, producer or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder or the producer.

Laws and Regulations Relating to Safety Production

Pursuant to the Safety Production Law of the PRC (《中華人民共和國安全生產法》) promulgated by the NPCSC on June 29, 2002 and amended on August 31, 2014 and June 10, 2021 respectively with the latest amendment taking effect on September 1, 2021, production and operation units shall abide by the Safety Production Law of the PRC and other laws and regulations related to production safety, strengthen production safety management, and establish a sound production safety responsibility system and formulate a set of production safety rules and regulations for all employees; increase the efforts to guarantee the input of funds, supplies, technology and personnel to production safety, improve production safety conditions, and strengthen standardization and informatization of production safety; 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, enhance production safety levels and ensure production safety.

Precursor Chemicals

Pursuant to the Regulation on the Administration of Precursor Chemicals (《易製毒化學品管理條例》) promulgated by the State Council on August 26, 2005, which became effective on November 1, 2005 and was amended on July 29, 2014, February 6, 2016 and September 18, 2018 respectively, the State regulates the production, operation, purchase, transport, import and

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export of precursor chemicals. Unit intending to purchase Category II and III precursor chemicals shall file with the public security authorities of the local people’s government at the county level for the types and quantities of precursor chemicals required before making the purchase.

Explosive Precursor Hazardous Chemicals

Pursuant to Measures for Public Security Administration of Explosive Precursor Hazardous Chemicals (《易製爆危險化學品治安管理办法》) promulgated by the Ministry of Public Security on July 6, 2019 and effective from August 10, 2019, enterprises that have obtained the safe production permit for hazardous chemicals, the safe use permit for hazardous chemicals and the business permit for hazardous chemicals in accordance with the laws can purchase explosive dangerous chemicals with the corresponding permits; and other units purchasing explosive precursor hazardous chemicals shall provide the following materials to the selling unit: (i) photocopies of legal certificates of the unit such as industrial and commercial license (《工商營業執照》), and legal person certificate for a public institution (《事業單位法人證書》), as well as a photocopy of the identity certificate of the responsible person; (ii) the instructions of legal use of the explosive precursor hazardous chemicals, in which should contain the contents about their specific purpose, variety and quantity. Unit intending to purchase explosive precursor hazardous chemicals shall file with the public security authorities at the county level where it operates within five days after the purchase, through the explosive hazardous chemicals information system, about the information of the variety, quantity and flow of the explosive precursor hazardous chemicals it purchased.

Labor, Social Insurance and Housing Fund

The Labor Law of the PRC (《中華人民共和國勞動法》) promulgated by the NPCSC on July 5, 1994 and last amended on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) promulgated on June 29, 2007, effective from January 1, 2008, and last amended on December 28, 2012 and effective on July 1, 2013 stipulate the relationship between the employers and the employees, and specifies the terms and conditions of the labor contracts.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) promulgated by the NPCSC on October 28, 2010, effective from July 1, 2011, and last amended on December 29, 2018, the Provisional Regulations for the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) issued by the State Council on January 22, 1999 and last amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》) issued by the State Council on April 3, 1994, and amended on March 24, 2002 and March 24, 2019, respectively, employers are required to pay social insurance premiums such as basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance for their employees, and contribute to housing provident funds.

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Regulations Relating to Information Security and Data Privacy

Data Security and Data Outbound Transfer

On June 10, 2021, the NPCSC promulgated the Data Security Law of the People’s Republic of China (《中華人民共和國數據安全法》), with effect on September 1, 2021, which establishes a classified and tiered system for data protection. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound data security management system that covers the whole process of data processing, organize data security education and training, and take corresponding technological measures and other necessary measures to protect data security.

On July 7, 2022, the Cyberspace Administration of China promulgated the Measures for the Security Assessment of Cross-border Data Transmission (《數據出境安全評估辦法》), which came into effect on September 1, 2022, according to which under any of the following circumstances, a data processor who shall process cross-border data transmission shall report to the national cyberspace department through the local cyberspace department at the provincial level for security assessment of cross-border data transmission: (i) transferring important data outside the PRC by a data processor; (ii) transferring personal information outside the PRC by a Critical Information Infrastructure Operator or a data processor that has processed personal information of more than one million individuals; (iii) transferring personal information outside the PRC by a data processor that has transferred personal information of more than 100,000 individuals or sensitive personal information of more than 10,000 individuals since January 1 of the previous year; and (iv) other circumstances under which security assessment of data cross-border transfer is required as prescribed by the national cyberspace department.

On February 22, 2023, the Cyberspace Administration of China promulgated the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》), with effect from June 1, 2023. Accordingly, the personal information processor who provides personal information to any overseas recipient through standard contract shall meet the following criteria: (i) it is not a critical information infrastructure operator; (ii) it handles personal information of less than one million individuals; (iii) it provided personal information of less than 100,000 individuals in aggregate to overseas recipients since January 1 of the previous year; and (iv) it provided sensitive personal information of less than 10,000 individuals in aggregate to any overseas recipients since January 1 of the previous year. In addition, the Measures for Standard Contract for Outbound Transfer of Personal Information require that all outbound transfers of personal information that have been carried out before June 1, 2023 and do not comply with the provisions of the Measures for Standard Contract for Outbound Transfer of Personal Information be rectified within six months.

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Protection of personal information

Pursuant to the Civil Code, the personal information of a natural person shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the security of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase, sell, provide or make public the personal information of others. On August 20, 2021, the Standing Committee of the National People’s Congress promulgated the Personal Information Protection Law of the People’s Republic of China (《中華人民共和國個人信息保護法》), which took effect on November 1, 2021. The Personal Information Protection Law further emphasizes the obligation and responsibility of personal information processors on personal information and implements stricter protection measures on processing sensitive personal information.

On November 7, 2016, the Standing Committee of the National People’s Congress issued the Cyber Security Law of the People’s Republic of China, which came into effect on June 1, 2017. Network operators who collect and utilize personal information shall compile with the principles of legality, rationality and necessity to disclose the rules of collecting and utilizing personal information, indicate the purpose, method and scope of collecting and utilizing such personal information explicitly, and shall obtain consent from the person whose personal information are being collected. Network operators shall not collect personal information not related to the services they provide. Network operators may not leak, tamper with, or damage the personal information that they have collected, and shall not provide such personal information to other parties without the consent from the person whose personal information are being collected. However, this does not apply to cases where a specific individual cannot be identified and the identity cannot be recovered after processing. Network operators shall adopt technological and other necessary measures to ensure the security of the personal information collected in order to prevent the leakage, damage and loss of such personal information.

Regulations Relating to Overseas [REDACTED]

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (“**Trial Administrative Measures**”) released by the China Securities Regulatory Commission (“**CSRC**”) on February 17, 2023 and come into effect on March 31, 2023, domestic enterprise in the PRC that directly [REDACTED] outside the PRC shall file with the CSRC in accordance with the Trial Administrative Measures. For the overseas [REDACTED] or [REDACTED], issuers shall file with the CSRC within three working days after the submission of its [REDACTED] for [REDACTED] in overseas region. If the filing materials are complete and comply with regulations, the CSRC will complete the filing within 20 working days from the date of receipt of the filing materials and will announce the filing information through its website publicly.

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According to the Trial Administrative Measures, an overseas [REDACTED] and [REDACTED] are prohibited under any of the following circumstances: (i) financing through [REDACTED] is explicitly prohibited by laws, administrative regulations or relevant national regulations; (ii) the overseas [REDACTED] and [REDACTED] may endanger national security as determined by the relevant competent department under the State Council after examination according to the law; (iii) a domestic enterprise or its controlling shareholder or actual controller has committed a criminal crime of corruption, bribery, embezzlement, misappropriation of property or disrupting the order of the socialist market economy in the last three years; (iv) a domestic enterprise is under formal investigation according to the law for being suspected of any crime or major violation of laws and regulations, but no clear conclusions have been made; or (v) there is a major dispute over ownership of the equity held by the controlling shareholder or a shareholder controlled by the controlling shareholder or the actual controller.

Confidentiality and Archives Administration Concerning Overseas [REDACTED]

Pursuant to the Provisions on Strengthening Confidentiality and Archives Administration Concerning Overseas Securities Offerings and Listings 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》), which was jointly announced by numerous departments including CSRC on February 24, 2023 and came into effect since March 31, 2023, during the overseas [REDACTED] and [REDACTED] activities of domestic enterprises, such enterprises and securities companies, securities service institutions which provide corresponding services shall strictly comply with the relevant laws and regulations of PRC and the requirements of these Provisions, in order to strengthen the legal awareness on safeguarding national secret and strengthening archives administration, establish a sound system on confidentiality and archives administration, and adopt necessary measures for fulfilling its obligations on confidentiality and archives administration, They shall not leak any national secrets and work secrets of national authorities, and shall not jeopardize the national and public interests. A domestic enterprise, which provides or publicly discloses documents and information about the national secrets and the work secrets of national authorities to entities or individuals such as securities companies, securities service institutions and overseas regulatory authorities, or provides such documents and information through its overseas [REDACTED] entity, shall report to, and obtain approval from competent authority with approval authorizations in accordance with law, and shall report to the administrative department of confidentiality at the same level for filing. A domestic company that provides or publicly discloses documents and information that may pose adverse effects to national security or public interests to relevant entities or individuals including securities companies, securities service institutions, and overseas regulators, or provides or publicly discloses such documents and information through its overseas [REDACTED] entity, shall strictly fulfill relevant procedures stipulated by applicable national regulations.

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Regulations Relating to “Full Circulation” of H Shares

According to the Trial Administrative Measures, if a domestic enterprise is directly [REDACTED] overseas, when its shareholders of its domestic unlisted shares apply to convert their domestic unlisted shares held to overseas [REDACTED] shares and to be [REDACTED] in overseas exchanges, it shall comply with the relevant regulations of CSRC and entrust the domestic enterprises to file with the CSRC.

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》) announced by the CSRC on November 14, 2019 and amended on August 10, 2023, shareholders of domestic unlisted shares may, under the premise of complying with the relevant laws and regulations and the requirements of the policies on management of state-owned assets, foreign investment, and industry regulation, among others, determine the amount and proportion of shares whose circulation is applied for on their own through consultation, and entrust H-share companies with undergoing the filing formalities with the CSRC. Domestic companies with limited liability which have not been [REDACTED] in any exchanges, may file with the “full circulation” of its H-shares with the CSRC along with its overseas [REDACTED]. Shareholders of domestic unlisted shares shall, according to the relevant business rules of China Securities Depository and Clearing Corporation Limited (the “CSDC”), handle registration of transfer of shares, undergo the formalities of registration of shares, and quotation and [REDACTED] of shares, among others, according to the relevant provisions of the Hong Kong market, and conduct information disclosure according to the laws and regulations. H-share companies shall submit relevant status report to the CSRC within 15 days after the shares involved in the [REDACTED] are transferred to the CSDC.

On December 31, 2019, the CSDC and Shenzhen Stock Exchange jointly announced the Measures for Implementation of H-share “Full Circulation” Business (《H股“全流通”業務實施細則》), which are applicable to businesses of cross-border share transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, nominal holder services and other related operations in relation to the H-share “full circulation business”.

On September 20, 2024, the Shenzhen Branch of CSDC issued the Guidelines to the Program for “Full Circulation” of H-shares of Shenzhen Branch of China Securities Depository and Clearing Corporation Limited (《中國證券登記結算有限責任公司深圳分公司H股“全流通”業務指南》), which are applicable to the business preparation, cross-border share transfer registration and overseas centralized custody, the initial maintenance of details of domestic shareholding and the maintenance of its changes, corporate actions, clearing, settlement and risk management measures. On the same day, China Securities Depository and Clearing (Hong Kong) Company Limited issued the H-Share Full Circulation Business Guide of China Securities Depository and Clearing (Hong Kong) Limited (《中國證券登記結算(香港)有限公司H股“全流通”業務指南》), which is applicable to businesses such as share custody and depository, agent service, arrangement for settlement and delivery, and risk management measures.

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OVERVIEW OF EU LAWS AND REGULATIONS

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

Clinical Trial Approval

The European Medicines Agency (“**EMA**”) is the scientific agency of the EU that coordinates the evaluation and monitoring of new and approved medicinal products such as drugs and biologics. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors.

The process regarding approval of medicinal products in the EU follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant regulatory agencies in EU member states, or national authorities, of a clinical trial application (“**CTA**”) for each clinical trial, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the Marketing Authorization Application (“**MAA**”); and
- in the event that the sponsor elects the mutual recognition procedure or the national procedure for submitting an MAA, review and approval by the relevant national authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical studies include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential efficacy and toxicity in animals. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA when seeking approval to start a clinical trial, and with the MAA when seeking marketing authorization.

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Requirements for the conduct of clinical trials in the EU including Good Clinical Practice (“GCP”), are implemented in the currently Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the EU has been implemented through national legislation of the EU member states. Under this system, approval must be obtained from the competent national authority in which a trial is planned to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. The EMA, however, as the centralized agency, is not involved in the clinical trials approval process. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier (“IMPD”) and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

On January 31, 2022, the Clinical Trials Regulation (EU) No. 536/2014 repealed the Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the EU, the Clinical Trials Regulation (EU) No. 536/2014 was passed as a regulation which is directly applicable in all EU member states. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for the old system.

Regulation (EU) No 536/2014 aims to simplify and streamline the approval of clinical trial in the EU. The main characteristics of the regulation include:

- a streamlined application procedure via a single-entry point, known as the Clinical Trials Information System (“CTIS”);
- a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures which will spare sponsors from submitting broadly identical information separately to various and different national authorities;
- harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts;
- strictly defined deadlines for the assessment of clinical trial application; and
- the involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

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According to EMA, it does not evaluate applications for the authorization of clinical trials. Instead, such authorization occurs at EU member state level. The Clinical Trials Regulation enables sponsors to submit one online application via the CTIS maintained by the EMA, through which regulators and authorities of each state can collaboratively process clinical trial applications, request further information, authorize or refuse a trial and oversee an authorized trial. The evaluation process of an initial clinical trial application includes three main phases: validation, assessment and decision. The assessment phase includes two parts: Part I and Part II.

- Part I is a joint assessment by the member states concerned (“**MSCs**”) led by the reporting member state (“**RMS**”) on aspects primarily related to scientific documentation, manufacturing and importing requirements, labeling requirements and completeness and adequateness of the investigator’s brochure.
- Part II is a separate assessment performed by each MSC, each of which results in the submission of an individual conclusion. The scope of the Part II assessment is set out in the Clinical Trial Regulation and primarily relate to aspects such as informed consent, compensation, protection of data and samples, patient recruitment and suitability of clinical trial sites.

Request for information (“**RFIs**”) may be raised by RMS for Part I or by the MSC for Part II. Each MSC decides if the application is complete and adequate, and therefore if the clinical trial can be conducted in its territory.

A clinical trial sponsor may apply to its preferred MSC to conduct a clinical trial, including a Phase III or other pivotal studies following the completion of earlier trial phases, provided that the applicable procedures and requirements of that MSC are satisfied.

Clinical Trial Implementation

Article 47 of the Clinical Trials Regulation (EU) No. 536/2014 provides that the sponsor of a clinical trial and the investigator shall ensure that the clinical trial is conducted in accordance with the protocol and with the principles of good clinical practice. Also, the sponsor and the investigator, when drawing up the protocol and when applying this Regulation and the protocol, shall also take appropriate account of the quality standards and the guidelines established by the International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (“**ICH**”) on good clinical practice.

ICH E6(R3) Guideline for Good Clinical Practice provides that the sponsor may consider establishing a data review team or data monitoring committee to assess the progress of a clinical trial, including the safety data and the efficacy endpoints, at intervals and to recommend to the sponsor whether to continue, modify or stop a trial.

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Marketing Authorization

Centralized procedure

Authorization to market a product in the member states of the EU proceeds under one of four procedures: a centralized procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all EU member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, based on the opinion of the EMA, is automatically valid in all EU member states. Sponsors may elect to file an MAA through the centralized procedures for other classes of products.

The centralized procedure is mandatory for certain types of products such as, medicines derived from biotechnology processes such as genetic engineering, advanced-therapy medicines such as gene-therapy or tissue engineered medicine, orphan medicines, and medicinal products containing a new active substance indicated for the treatment of cancer, diabetes, neurodegenerative disorders, autoimmune and other immune dysfunctions, and viral diseases. The centralized procedure is mandatory for GFH925, because it is a new active substance for which the therapeutic indication is the treatment of cancer.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance, if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation, or that the granting of authorization is in the public interest of the EU.

The mutual recognition procedure refers to a procedure through which an authorization of a medicine in one EU Member State is recognized by another Member State. The decentralized procedure refers to the procedure for authorizing medicines in more than one EU Member State in parallel. It can be used for medicines that do not need to be authorized via the centralized procedure and have not already been authorized in any Member State. The national procedure refers to the procedure in which the competent authorities of respective EU Member States are responsible for reviewing the marketing authorisation applications made by pharmaceutical companies.

Administration Procedure

MAAs should first be electronically submitted to the EMA through the eSubmission gateway. The MAA shall include data in line with the EU legislation. This includes details of the target patient population, as well as an explanation of whether the medicine addresses an unmet medical need. The application must present information on the medicine’s quality, including its chemical, physical, and biological properties such as stability, purity, and

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biological activity, and demonstrate compliance with international standards for laboratory testing, manufacturing, and clinical trials, namely good laboratory practice, good manufacturing practice, and good clinical practice.

The MAA should describe the medicine’s mechanism of action based on laboratory studies, how it is distributed and eliminated in the body, and the clinical benefits observed in the intended patient group. It must also set out the safety profile, including side effects identified in patients, with specific attention to special populations such as children or the elderly. The application should detail how potential risks will be managed and monitored after authorization, and what follow-up studies are planned; these elements are contained in a risk management plan (RMP), which is reviewed by the European Medicines Agency’s safety committee, PRAC, for suitability.

Additionally, the applicant must provide the information intended for patients and healthcare professionals, including the Summary of Product Characteristics (SmPC), labelling, and package leaflet. These documents are reviewed and approved by the CHMP to ensure they are accurate and appropriate. EMA then performs a technical validation of the MAAs it receives. The objective is to make sure that all essential regulatory elements required for scientific assessment are included in the application prior to the start of the procedure. If EMA needs additional information to complete its validation of the application, it will ask the applicant to supply the additional by a deadline. After the MAA is validated by the EMA, it will be referred to EMA’s Committee for Human Medicinal Products (“CHMP”).

Under the centralized procedure, the CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The standards and requirements of the evaluation by the CHMP are the same across member states throughout the E.U. The CHMP is composed of experts nominated by each member state’s national authority for medicinal products, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 active days, to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may, pursuant to Article 14(9) Regulation (EC) No 726/2004, request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days, but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. The final CHMP recommendation is reached by a formal vote. Ideally, the CHMP will come to a consensus and unanimously recommend either the approval or refusal of the marketing authorisation; such a consensus is reached in most of the cases. However, when a final recommendation by consensus cannot be reached,

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CHMP’s final recommendation will represent the majority view. The divergent opinions and the names of the members expressing them are attached to the opinion of the committee and mentioned in the meeting minutes. The divergent opinions are then published together with the public assessment report. Once the procedure is completed, a European Public Assessment Report (“EPAR”) is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the EU member states, which in total can take more than 60 days. During such consultation period, each member state has 22 days to forward their written observations on the draft decision to the European Commission. Concerned member states may request in writing that the draft decision referred be discussed by a plenary meeting of the Standing Committee on Medicinal Products for Human Us, stating their reasons in detail. Where, in the opinion of the European Commission, a member state’s written observations raise important new questions of a scientific or technical nature which the opinion delivered by the EMA has not addressed, the Chairman of the European Commission shall suspend the procedure and refer the application back to the EMA for further consideration. In other words, under the centralized procedure, if a member state has significant concerns, different opinions or negative findings about a medicine during the evaluation phase, it can be raised within the CHMP and the European Commission. However, the final decision rests with the European Commission, and if the European Commission renders a favorable decision, such significant concerns, different opinions or negative findings from a member state cannot override such favorable decision. An applicant for a marketing authorisation is not required to obtain prior consent or clearance from the member states in which the clinical trial was conducted. A centralized marketing authorisation shall be valid throughout the European Commission and EEA-EFTA states (Iceland, Liechtenstein and Norway). It shall confer the same rights and obligations in each of the member states as a marketing authorisation granted by that member state. The European Commission carefully evaluates the application to verify compliance with stringent EU standards for safety, efficacy, and quality, culminating in the decision to grant or deny marketing authorization. After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review.

Import of Investigational Medicinal Products

In the European Union, the manufacture and import of investigational medicinal products (“IMPs”) for clinical trial use are subject to prior authorization, subject to certain exemptions. Such authorisation requires the applicant to maintain suitable premises, equipment and quality control facilities that meet prescribed standards, and to have at least one permanently available qualified person meeting the professional requirements under applicable EU legislation. Each batch manufactured or imported into the EU must be certified by the qualified person as meeting the applicable quality and compliance requirements. IMPs must be manufactured in accordance with EU GMP, and imported IMPs must meet quality standards at least equivalent to EU GMP. The European Commission issues detailed GMP guidelines and Member States monitor compliance through inspections.

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Exemptions from the authorisation requirement referred to in the above paragraph apply to the preparation of medicinal products for use as investigational medicinal products, where this process is carried out in hospitals, health centres or clinics legally authorised in the member state concerned to carry out such process and if the investigational medicinal products are intended to be used exclusively in hospitals, health centers or clinics taking part in the same clinical trial in the same member state.

Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No. 726/2004 and Regulation (EC) No. 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for products (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs, and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data.

Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Post-Authorization Measures

After obtaining a marketing approval in the EU, the applicant may be required by the EMA, on a case-by-case basis, to provide certain additional data post-authorization, including data about the safety and, in certain cases, the efficacy or quality of authorized medicinal products. Such post-authorization measures may be aimed at collecting or providing data to enable the assessment of the safety or efficacy of medicinal products in the post-approval setting. An applicant will not be notified about the requirement of post-authorization measures, if any, with respect to their approved products until and after the receipt of marketing approval from the EMA. Under centralized procedures, member states do not have unilateral authority to impose a post-authorization study on the drugs approved by the European Commission.

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OVERVIEW OF U.S. LAWS AND REGULATIONS

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

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.

Once a product candidate is identified for development, it enters pre-clinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Pre-clinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of IND must submit the results of the pre-clinical 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.

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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.

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, pre-clinical 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

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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 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

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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

The FDA has various programs that are intended to expedite or streamline the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. The programs include fast track designation, breakthrough therapy designation, accelerated approval, priority review and orphan drug designation, among others.

Fast Track Designation

To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrates the potential to address an unmet medical need for the disease or condition. Under the fast-track program, the sponsor of a drug candidate may request FDA to designate the product for a specific indication as a fast-track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast-track designation determination within 60 days after receipt of the sponsor’s request.

In addition to other benefits, such as the ability to use surrogate endpoints and have more interactions with FDA, FDA may initiate review of sections of a fast-track product’s NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA’s time period goal for reviewing a fast-track application does not begin until the last section of the NDA is submitted. In addition, the fast-track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Orphan Drug Designation

Under The Orphan Drug Act of 1983, 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. or for which a manufacturer has no reasonable expectation of recovering drug treatment research and development costs. 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 circumstances.

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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.

Breakthrough Therapy 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 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 pre-clinical and clinical data is as efficient as practicable.

Priority Review

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act guidelines. These six- and ten-month review periods are measured from the “filing” date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast-track designation are also likely to be considered appropriate to receive a priority review.

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Post-Marketing Requirements

Following the approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (“**REMS**”), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP.

Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including recall.

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Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases

In August 2024, the U.S. Food and Drug Administration (FDA) issued guidance on optimizing the dosage of oncology drugs and biological products, encouraging sponsors to determine an optimal dosage that maximizes therapeutic benefit while minimising toxicity early in clinical development.

This guidance is intended to assist sponsors in identifying an optimized dosage(s) for human prescription drugs or biological products for the treatment of oncologic diseases during clinical development and prior to submitting an application for approval of a new indication and usage.

This reflects a shift from the traditional focus on identifying the maximum tolerated dose, which may not be appropriate for modern targeted therapies that can achieve similar efficacy at lower, more tolerable doses. The guidance notes that unnecessarily high doses may adversely affect patient quality of life, treatment adherence and clinical outcomes. The guidance encourages early engagement with the FDA, including through formal meetings or the Model-Informed Drug Development paired meeting programme, to discuss dosage optimization plans.

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Key Data Collection and Evaluation Areas

Sponsors are encouraged to initiate early evaluations of population pharmacokinetics, dose- and exposure-response relationships, the impact of intrinsic factors on pharmacokinetics, pharmacodynamics and safety, and potential drug–drug interactions.

- PK/PD/Pharmacogenomics: Implement sampling plans to characterize drug behavior and variability; analyze exposure–response early; consider intrinsic factors (e.g., genetics, organ impairment) and alternative dosing strategies.
- Trial Design: Compare multiple dosages in randomized, parallel, or adaptive trials to assess efficacy, safety, and tolerability; use model-informed approaches to select dose levels; ensure trials are sized to detect meaningful safety and activity differences.
- Safety/Tolerability: Evaluate dose modifications, discontinuations, and patient-reported outcomes (PROs); predefined stopping rules for toxicity; consider strategies like dose titration for drugs with early-onset toxicities.
- Drug Formulation: Ensure suitable dose strengths and forms are available to facilitate evaluation of multiple dosages.
- Subsequent Indications: Dosage may differ by disease setting; further dose-finding may be required for new indications or combinations.

The use of modeling approaches, including semi-mechanistic or mechanistic methods, is recommended to inform dosage selection for both current and future indications. Dose optimization studies are expected to compare multiple dosages using relevant clinical endpoints such as overall response rate or progression-free survival, and may incorporate data from similar therapies where appropriate. Features such as blinding to reduce bias, pre-specified crossover analysis plans, and intra-patient dose adjustments to improve tolerability are also encouraged.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of an NDA or a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between IND and NDA/BLA submission, and all of the review phase, which is the time between NDA/BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not

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exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which an NDA or a BLA has not been submitted.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

We are a biopharmaceutical company based in China, featuring a global vision, international collaborations and operations. Our history can be traced back to 2017 when our Company was established in August 2017 as a limited liability company under the PRC Company Law with the name “勁方藥業(上海)有限公司”. In April 2018, our Company was renamed as “勁方醫藥科技(上海)有限公司”. On September 29, 2024, our Company was converted into a joint stock company with limited liability, and was renamed as GenFleet Therapeutics (Shanghai) Inc. (勁方醫藥科技(上海)股份有限公司).

Our Group was founded by Dr. Lu, our Chairman and executive Director and Dr. Lan, our executive Director, Chief Executive Officer and General Manager. Dr. Lu and Dr. Lan have extensive research and managerial experience in the biotechnology and pharmaceutical industry across the PRC and the United States. For details of the biographical background and relevant industry experience of Dr. Lu and Dr. Lan, see “Directors, Supervisors and Senior Management.”

BUSINESS DEVELOPMENT MILESTONES

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

Year	Milestone
2017	Our Company was established in the PRC
2018	We commenced our endeavor to discover and develop innovative RAS-targeting therapies, including our Core Product GFH925
	We completed an angel financing round with investors including, among others, HighLight Capital, in an aggregate amount of RMB60 million
	Our first R&D laboratory commenced operation in Zhangjiang, Shanghai
2019	We completed series A and series A+ financing with investors including Ningbo Hongjia, Jianyi Capital, CSPC and Haibang Venture Capital, in an aggregate amount of approximately RMB140 million
	We submitted our first IND application in China within 19 months after our establishment

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
2020	We received the IND approval in China and the United States with respect to GFH009
2021	We received the IND approval from the NMPA for GFH925 for a Phase I/II clinical trial in patients with advanced solid tumors with the KRAS G12C mutation We commenced our Phase I clinical trial of GFH312 in Australia We arranged eight clinical sites in multiple provinces in China, and activated one clinical trial site in 2021 in preparation for the clinical trial of GFH925 in China We entered into collaboration agreement with Innovent (Hong Kong Stock Exchange: 1801) in relation to the clinical development and commercialization of GFH925 We completed series B and B+ financing with investors including, among others, CDH Investments, Shenzhen Capital, Panlin Capital and Northern Light Venture Capital, in an aggregate amount of approximately RMB543 million
2022	We submitted the investigational medicinal product dossier to the CTIS maintained by the EMA for the KROCUS trial, which is a Phase Ib/II trial of GFH925 in combination with cetuximab to assess the combination therapy as a first-line treatment of advanced NSCLC We entered into a clinical trial collaboration and supply agreement with Merck Healthcare KGaA to secure cetuximab for the KROCUS trial We completed the Phase I clinical trial of GFH312 in Australia We received the IND approval for a Phase I clinical trial of GFH312 in healthy participants in China, and we initiated the trial

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
	The FDA approved our Phase II clinical trial of GFH312 for peripheral artery disease with intermittent claudication We entered into collaboration agreement with SELLAS (NASDAQ: SLS) in relation to the co-development of GFH009 We completed series C financing with investors including, among others, Huagai Capital, Cherami Sun Tour, Shanjin Capital and Huimei Capital, in an aggregate amount of approximately RMB483 million
2023	Italy, Spain and Greece authorized the KROCUS trial and we initiated the KROCUS trial in these countries The Phase Ib trial of KROCUS reached the primary endpoints, and there were no objection from the data review team or relevant health authorities to the commencement of the Phase II trial The GFH925 monotherapy received two Breakthrough Therapy Designations from the NMPA for treating advanced KRAS G12C-mutant NSCLC and CRC patients We completed the Phase I clinical trial of GFH312 in China We entered into a collaboration and option agreement with Verastem, pursuant to which, on a program-by-program basis, we granted Verastem options to acquire an exclusive license to develop and commercialize three product candidates, including GFH375, in territories outside of Greater China within the specified option exercise period
2024	GFH925 (marketed under the name Dupert[®]) was approved by NMPA for the treatment of patients with advanced NSCLC harboring KRAS G12C mutation who have received at least one systemic therapy We reported the results of the KROCUS trial for GFH925 as a late-breaking oral presentation at the 2024 American Society of Clinical Oncology annual meeting

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
	The FDA approved our Phase III clinical trial of GFH925 for the treatment of refractory metastatic CRC patients
	We initiated our Phase I clinical trial of GFH375, an orally bioavailable small molecule inhibitor of KRAS G12D, in China
	We completed series C+ financing with investors including Asia Investment Capital, Huajin Capital, Tailong Investment and Jiangmen Qishun, in an aggregate amount of approximately RMB195 million
2025	NMPA accepted our Breakthrough Therapy Designation (BTD) application with respect to GFH375 for the treatment of PDAC
	NMPA granted IND approval in China in relation to GFS202A for a Phase I study treating cancer cachexia patients
	Our IND application with respect to GFH276, an oral novel small-molecule Pan RAS (ON) inhibitor was submitted to the NMPA

OUR SUBSIDIARIES

The principal business activities and the dates of incorporation of all of our subsidiaries (all of which are wholly-owned) are as follows:

Name of major subsidiary	Place of incorporation	Date of incorporation and commencement of business	Principal business activities
GenFleet Zhejiang . . .	PRC	April 8, 2018	Research and development of innovative drugs
GenFleet U.S.	U.S.	April 13, 2020	Research and development of innovative drugs
GenFleet Australia . . .	Australia	July 15, 2020	Research and development of innovative drugs
GenFleet Hangzhou . .	PRC	September 26, 2023	Technical services, technology development and production of drugs

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of major subsidiary	Place of incorporation	Date of incorporation and commencement of business	Principal business activities
GenFleet Zhuhai	PRC	November 1, 2023	Technical services, technology development and production of drugs
GenFleet Shanghai . . .	PRC	March 30, 2021	No substantial business activities
GenFleet Beijing	PRC	February 22, 2022	No substantial business activities

CORPORATE DEVELOPMENT AND MAJOR SHAREHOLDING CHANGES

(1) Establishment of our Company

On August 23, 2017, our Company was established as a limited liability company under the laws of the PRC, with an initial registered capital of RMB5,000,000. The shareholding structure of our Company upon establishment is set forth in the table below:

Beneficial Shareholders	Registered capital subscribed for	Corresponding equity interest in our Company
	(RMB)	(%)
GenFleet HK ^(Note 1)	4,540,000	90.8
Ms. Zhang ^(Note 2)	460,000	9.2
Total	5,000,000	100.0

Notes:

- GenFleet HK was held as to 54% by Dr. Lu and 46% by Dr. Lan when our Company was established on August 23, 2017. On October 11, 2017, each of Dr. Lu and Dr. Lan transferred 300 shares and 200 shares of GenFleet HK to Snow Owl, LLC (“**Snow Owl**”), upon which GenFleet HK was held as to 51%, 44% and 5% by Dr. Lu, Dr. Lan and Snow Owl, respectively. Snow Owl is an Independent Third Party. It is an early investor of the Company invested in the Company indirectly through GenFleet HK. It is a private investor and was not involved in the day-to-day management of the Company nor GenFleet HK. After a series of shareholding changes, since August 2023, GenFleet HK was held as to 53.69% by Dr. Lu and 46.31% by Dr. Lan.
- Ms. Zhang is an executive Director and member of the senior management of our Company, and an initial subscriber of our Company when our Company was established. The equity interests of our Company were held by Ms. Zhang for subsequent share incentive purpose. Pursuant to an equity transfer agreement dated October 24, 2017, Ms. Zhang transferred her equity interests held in our Company to Shanghai Kunjue, our ESOP Platform, at nil consideration.

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(2) Overview of [REDACTED] Investments

Our Company entered into several rounds of [REDACTED] Investments pursuant to the respective capital increase agreements with our [REDACTED] Investors. For details, see “[REDACTED] Investments” in this section.

Apart from such capital increases, since our incorporation, there were also equity transfers between our [REDACTED] Investors and members of our Single Largest Group of Shareholders. As at the Latest Practicable Date, our Single Largest Group of Shareholders had transferred an insignificant portion of the equity interests that represented an aggregate registered capital of RMB1.41 million to various [REDACTED] Investors. The last round of equity transfers between our Single Largest Group of Shareholders and the [REDACTED] Investors were completed in January 2024, whereby GenFleet HK transferred registered capital of our Company in an aggregate amount of RMB627,536.93 to our [REDACTED] Investors at an aggregate consideration of approximately RMB57.25 million.

(3) Conversion into a joint stock limited company

On June 28, 2024, our then Shareholders passed resolutions approving, among other matters, the conversion of our Company from a limited liability company into a joint stock limited company and the change of name of our Company to GenFleet Therapeutics (Shanghai) Inc. (勁方醫藥科技(上海)股份有限公司). Pursuant to the promoters’ agreement dated July 25, 2024 entered into by all the then Shareholders, all promoters approved the conversion of the net assets value of our Company as of March 31, 2024 into 26,774,063 Shares of our Company, with the remaining RMB733,504,174.20 in net assets included as capital reserves of our Company. Upon completion of the conversion, the registered capital of our Company became RMB26,774,063 divided into 26,774,063 Shares with a nominal value of RMB1.00 each, which were subscribed by all the then Shareholders in proportion to their respective equity interests in our Company before the conversion. The conversion was completed on September 29, 2024 when our Company obtained a new business license. Immediately after the conversion into a joint stock company, the Company is held by the following shareholders who acted as promoters for the purpose of the stock conversion of our Company. The information of our promoters is set forth as follows:

Shareholders	Number of Shares	Ownership percentage
GenFleet HK	4,372,465	16.3309%
Ourea Biotech HK Limited	2,505,596	9.3583%
Long Star Growth Group Limited (長星成長集團有限公司).	1,509,115	5.6365%
Shanghai Kunjin	1,383,607	5.1677%
Hongyong Bingde (Hong Kong) Limited (鴻永秉德(香港)有限公司)	1,317,182	4.9196%

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Shareholders	Number of Shares	Ownership percentage
Ningbo Huiqiao Hongjia Venture Capital Partnership (Limited Partnership) (寧波匯橋弘甲創業投資合夥企業(有限合夥))	1,150,894	4.2985%
Auspicious Delight	1,000,000	3.7350%
Sinopharm (Shanghai) Biological Equity Investment Fund Partnership (Limited Partnership) (國藥中生(上海)生物股權投資基金合夥企業(有限合夥))	947,615	3.5393%
Shenzhen Hongtu Healthcare Industry Equity Investment Fund Partnership (Limited Partnership) (深圳紅土醫療健康產業股權投資基金合夥企業(有限合夥))	896,012	3.3466%
Capital Health Industry (Beijing) Fund (Limited Partnership) (首都大健康產業(北京)基金(有限合夥))	746,755	2.7891%
Beijing Huagai Xincheng Yuanhang Medical Industry Investment Partnership (Limited Partnership) (北京華蓋信誠遠航醫療產業投資合夥企業(有限合夥))	746,755	2.7891%
Guangzhou Chenhui Venture Capital Fund Partnership Enterprise (Limited Partnership) (廣州辰輝創業投資基金合夥企業(有限合夥))	564,325	2.1077%
Xiamen Zhongnan Hongyuan Equity Investment Fund Partnership (Limited Partnership) (廈門中南弘遠股權投資基金合夥企業(有限合夥))	487,719	1.8216%
Zhuhai Huajin Lingjian Equity Investment Fund Partnership (Limited Partnership) (珠海華金領健股權投資基金合夥企業(有限合夥))	470,271	1.7564%
Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥))	470,271	1.7564%
Shanghai Panlong Venture Capital Partnership (Limited Partnership) (上海磐隴創業投資合夥企業(有限合夥))	448,006	1.6733%
Hangzhou Jingxin Venture Capital Partnership (Limited Partnership) (杭州鏡心創業投資合夥企業(有限合夥))	448,006	1.6733%
CSPC NBP Pharmaceutical Co., Ltd. (石藥集團恩必普藥業有限公司)	441,176	1.6478%
Beta Achieve Limited	406,919	1.5198%

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Shareholders	Number of Shares	Ownership percentage
Shanghai Yuhan Equity Investment Fund Partnership (Limited Partnership) (上海譽瀚股權投資基金合夥企業(有限合夥))	402,956	1.5050%
Shijiazhuang High-Tech Zone Pu'en Guoxin Equity Investment Centre (Limited Partnership) (石家莊高新區普恩國新股權投資中心(有限合夥))	395,607	1.4776%
Shaoxing Haibang Caizhi Venture Capital Partnership (Limited Partnership) (紹興海邦才智創業投資合夥企業(有限合夥))	348,788	1.3027%
Shanghai Taiyi Venture Capital Partnership (Limited Partnership) (上海泰沂創業投資合夥企業(有限合夥))	339,919	1.2696%
Shaoxing Haibang Talent Venture Capital Partnership (Limited Partnership) (紹興海邦人才創業投資合夥企業(有限合夥))	322,129	1.2031%
Huimei Jiankang Haihe (Tianjin) Private Equity L.P. (惠每健康海河(天津)股權投資基金合夥企業(有限合夥))	307,213	1.1474%
Faithful Way Investment Limited (信運投資有限公司)	295,885	1.1051%
LBC Sunshine Healthcare Fund II L.P.	294,024	1.0982%
Suzhou Jichuang Xinyuan Venture Capital Partnership (Limited Partnership) (蘇州極創欣源創業投資合夥企業(有限合夥))	290,557	1.0852%
Guangzhou Chentu No. 14 Venture Capital Fund Partnership Enterprise (Limited Partnership) (廣州辰途十四號創業投資基金合夥企業(有限合夥))	280,017	1.0459%
Xiamen Dyee Evergreen Venture Capital Partnership (Limited Partnership) (廈門德屹長青創業投資合夥企業(有限合夥))	280,017	1.0459%
Jiaxing Runji Equity Investment Partnership (Limited Partnership) (嘉興閏濟股權投資合夥企業(有限合夥))	232,525	0.8685%
Suqian Lingdao Shengming Changqing Equity Investment Partnership (Limited Partnership) (宿遷領道生命常青股權投資合夥企業(有限合夥))	192,661	0.7196%

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Shareholders	Number of Shares	Ownership percentage
BOCOM Sci-Tech Innovation Equity Investment Fund (Shanghai) Partnership (Limited Partnership) (交銀科創股權投資基金(上海)合夥企業(有限合夥))	189,048	0.7061%
Suzhou Suxin Guokang Venture Capital Partnership (Limited Partnership) (蘇州市蘇信國康創業投資合夥企業(有限合夥))	186,695	0.6973%
Suzhou Suxin Junnuo Venture Capital Partnership (Limited Partnership) (蘇州市蘇信君諾創業投資合夥企業(有限合夥))	186,695	0.6973%
Suzhou Jingtian Medical Investment Partnership (Limited Partnership) (蘇州景天醫療投資合夥企業(有限合夥))	186,695	0.6973%
BV Fund II L.P.	186,695	0.6973%
Hangzhou Panlin Xukang Venture Capital Partnership (Limited Partnership) (杭州磐霖旭康創業投資合夥企業(有限合夥))	186,695	0.6973%
Qingdao Shanjin Anjia Equity Investment Partnership (Limited Partnership) (青島善金安嘉股權投資合夥企業(有限合夥))	186,695	0.6973%
Zhuzhou Wenzhou Junzhe Venture Capital Partnership (Limited Partnership) (株洲市文周君喆創業投資合夥企業(有限合夥))	186,695	0.6973%
Qingdao Panlin Hongyu Venture Capital Partnership (Limited Partnership) (青島磐霖鴻裕創業投資企業(有限合夥))	174,394	0.6514%
Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司)	149,335	0.5578%
Jiangmen Qishun Technology Partnership (Limited Partnership) (江門啓順科技合夥企業(有限合夥))	149,335	0.5578%
Guangzhou Chentu No. 15 Venture Capital Fund Partnership Enterprise (Limited Partnership) (廣州辰途十五號創業投資基金合夥企業(有限合夥))	140,021	0.5230%
Chongqing Jichuang Fengyuan Private Equity Investment Fund Partnership (Limited Partnership) (重慶極創豐源私募股權投資基金合夥企業(有限合夥))	116,362	0.4346%
Suzhou Suxin Qikang Venture Capital Partnership (Limited Partnership) (蘇州市蘇信啟康創業投資合夥企業(有限合夥))	93,347	0.3486%

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Shareholders	Number of Shares	Ownership percentage
Nantong Ruiyi Equity Investment Partnership (Limited Partnership) (南通瑞宜股權投資合夥企業(有限合夥))	93,347	0.3486%
Hangzhou Yantong Investment Partnership (Limited Partnership) (杭州岩桐投資合夥企業(有限合夥))	58,131	0.2171%
Shanghai Shengcheng Investment Management Partnership (Limited Partnership) (上海聖成投資管理合夥企業(有限合夥))	8,891	0.0332%
Total	26,774,063	100.00%

(4) [REDACTED] before the [REDACTED]

Pursuant to the resolutions of the Shareholders dated December 3, 2024, the Shares will be split on a [REDACTED] basis immediately prior to the [REDACTED], and the nominal value of the Shares will be changed from RMB1.0 each to RMB[REDACTED] each. Immediately after the [REDACTED], the registered share capital of the Company will be RMB26,774,063 with [REDACTED] Shares in a nominal value of RMB[REDACTED] each.

COMPLIANCE WITH PRC LAWS AND REGULATION

Our PRC Legal Advisor confirmed that all material regulatory approvals in relation to the equity transfers, conversion into joint stock limited company and the capital increases as described in this section were properly and legally completed and all necessary approvals, filings and registrations from the relevant PRC authorities have been obtained and completed.

MAJOR ACQUISITIONS AND INVESTMENTS

We have not conducted any acquisitions, disposals or mergers since our inception that we consider to be material to us.

CONCERT PARTY AGREEMENT

Dr. Lu and Dr. Lan shared the same values and goals, as well as the belief in our prospects. Since the establishment of the Company, as the co-founders of the Group, they have decided to act in concert in respect of the decision making at the Board meeting level and Shareholders’ meeting level relating to the business operation and major issues of the Company. Dr. Lu, Dr. Lan, GenFleet HK, Shanghai Kunjin, Shanghai Kunjue and Auspicious Delight entered into the currently effective concert party agreement dated March 25, 2022 (for the purpose of replacing the previous versions of the concert party agreements as Shanghai Kunjin was established in April 2021 as a new ESOP Platform, which therefore joined as a

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party to the concert party agreement) (the “Concert Party Agreement”). Pursuant to the Concert Party Agreement, the parties acknowledged and confirmed their relationship of acting in concert in exercising the rights of the Shareholders and Directors of the Company. In the event the parties are unable to reach consensus on matters of our Company, each of the parties shall act in accordance with the instructions of Dr. Lu. The Concert Party Agreement shall remain effective until 36 months after the [REDACTED]. Notwithstanding Dr. Lu is the sole general partner of, and is able to control and exercise the voting rights attached to, each of Shanghai Kunjin and Shanghai Kunjue, Shanghai Kunjin and Shanghai Kunjue joined as parties to the Concert Party Agreement as (i) Shanghai Kunjin is a Shareholder of the Company and (ii) Shanghai Kunjue had been a party to the historical concert party agreement, and thus remained as a party to the Concert Party Agreement.

REASONS FOR THE [REDACTED]

Our Company is seeking a [REDACTED] of its H Shares on the Stock Exchange in order to provide further capital for the development and expansion of our Company’s business, to strengthen our Company’s working capital and to further raise our business profile and global presence. For further details of our future plans, see “Future Plans and Use of [REDACTED].”

OUR ESOP PLATFORMS

In recognition of the contributions of our employees and to incentivize them to further promote our development, we adopted the [REDACTED] Equity Incentive Scheme in 2020 as amended and restated in July 2023. The [REDACTED] Equity Incentive Scheme shall be administered by the department designated by the Board. The Board shall have the right to, among others, (i) interpret and construe the provisions of the [REDACTED] Equity Incentive Scheme, (ii) determine the persons who will be granted awards under the [REDACTED] Equity Incentive Scheme and the relevant terms of the awards, (iii) amend any of the provisions of the [REDACTED] Equity Incentive Scheme, (iv) terminate the [REDACTED] Equity Incentive Scheme, and (v) make such other decisions or determinations as it shall deem appropriate in the administration of the [REDACTED] Equity Incentive Scheme.

Our ESOP Platforms include (i) Shanghai Kunjin, a limited partnership established in the PRC on April 2, 2021, holding 5.1677% of the issued Shares as at the Latest Practicable Date, (ii) Shanghai Kunjue and Shanghai Kunqian, each being a limited partner of Shanghai Kunjin holding approximately 20.60% and 7.19% limited partnership interests of Shanghai Kunjin as at the Latest Practicable Date, respectively; and (iii) Auspicious Delight, a limited company incorporated in the BVI on May 25, 2018, holding 3.7350% of the issued Shares as at the Latest Practicable Date. The Company established Auspicious Delight to facilitate the vesting of awards of grantees under the [REDACTED] Equity Incentive Scheme who are non-PRC employees. The Company further established three ESOP Platforms (including Shanghai Kunjue, Shanghai Kunjin and Shanghai Kunqian) to facilitate the vesting of awards of grantees under the [REDACTED] Equity Incentive Scheme who are PRC employees. Different ESOP Platforms were established having considered, among others, (i) there is restriction on the

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maximum number of limited partners in a limited partnership and (ii) for the ease of management to register the partnership interests accordingly based on the different terms of the share incentives granted to the grantees.

Shanghai Kunjin

The sole general partner of Shanghai Kunjin is Dr. Lu, who manages the day-to-day affairs and exercise the voting rights of Shanghai Kunjin. Therefore, in effect, all management powers and voting rights of Shanghai Kunjin reside with Dr. Lu as the sole general partner. Our Company had granted awards to selected participants under the [REDACTED] Equity Incentive Scheme for (i) direct limited partnership interests in Shanghai Kunjin, and (ii) indirect limited partnership interests in Shanghai Kunjin (i.e. limited partnership interests in Shanghai Kunjue and Shanghai Kunqian, each of which is a limited partner of Shanghai Kunjin) corresponding to underlying H Shares of the Company. Dr. Lu is also the sole general partner of each of Shanghai Kunjue and Shanghai Kunqian, who is able to exercise the voting rights attached to Shanghai Kunjue and Shanghai Kunqian.

As of the Latest Practicable Date, Dr. Lu held approximately 0.04% partnership interests in Shanghai Kunjin, 1.00% partnership interests in Shanghai Kunjue, and 0.50% partnership interests in Shanghai Kunqian. The remaining partnership interests of Shanghai Kunjin were held by 47 limited partners of Shanghai Kunjin, namely (i) Shanghai Kunjue (holding approximately 20.60% partnership interests of Shanghai Kunjin), (ii) Shanghai Kunqian (holding approximately 7.19% partnership interests of Shanghai Kunjin), (iii) five connected persons of our Company, including Ms. Zhang, our executive Director (holding approximately 4.88% interests of Shanghai Kunjin), Mr. Lin Chonglan and Ms. Ma Rui, each a Supervisor (holding approximately 0.58% and 0.80% interests of Shanghai Kunjin respectively), and Dr. Wang Yu and Dr. Shen Haige, each a current employee and also a former director of our Company in the last 12 months before the [REDACTED] (holding approximately 14.82% and 5.06% interests of Shanghai Kunjin respectively), and (iv) other 40 current employees who are not Directors, Supervisors or connected persons of our Company (holding in aggregate approximately 46.03% interests of Shanghai Kunjin). None of the limited partners of Shanghai Kunjin held more than 30% or more of the partnership interests in Shanghai Kunjin.

The remaining partnership interests of Shanghai Kunjue were held by 22 limited partners of Shanghai Kunjue, namely (i) four connected persons of our Company, including Ms. Zhang, our executive Director (holding approximately 4.38% interests of Shanghai Kunjue), Mr. Lin Chonglan, a Supervisor (holding approximately 0.70% interests of Shanghai Kunjue), and Dr. Wang Yu and Dr. Shen Haige, each a current employee and also a former director of our Company in the last 12 months before the [REDACTED] (holding approximately 43.86% and 17.54% interests of Shanghai Kunjue respectively), and (ii) other 18 current employees who are not Directors, Supervisors or connected persons of our Company (holding in aggregate approximately 32.52% interests of Shanghai Kunjue). Save as disclosed above, none of the limited partners of Shanghai Kunjue held more than 30% or more of the partnership interest in Shanghai Kunjue.

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The remaining 99.50% partnership interests of Shanghai Kunqian were held by 16 limited partners of Shanghai Kunqian, all of whom are current employees who are not Directors, Supervisors or connected persons of our Company. None of the limited partner of Shanghai Kunqian held more than 30% or more of the partnership interest in Shanghai Kunqian.

Auspicious Delight

As of the Latest Practicable Date, four current employees, including (i) three employees who are not the Directors, Supervisors or connected persons of our Company (holding 19.5% of the issued share capital of Auspicious Delight in aggregate) and (ii) Dr. LI Jingrong, who is also a former director of our Company in the last 12 months before the [REDACTED] (holding approximately 16.0% of the issued share capital of Auspicious Delight) had their awards vested through Auspicious Delight. The rest of the issued share capital of Auspicious Delight, representing 64.5% of the issued share capital of Auspicious Delight were held by GenFleet HK. Such issued share capital of Auspicious Delight held by GenFleet HK will not be further granted to other grantees under the [REDACTED] Equity Incentive Scheme.

As of the Latest Practicable Date, there were 66 grantees under the [REDACTED] Equity Incentive Scheme, and all awards granted under the [REDACTED] Equity Incentive Scheme had been vested and exercised and no further awards will be granted under the [REDACTED] Equity Incentive Scheme upon [REDACTED].

[REDACTED] INVESTMENTS

Our Company entered into several rounds of [REDACTED] Investments pursuant to the respective capital increase agreements with our [REDACTED] Investors.

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Principal Terms of the [REDACTED] Investments and [REDACTED] Investors’ Rights

The following table summarizes the key terms of the [REDACTED] Investments to our Company made by the [REDACTED] Investors:

	Series Angel	Series A	Series A+	Series B ⁽⁶⁾	Series B+	Series C	Series C+
Amount of registered capital/shares acquired by [REDACTED] Investors	RMB2,500,000	RMB2,647,059	RMB322,129	RMB5,122,199	RMB2,156,401	RMB4,503,387 ⁽⁴⁾	RMB1,673,807
Amount of consideration paid	RMB60,000,000	RMB120,000,000	RMB20,000,000	RMB343,000,000	RMB200,000,000	RMB482,450,000	RMB195,299,600
Implied post-money valuation	RMB180,000,000	RMB460,000,000 ⁽²⁾	RMB650,000,000	RMB1,083,000,000 ⁽³⁾	RMB1,700,000,000	RMB2,662,450,000 ⁽⁴⁾	RMB3,123,994,600 ⁽⁵⁾
Date of agreement(s)	November 13, 2017 and January 3, 2018	October 11, 2018, November 21, 2018 and December 4, 2018	February 28, 2019	February 8, 2020	December 30, 2020	March 25, 2022 and November 15, 2022 ⁽⁴⁾	December 28, 2023
Date of payment of full consideration	January 29, 2018	January 7, 2019	April 16, 2019	March 30, 2020	March 22, 2021	December 21, 2022	March 21, 2024
Cost per Share paid under the [REDACTED] Investments (approximately) (RMB)	24.00	45.33	62.09	66.96	92.75	107.13	116.68
Discount to the [REDACTED] (approximately) ⁽¹⁾	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%
Basis of determination of the valuation and consideration	The considerations for each round of [REDACTED] Investments were determined based on arm’s length negotiation amongst the respective [REDACTED] Investors and our Group after taking into consideration of the timing of the investments, the status of our business operations, financial performance of our Group, and the prospects of our business.						
Lock-up Period	Pursuant to the PRC Company Law, Shares issued by our Company prior to the [REDACTED] (including those held by the [REDACTED] Investors) will be subject to a lock-up period of one year from the [REDACTED].						

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	Series Angel	Series A	Series A+	Series B ⁽⁶⁾	Series B+	Series C	Series C+

Use of proceeds from the [REDACTED] Investments We utilized the proceeds, and expect to continue to utilize the [REDACTED] Investments, for the principal business of our Group, including but not limited to research and development of our products, the growth and expansion of our business and general working capital purposes. As of the Latest Practicable Date, we have utilized approximately 75% of the proceeds from the [REDACTED] Investments.

Strategic benefits to our Company brought by the [REDACTED] Investors At the time of the [REDACTED] Investment, we believed that our Group could benefit from the [REDACTED] Investments as well as their knowledge and experience.

- Notes:
- (1). Calculated based on the assumption that the [REDACTED] is HK\$[REDACTED] per H Share (being the mid-point of the indicative [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED]).
 - (2). The increase in the valuation of the Company in Series A investment compared with Series Angel investment was due to the research and development progress we achieved in our drug candidates. In particular, we commenced our endeavor to discover and develop GFH018.
 - (3). The valuation of the Company increased in Series B investment compared with Series A investment as a result of the progress we made in our research and development, as we submitted our first IND application in China in 2019 within 19 months after our establishment. Further, the market was optimistic about the future development of KRAS G12C, in particular having considered the results of the first-in-human clinical trial of KRAS G12C presented at the 2019 American Society of Clinical Oncology annual meeting.
 - (4). The implied post-money valuation of Series C investment has taken into account (i) the subscription of a total of RMB3,889,673 registered capital of the Company by the [REDACTED] Investors at a consideration of RMB482,450,000 and (ii) the transfer of a total of RMB613,714 registered capital of the Company by Shanghai Kunjin (our ESOP Platform) to the relevant [REDACTED] Investors in Series C investment, each at a consideration of RMB1. The increase in the valuation of the Company in Series C investment compared with Series B investment was due to the research and development progress we achieved in our drug candidates. In particular, we commenced our Phase I clinical trial of GFH312 in Australia and arranged eight clinical sites in multiple provinces in China, and activated one clinical trial site in 2021 in preparation for the clinical trial of GFH925 in China. We also received the IND approval in China and the United States with respect to GFH009.
 - (5). The increase in the valuation of the Company in Series C+ investment compared with Series C investment was due to the research and development progress we achieved in our drug candidates. In particular, NDA with respect to our GFH925 was submitted and our GFH925 monotherapy received two Breakthrough Therapy Designations from the NMPA for treating advanced KRAS G12C-mutant NSCLC and CRC patients. We also entered into collaboration agreement with SELLAS in relation to the co-development of GFH009.
 - (6). As at the Latest Practicable Date, the market capitalization of the Company upon completion of the [REDACTED] is expected to be approximately HK\$[REDACTED] (based on the [REDACTED] of HK\$[REDACTED], being the mid-point of the indicative [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED]), assuming the [REDACTED] and the [REDACTED] are not exercised). The increase in the valuation of the Company upon [REDACTED] since Series C+ investment was due to the business growth of our Company, in particular, we have started generating sales revenue from the supply of GFH925 to Innovent in 2024. Further, we have also achieved significant research and

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development progress in our drug candidates. For example, the FDA approved our Phase III clinical trial of GFH925 for the treatment of refractory metastatic CRC patients in April 2024, GFH925 (marketed under the name Dupert®) was approved by NMPA for the treatment of patients with advanced NSCLC harboring KRAS G12C mutation who have received at least one systemic therapy in August 2024, and NMPA accepted our Breakthrough Therapy Designation (BTD) application with respect to GFH375 for the treatment of PDAC and we submitted our IND application with respect to GFH276, an oral novel small-molecule Pan RAS (ON) inhibitor to NMPA in June 2025. In addition, we submitted an IND application for a Phase II clinical trial of GFH312 for the treatment of PBC in March 2025 and obtained NMPA's approval in May 2025. The increase in valuation upon the completion of the [REDACTED] has also taken into account the potential business development of the Company, the increased liquidity of the Shares subsequent to the [REDACTED], and the current market conditions.

(7). Prior to the Series B [REDACTED] Investment, on January 18, 2020, a capital increase agreement was entered into by and among others, our Company and our then Shareholders, pursuant to which Ourea Biotech, Shanghai Yuhuan, Shanghai Taiyi, Ningbo Hongjia, Sinopharm, Shanghai Shengcheng and Pu'en Guoxin, each of which (except Pu'en Guoxin) is a then Shareholder of our Company, collectively agreed to subscribe for registered capital in the aggregate amount of RMB581,622 of our Company at an aggregate consideration of RMB30,000,000.

(8). In April 2025, Suzhou Apricot Xingyong Emerging Medical Industry Investment Fund Management Partnership (Limited Partnership) (蘇州杏澤興湧新興醫療產業投資基金管理合夥企業(有限合夥)) (“Suzhou Apricot”) entered into equity transfer agreements with each of Faithful Way Investment Limited (“Faithful Way Investment”), Ourea Biotech HK Limited, Shanghai Yuhuan Equity Investment Fund Partnership (Limited Partnership) (上海譽瀚股權投資基金合夥企業(有限合夥)) (“Shanghai Yuhuan”) and Ningbo Hongjia Hongjia Venture Capital Partnership (Limited Partnership) (寧波匯橋弘甲創業投資合夥企業(有限合夥)) (“Ningbo Hongjia”), pursuant to which Suzhou Apricot agreed to acquire 177,531 Shares, 263,707 Shares, 71,254 Shares and 263,707 Shares from Faithful Way Investment, Ourea Biotech HK Limited, Shanghai Yuhuan and Ningbo Hongjia at a consideration of approximately RMB13.5 million, RMB20 million, RMB5.4 million and RMB20 million, respectively. The consideration of such share transfers was completely settled on May 21, 2025.

In April 2025, Xiamen Zhongnan Hongyuan Equity Investment Fund Partnership (Limited Partnership) (廈門中南弘遠股權投資基金合夥企業(有限合夥)) (“Zhongnan Hongyuan”) entered into an equity transfer agreement with GF Qianhe Investment Co., Ltd. (廣發乾和投資有限公司) (“GF Qianhe”) and Qingding (Beijing) Management Consulting Partnership (Limited Partnership) (擎鼎(北京)管理諮詢合夥企業(有限合夥)) (“Qingding Beijing”), pursuant to which Zhongnan Hongyuan agreed to transfer 476,496 Shares and 11,223 Shares GF Qianhe and Qingding Beijing at a consideration of approximately RMB35 million and RMB0.8 million, respectively. The consideration of such share transfers was completely settled on April 16, 2025.

The considerations of the above equity transfers were determined after arm's length negotiations between the relevant parties, with reference to, among others, the investment cost of subscribing for such registered capital in our Company paid by the transferors (in particular, having considered the increase in the valuation of our Company since their respective initial investment in our Company), the funding needs and investment plan of the transferors, the business growth prospect of our Company and the valuation of our Company in the Series C+ investment.

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Rights of the [REDACTED] Investors

Pursuant to the shareholders agreement and capital increase agreement dated December 28, 2023, the [REDACTED] Investors were granted customary special rights, including but not limited to redemption rights, liquidation rights, right of first refusal, anti-dilution rights, and directors nomination rights. Pursuant to a supplemental agreement entered into by our Company with, among others, the then Shareholders of the Company dated November 30, 2024, (a) the redemption rights and the related compulsory liquidation right of the [REDACTED] Investors shall be terminated on the day before the submission of the [REDACTED] for an [REDACTED] to the Hong Kong Stock Exchange by the Company (the “[REDACTED]”), subject to reinstatement in the event of (i) the [REDACTED] not being accepted (including being rejected or returned); (ii) the Company withdrawing its [REDACTED]; (iii) the Company failing to complete the [REDACTED] within two years after date of the [REDACTED]; or (iv) the Listing Committee not approving the [REDACTED] (the “Reinstatement”); and (b) all of the other special rights shall be terminated completely from the [REDACTED].

Sole Sponsor’s Confirmation

On the basis that (i) the considerations for the [REDACTED] Investments were settled at least 120 clear days before the [REDACTED], (ii) the redemption rights and the related compulsory liquidation right of the [REDACTED] Investors shall be terminated on the day before the submission of the [REDACTED] subject to the Reinstatement, and (iii) all the special rights granted to the [REDACTED] Investors shall cease to be effective and be terminated before the [REDACTED], the Sole Sponsor confirms that the [REDACTED] Investments are in compliance with the [REDACTED] Investment Guidance in Chapter 4.2 of the Guide for New Listing Applicants.

Information about our [REDACTED] Investors

Ourea Biotech (details of which are set out under “HighLight Capital” below) is our Sophisticated Investor. To the best knowledge of our Directors, save as disclosed below, each of our [REDACTED] Investors and their respective ultimate beneficial owner (where applicable) is an Independent Third Party. Set out below are details of our [REDACTED] Investors.

HighLight Capital

Ourea Biotech HK Limited (“**Ourea Biotech**”) is a limited liability company incorporated in Hong Kong on May 22, 2017 and is wholly owned by HL Partners II L.P., a limited partnership established under the laws of the Cayman Islands. The general partner of HL Partners II L.P. is HL GP II Company Limited, which is owned as to 91.25% by Mr. Wang, Stephen Hui (王暉), an Independent Third Party to the Company. None of the limited partners of HL Partners II L.P. holds one-third or more of its partnership interests.

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Ourea Biotech invested in the Company in December 2017. It is a dedicated healthcare and biotech fund controlled by HL Partners II L.P., an investment fund operated under HighLight Capital principally focusing on investment opportunities in medical and healthcare and related industries. The value of assets under management of HL Partners II L.P., and other investment funds under the control of Mr. Wang, Stephen Hui as of December 31, 2024, exceeds US\$2.5 billion. The investment portfolio of HL Partners II L.P. in the medical and healthcare and related industries include, among others, Zylox-Tonbridge Medical Technology Co., Ltd. (a company listed on the Hong Kong Stock Exchange, stock code: 2190), Kintor Pharmaceutical Limited (a company listed on the Hong Kong Stock Exchange, stock code: 9939) and Chemclin Diagnostics Co., Ltd. (a company listed on the Shanghai Stock Exchange, stock code: 688468). Ourea Biotech is therefore a Sophisticated Investor.

CDH Investments

Long Star Growth Group Limited (長星成長集團有限公司) (“**Long Star**”), a company incorporated in Hong Kong with limited liability, is indirectly wholly owned by CDH Growth Fund III (USD Parallel), L.P., a limited partnership registered in the Cayman Islands. The general partner of CDH Growth Fund III (USD Parallel), L.P. is CDH R-III Parallel Holdings Company Limited (together with its affiliates, “**CDH Investments**”), which is ultimately controlled by Wu Shangzhi (吳尚志), an Independent Third Party. Wu Shangzhi indirectly controls 26.97% of the equity interests of CDH R-III Parallel Holdings Company Limited. No other shareholders controls one-third or more of the equity interests in CDH R-III Parallel Holdings Company Limited.

CDH Investments is an asset management group focusing on investment in China. From its roots in private equity, CDH Investments has expanded to become a diversified alternative asset management platform covering private equity, venture and growth capital, mezzanine & credit, public equities and real estate. The investment portfolio of CDH Investments in the medical and healthcare and related industries include, among others, Wuhan YZY Biopharma Co., Ltd. (a company listed on the Hong Kong Stock Exchange, stock code: 2496), SciClone Pharmaceuticals (Holdings) Limited (a company listed on the Hong Kong Stock Exchange, stock code: 6600) and HitGen Inc. (成都先導藥物開發股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688222).

Huagai Capital

Beijing Huagai Xincheng Yuanhang Medical Industry Investment Partnership (Limited Partnership) (北京華蓋信誠遠航醫療產業投資合夥企業(有限合夥)) (“**Huagai Xincheng**”) is a limited partnership incorporated under the laws of the PRC, with its general partner being Huagai Medical Investment Management (Beijing) Co., Ltd. (華蓋醫療投資管理(北京)有限公司) which is effectively controlled and held as to 70% equity interests by Huagai Capital Co., Ltd. (華蓋資本有限責任公司), the ultimate controller of which is Xu Xiaolin (許小林), an Independent Third Party. Huagai Xincheng has more than 30 partners, and none of any of the partners holds one-third or more of the partnership interests.

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Capital Health Industry (Beijing) Fund (Limited Partnership) (首都大健康產業(北京)基金(有限合夥)) (“**Capital Health**”) is a limited partnership incorporated under the laws of the PRC. Its general partner is Bei Guang Huagai Consulting Management (Beijing) Co., Ltd. (北廣華蓋諮詢管理(北京)有限公司), which is held as to 35% respectively by Huagai Medical Investment Management (Beijing) Co., Ltd. (華蓋醫療投資管理(北京)有限公司) and Beijing Broadcasting Group Co., Ltd. (北京廣播集團有限公司) (ultimately controlled by Beijing Radio and Television Station, a public institution directly under the Beijing municipal government). Capital Health has more than 10 partners, and none of whom holds one-third or more of the partnership interests.

Huagai Xincheng and Capital Health are investment funds of Huagai Capital (華蓋資本), which focuses on private equity investments in the two major fields of healthcare and technology. The investment portfolio of Huagai Capital in the medical and healthcare and related industries include, among others, Antengene Corporation Limited (a company listed on the Hong Kong Stock Exchange, stock code: 6996), Hygeia Healthcare Holdings Co., Limited (a company listed on the Hong Kong Stock Exchange, stock code: 6078) and Shanghai Henlius Biotech, Inc. (a company listed on the Hong Kong Stock Exchange, stock code: 2696).

Asia Investment Capital

Hongyong Bingde (Hong Kong) Limited (鴻永秉德(香港)有限公司) (“**Hongyong Bingde**”) is a private limited liability company incorporated in Hong Kong and is wholly-owned by Hongyong Bingde Capital (Cayman) Limited. Hongyong Bingde Capital (Cayman) Limited is owned as to approximately 99% by Asia Ascent Holding (Cayman) Ltd., which is in turn wholly owned by Asia Investment Limited Partnership Fund (亞洲投資有限合夥基金). The general partner of Asia Investment Limited Partnership Fund is Asia Investment Capital Limited (亞投資本有限公司), and none of the limited partners of Asia Investment Limited Partnership Fund owns more than one-third of its partnership interests. Asia Investment Capital Limited is a wholly-owned subsidiary of AIC Holdings Limited (亞投資本控股有限公司). AIC Holdings Limited is held as to 43.13% by Liu Erh Fei (劉二飛), an Independent Third Party, and none of its other shareholders holds one-third or more of its equity interests. Each of the limited partners of Asia Investment Limited Partnership Fund (亞洲投資有限合夥基金) is an Independent Third Party. The investment portfolio of Asia Investment Capital include, among others, Innovation New Material Technology Co., Ltd. (創新新材料科技股份有限公司), WeRide Inc., and Hive Box Holdings Limited (豐巢控股有限公司).

Shenzhen Capital

Shenzhen Hongtu Healthcare Industry Equity Investment Fund Partnership (Limited Partnership) (深圳紅土醫療健康產業股權投資基金合夥企業(有限合夥)) (“**Shenzhen Hongtu**”) is a limited partnership established under the laws of the PRC, with its general partner being Shenzhen City Hongtu Gaocheng Investment Co., Ltd. (深圳市紅土高成投資有限公司), whose de facto controller is the State-owned Asset Supervision and Administration Commission of the Shenzhen Municipal People’s Government and is held as to 95.00% by Shenzhen Venture Capital Hongtu Private Equity Investment Fund Management (Shenzhen)

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Co., Ltd. (深創投紅土私募股權投資基金管理(深圳)有限公司). Shenzhen Venture Capital Hongtu Private Equity Investment Fund Management (Shenzhen) Co., Ltd. is a wholly-owned subsidiary of Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司) (“**Shenzhen Capital**”). None of any partners of Shenzhen Hongtu holds one-third or more of the partnership interests. Shenzhen Hongtu is engaged in investments in the medical and healthcare industry of the PRC and its investment portfolio include, among others, OrbusNeich Medical Group Holdings Limited (a company listed on the Hong Kong Stock Exchange, stock code: 6929), Nanjing Leads Biolabs Co., Ltd. (南京維立志博生物科技股份有限公司) and Shanghai Zhimeng Biopharma Inc. (上海摯盟醫藥科技有限公司).

Shenzhen Capital is a limited liability company incorporated in the PRC, initially co-founded by the Shenzhen Municipal People’s Government and a group of private shareholders in 1999, approximately 28.20% of equity of which is currently held by its largest shareholder and de facto controller, the State-owned Asset Supervision and Administration Commission of the Shenzhen Municipal People’s Government. Shenzhen Capital currently is a state-controlled and independently-managed investment institution concentrated on venture capital, primarily investing in innovative high-tech companies in emerging industries at their start-up, growth, or [REDACTED] stages, including in IT, new media, medical, new energy, environmental protection, chemical engineering, new materials, advanced manufacturing, and consuming goods. The investment portfolio of Shenzhen Capital in the medical and healthcare and related industries include, among others, Akeso, Inc. (a company listed on the Hong Kong Stock Exchange, stock code: 9926), RemeGen Co., Ltd. (a company listed on the Hong Kong Stock Exchange, stock code: 9995) and BGI Genomic Co., Ltd. (深圳華大基因股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 300676).

Cherami Sun Tour

Guangzhou Chentu No. 14 Venture Capital Fund Partnership Enterprise (Limited Partnership) (廣州辰途十四號創業投資基金合夥企業(有限合夥)) (“**Chentu No. 14**”), Guangzhou Chentu No. 15 Venture Capital Fund Partnership Enterprise (Limited Partnership) (廣州辰途十五號創業投資基金合夥企業(有限合夥)) (“**Chentu No. 15**”) and Guangzhou Chenhui Venture Capital Fund Partnership Enterprise (Limited Partnership) (廣州辰輝創業投資基金合夥企業(有限合夥)) (“**Guangzhou Chenhui**”) are all limited partnerships incorporated under the laws of the PRC. The general partner of Chentu No. 14, Chentu No. 15, and Guangzhou Chenhui is Guangzhou Cherami Sun Tour Equity Investment Management Co., Ltd. (廣州謝諾辰途股權投資管理有限公司) (“**Cherami Sun Tour**”), which is wholly owned by Guangzhou Cherami Chenhui Investment Co., Ltd. (廣州謝諾辰暉投資有限公司). Guangzhou Cherami Chenhui Investment Co., Ltd. is owned as to approximately 90.00% by Guangzhou Cherami Investment Group Co., Ltd. (廣州謝諾投資集團有限公司), and is ultimately controlled by Chen Ruibin (陳銳彬), an Independent Third Party to the Company. Each of Chentu No. 14, Chentu No. 15, and Guangzhou Chenhui has more than 40 partners, and none of any of the partners holds one-third or more of the partnership interests.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Chentu No. 14, Chentu No. 15 and Guangzhou Chenhui are investment funds controlled by Cherami Sun Tour, which focuses on three major industries: new energy, semiconductors/new materials, and healthcare. The investment portfolio of Cherami Sun Tour in the medical and healthcare and related industries include, among others, TINAVI Medical Technologies Co., Ltd. (北京天智航醫療科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688277), Mindrank AI Ltd. (杭州德睿智藥科技有限公司) and EnKang (Guangzhou) Pharmaceuticals, Ltd. (恩康藥業科技(廣州)有限公司).

Jianyi Capital

Sinopharm (Shanghai) Biological Equity Investment Fund Partnership (Limited Partnership) (國藥中生(上海)生物股權投資基金合夥企業(有限合夥)) (“**Sinopharm**”) is a limited partnership established under the laws of the PRC and its general partner, Shanghai Jianyi Private Fund Management Co., Ltd. (上海健壹私募基金管理有限公司) is held as to 65% and controlled by Shanghai Shenghui Investment Management Partnership (Limited Partnership) (上海聖匯投資管理合夥企業(有限合夥)), and as to 35% by China National Pharmaceutical Investment Co., Ltd. (中國醫藥投資有限公司). Shanghai Shenghui Investment Management Partnership (Limited Partnership) is ultimately controlled by an Independent Third Party to the Company, Wu Aimin (吳愛民), holding 95.00% of its partnership equity. None of any partners of Sinopharm holds one-third or more of the partnership interests.

Sinopharm is an investment fund operated under and managed by Jianyi Capital (健壹資本) focusing on investing in the medical healthcare sector. The value of assets under management of Jianyi Capital exceeds RMB6.5 billion as of December 31, 2024. The investment portfolio of Jianyi Capital in the medical healthcare and biotechnology sectors includes, among others, Eyebright Medical Technology (Beijing) Co., Ltd. (a company listed on the Shanghai Stock Exchange, stock code: 688050), Shenzhen YHLO Biotech Co., Ltd. (a company listed on the Shanghai Stock Exchange, stock code: 688575) and Abbisko Cayman Limited (a company listed on the Hong Kong Stock Exchange, stock code: 2256).

Apricot Capital

Suzhou Apricot Xingyong Emerging Medical Industry Investment Fund Management Partnership (Limited Partnership) (蘇州杏澤興湧新興醫療產業投資基金管理合夥企業(有限合夥)) (“**Suzhou Apricot**”) is a limited partnership incorporated under the laws of the PRC, with its general partner being Suzhou Apricot Equity Investment Centre (Limited Partnership) (蘇州杏澤股權投資中心(有限合夥)), which is owned as to approximately 52% and 47% by its limited partners, Shanghai Zhushou Enterprise Management Centre (Limited Partnership) (上海築手企業管理中心(有限合夥)) and Shanghai Yueyi Investment Centre (Limited Partnership) (上海月溢投資中心(有限合夥)), respectively. The general partner of Suzhou Apricot Equity Investment Centre (Limited Partnership) is Shanghai Apricot Investment Management Co., Ltd. (上海杏澤投資管理有限公司) (“**Apricot Capital**”). Apricot Capital is held as to 46.67% and ultimately controlled by Liu Wenyi (劉文溢), an Independent Third Party, and no other shareholders of Apricot Capital holds one-third or more of its equity interest. None of the partners of Suzhou Apricot holds one-third or more of the partnership interests in it.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Apricot Capital focuses on investing in outstanding early-stage and growth-stage companies in the life sciences industry with a total asset under management of approximately RMB5 billion as of Latest Practicable Date. The investment portfolio of Apricot Capital in the biopharmaceuticals and medical and related industries include, among others, Shanghai Junshi Biosciences Co., Ltd. (上海君實生物醫藥科技股份有限公司) (a company listed on the Shanghai Stock Exchange (stock code: 688180) and the Hong Kong Stock Exchange (stock code: 01877)), SinoMab BioScience Limited (a company listed on the Hong Kong Stock Exchange (stock code: 3681)) and RemeGen Co., Ltd. (榮昌生物製藥(煙台)股份有限公司) (a company listed on the Shanghai Stock Exchange (stock code: 688331) and the Hong Kong Stock Exchange (stock code: 9995)).

Ningbo Hongjia

Ningbo Huiqiao Hongjia Venture Capital Partnership (Limited Partnership) (寧波匯橋弘甲創業投資合夥企業(有限合夥)) (“**Ningbo Hongjia**”) is a limited partnership established under the laws of the PRC engaged in investments in medical services, biopharmaceuticals, and related industries, the investment portfolio of which include, among others, Bloomage Biotechnology Corporation Limited (華熙生物科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688363) and SMO ClinPlus Co., Ltd. (普蕊斯(上海)醫藥科技開發股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 301257). Shanghai Hongjia Private Fund Management Co., Ltd. (上海弘甲私募基金管理有限公司), as its general partner, is a private fund manager regulated by the Asset Management Association of China (中國證券投資基金業協會). Shanghai Hongjia Private Fund Management Co., Ltd. is ultimately controlled by an Independent Third Party. None of the limited partners of Ningbo Hongjia holds one-third or more of the partnership interests.

Northern Light Venture Capital

Beta Achieve Limited (“**Beta Achieve**”) is a limited liability company incorporated in Hong Kong and is ultimately controlled by Feng DENG, an Independent Third Party to the Company.

Suzhou Jichuang Xinyuan Venture Capital Partnership (Limited Partnership) (蘇州極創欣源創業投資合夥企業(有限合夥)) (“**Jichuang Xinyuan**”) is a limited partnership incorporated under the laws of the PRC. The general partner of Jichuang Xinyuan is Suzhou Peiyuan Venture Capital Partnership (Limited Partnership) (蘇州沛源創業投資合夥企業(有限合夥)). The de facto controller of Jichuang Xinyuan is Zhang Pengpeng (張朋朋), an Independent Third Party to the Company. None of any partners of Jichuang Xinyuan holds one-third or more of the partnership interests.

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Chongqing Jichuang Fengyuan Private Equity Investment Fund Partnership (Limited Partnership) (重慶極創灝源私募股權投資基金合夥企業(有限合夥)) (“**Jichuang Fengyuan**”) is a limited partnership incorporated under the laws of the PRC. The general partner of Jichuang Fengyuan is Chongqing Jichuang Liyuan Private Equity Investment Fund Management Partnership (Limited Partnership) (重慶極創灝源私募股權投資基金管理合夥企業(有限合夥)). The de facto controller of Jichuang Fengyuan is Zhang Pengpeng (張朋朋). None of the partners of Jichuang Fengyuan hold 40% or more of the partnership interests.

Beta Achieve, Jichuang Xinyuan and Jichuang Fengyuan are all investment institutions of Northern Light Venture Capital (北極光創投), a venture capital dedicated to investing in early-stage, technology-driven innovative companies, primarily focusing on enterprises in new technology, healthcare and new consumer industries. The investment portfolio of Northern Light Venture Capital in the medical and healthcare and related industries include, among others, Suzhou Zelgen Biopharmaceuticals Co., Ltd. (蘇州澤璟生物製藥股份有限公司) (a company listed on the Shanghai Stock Exchange STAR Market, stock code: 688266), BrainAurora Medical Technology Limited (a company listed on the Hong Kong Stock Exchange, stock code: 6681) and Zhejiang Taimei Medical Technology Co., Ltd. (a company listed on the Hong Kong Stock Exchange, stock code: 2576).

Panlin Capital

Shanghai Panlong Venture Capital Partnership (Limited Partnership) (上海磐隴創業投資合夥企業(有限合夥)) (“**Shanghai Panlong**”) is a limited partnership registered under the laws of the PRC, whose general partner, Shanghai Panlin Management Consulting Co., Ltd. (上海磐霖管理諮詢有限公司) is a wholly-owned subsidiary of Shanghai Panlin Asset Management Co., Ltd. (上海磐霖資產管理有限公司) (“**Shanghai Panlin Asset**”) and ultimately controlled by Li Yuhui (李宇輝), an Independent Third Party to the Company. Jiaxing Panlin Yuesheng Venture Capital Partnership (Limited Partnership) (嘉興磐霖悅生創業投資合夥企業(有限合夥)), the single largest partner of Shanghai Panlong, holds 49.00% of the partnership interests in Shanghai Panlong and its de facto controller is Shanghai Panlin Asset. None of the other partners of Shanghai Panlong hold one-third or more of the partnership interests.

Qingdao Panlin Hongyu Venture Capital Partnership (Limited Partnership) (青島磐霖鴻裕創業投資企業(有限合夥)) (“**Qingdao Panlin**”) is a limited partnership registered under the laws of the PRC, with Shanghai Panlin Asset, its general partner and single largest partner, holding 48.48% of its partnership interests. Shanghai Panlin Asset is owned as to 46% and ultimately controlled by Li Yuhui (李宇輝), an Independent Third Party. None of the other partners of Qingdao Panlin hold one-third or more of the partnership interests.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Hangzhou Panlin Xukang Venture Capital Partnership (Limited Partnership) (杭州磐霖旭康創業投資合夥企業(有限合夥)) (“**Hangzhou Panlin**”) is a limited partnership registered under the laws of the PRC, whose general partner is Shanghai Panlin Asset, which is owned as to 46% and ultimately controlled by Li Yuhui (李宇輝), an Independent Third Party. None of the partners of Hangzhou Panlin hold one-third or more of the partnership interests.

Shanghai Panlong, Qingdao Panlin, and Hangzhou Panlin are investment funds controlled by Panlin Capital (磐霖資本) (referring to Shanghai Panlin Asset, its related parties, and the private equity funds managed by the aforementioned entities), which focuses on two major fields: Healthcare and Biotechnology field, as well as To B and Technology field. Panlin Capital mainly invests in early-stage companies, and is dedicated to “Identifying the entrepreneurs among scientists, and fostering the innovators among entrepreneurs”. The investment portfolio of Panlin Capital in the healthcare and biotechnology field include, among others, Shenzhen Kangtai Biological Products Co., Ltd. (深圳康泰生物製品股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 300601) and Guangdong HybriBio Biotech Co., Ltd. (廣東凱普生物科技股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 300639) and Suzhou Ribo Life Science Co., Ltd. (蘇州瑞博生物技術股份有限公司).

Haibang Venture Capital

Shaoxing Haibang Talent Venture Capital Partnership (Limited Partnership) (紹興海邦人才創業投資合夥企業(有限合夥)) (“**Haibang Talent**”) is a limited partnership established under the laws of the PRC, with its general partner being Shaoxing Yuecheng Haibang Huirong Investment Management Co., Ltd. (紹興越城海邦匯融投資管理有限公司) (“**Shaoxing Yuecheng Haibang**”), whose de facto controller is Yao Naxin (姚納新), an Independent Third Party to the Company. Quzhou Haibang Shengrong Investment Partnership (Limited Partnership) (衢州海邦晟融投資合夥企業(有限合夥)), the single largest partner of Haibang Talent, holds approximately 66.19% of the partnership interests. Zhejiang Shangyu Investment Management Co., Ltd. (浙江商裕投資管理有限公司) is the single largest partner of Quzhou Haibang Shengrong Investment Partnership (Limited Partnership). The general partner of Quzhou Haibang Shengrong Investment Partnership (Limited Partnership) is Shaoxing Yuecheng Haibang. None of the other partners of Haibang Talent holds one-third or more of the partnership interests.

Shaoxing Haibang Caizhi Venture Capital Partnership (Limited Partnership) (紹興海邦才智創業投資合夥企業(有限合夥)) (“**Shaoxing Haibang**”) is a limited partnership registered under the laws of the PRC, with its general partner being Zhejiang Haibang Investment Management Co., Ltd. (浙江海邦投資管理有限公司). Zhejiang Haibang Investment Management Co., Ltd. is ultimately controlled by an Independent Third Party to the Company, Yao Naxin (姚納新), who holds 55.00% in equity, and is also held by Xie Li as to 45.00%. Shaoxing Binhai New Area Development Group Co., Ltd. (紹興濱海新區發展集團有限公司), the largest partner of Shaoxing Haibang, holds 40.00% of the partnership interests. None of the other partners of Shaoxing Haibang holds one-third or more of the partnership interests.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Haibang Talent and Shaoxing Haibang are all investment funds of Haibang Venture Capital (海邦投資), which primarily focuses on life health, biomedicine, digital economy, new materials, and high-end manufacturing, with the main investments in early to mid-stage projects founded by overseas high-level talents. The investment portfolio of Haibang Venture Capital in the medical and healthcare and related industries include, among others, Zylox-Tonbridge Medical Technology Co., Ltd. (a company listed on the Hong Kong Stock Exchange, stock code: 2190), Hangzhou Alltest Biotech Co., Ltd. (杭州奧泰生物技術股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688606) and TYK Medicines, Inc (浙江同源康醫藥股份有限公司) (a company listed on the Hong Kong Stock Exchange, stock code: 2410).

GF Qianhe

GF Qianhe Investment Co., Ltd. (廣發乾和投資有限公司) (“**GF Qianhe**”) is a limited liability company incorporated under the laws of the PRC. GF Qianhe is wholly owned by GF Securities Co., Ltd. (廣發證券股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 000776) and the Hong Kong Stock Exchange (stock code: 1776).

Huajin Capital

Zhuhai Huajin Lingjian Equity Investment Fund Partnership (Limited Partnership) (珠海華金領健股權投資基金合夥企業(有限合夥)) (“**Huajin Lingjian**”) is a limited partnership incorporated under the laws of the PRC, with its general partner being Zhuhai Huajin Lingchuang Fund Management Co., Ltd. (珠海華金領創基金管理有限公司), which is a wholly-owned subsidiary of Zhuhai Huajin Capital Co., Ltd. (珠海華金資本股份有限公司) (listed on the Shenzhen Stock Exchange, stock code: 000532, “**Huajin Capital**”). The single largest limited partner of Huajin Lingjian is Zhuhai Huajin Alpha No. 6 Equity Investment Fund Partnership (Limited Partnership) (珠海華金阿爾法六號股權投資基金合夥企業(有限合夥)), which holds approximately 99.80% of the partnership interests in Huajin Lingjian. The general partner of Zhuhai Huajin Alpha No. 6 Equity Investment Fund Partnership (Limited Partnership) is Zhuhai Huaying Investment Co., Ltd. (珠海鐸盈投資有限公司). None of the other partners of Huajin Lingjian hold one-third or more of the partnership interests.

Zhuhai Huajin Lingchuang Fund Management Co., Ltd. is a core private equity investment fund management company under Huajin Capital. Since its establishment, it has initiated and established a number of market-oriented equity investment funds and commenced the business of industrial fund equity investment. It initiated and established medical industry funds such as Huajin Lingfeng, Huajin Lingshang and Huajin Lingjian. The de facto controller of Huajin Capital is the State-owned Assets Supervision and Administration Commission of the Zhuhai Municipal People’s Government. Huajin Capital focuses on investment opportunities in growing and mature companies through private equity and mergers and acquisitions investment in strategic emerging industries such as new energy, advanced manufacturing, medical health, and new generation information technology. The investment portfolio of funds under Huajin Capital in the medical and healthcare and related industries include, among others, Bivision Biomedical Technology (Nanjing) Co. Ltd. (晶核生物醫藥科技(南京)有限公司), and Guangdong OptoMedic Technologies, Inc. (廣東歐譜曼迪科技股份有限公司).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Tailong Investment

Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)) (“**Hangzhou Taikun**”) is a limited partnership incorporated under the laws of the PRC, engaged in the investments of medical, pharmaceuticals, and related industries. Hangzhou Taikun has three limited partners, with its largest limited partner, Hangzhou Tiger Equity Investment Partnership (Limited Partnership) (杭州泰格股權投資合夥企業(有限合夥)) (“**Tiger Equity**”), holding approximately 49.00% of the equity interests in Hangzhou Taikun, and no other partners holds one-third or more of the partnership interests in Hangzhou Taikun. The general partner and fund manager of Hangzhou Taikun is Hangzhou Tailong Venture Investment Partnership (Limited Partnership) (杭州泰龍創業投資合夥企業(有限合夥)) (“**Hangzhou Tailong**”). The general partner of Hangzhou Tailong is Zhaotai (Zibo) Venture Capital Management Partnership (Limited Partnership) (昭泰(淄博)創業投資管理合夥企業(有限合夥)), and its general partner is Liu Chunguang (劉春光), an Independent Third Party to the Company, holding approximately 99.00% of the partnership interests. The largest limited partner of Hangzhou Tailong is also Tiger Equity. Tiger Equity is a wholly-owned subsidiary of Hangzhou Tigermed Consulting Co., Ltd., a biopharmaceutical company listed on the Hong Kong Stock Exchange (stock code: 3347) and the Shenzhen Stock Exchange (stock code: 300347).

Hangzhou Taikun is an investment fund of Tailong Investment, which is a professional equity investment management organization focused on the fields of biopharmaceuticals, medical devices, and big health, with a fund management scale of RMB20 billion. The investment portfolio of Tailong Investment in the medical and healthcare and related industries include, among others, Duality Biotherapeutics, Inc., Jiangsu CuroVax Biotechnology Co., Ltd. (江蘇康潤生物科技股份有限公司) and Beijing Luzhu Biotechnology Co., Ltd. (a company listed on the Hong Kong Stock Exchange, stock code: 2480).

Yihe Fund

Suzhou Suxin Guokang Venture Capital Partnership (Limited Partnership) (蘇州市蘇信國康創業投資合夥企業(有限合夥)) (“**Suxin Guokang**”) is a limited partnership incorporated under the laws of the PRC. The general partner of Suxin Guokang is Suzhou Yihe Private Fund Management Co., Ltd. (蘇州市宜和私募基金管理有限公司) (“**Yihe Private Fund**”), which is an indirect wholly-owned subsidiary of Suzhou International Development Group Co., Ltd. (蘇州國際發展集團有限公司). Suzhou International Development Group Co., Ltd. is a wholly-owned subsidiary of the Finance Bureau of Suzhou (蘇州市財政局). The single largest partner of Suxin Guokang is Suzhou Suxin Qikang Venture Capital Partnership (Limited Partnership) (蘇州市蘇信啟康創業投資合夥企業(有限合夥)) (“**Suxin Qikang**”), which holds approximately 52.08% of the partnership interests. None of other partners of Suxin Guokang holds one-third or more of the partnership interests.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Suzhou Suxin Junnuo Venture Capital Partnership (Limited Partnership) (蘇州市蘇信君諾創業投資合夥企業(有限合夥)) (“**Suxin Junnuo**”) is a limited partnership incorporated under the laws of the PRC. The general partner of Suxin Junnuo is Yihe Private Fund and is ultimately controlled by the Finance Bureau of Suzhou. The single largest partner of Suxin Junnuo is Suxin Qikang, which holds approximately 61.88% of the partnership interests, and none of other partners of Suxin Junnuo holds one-third or more of the partnership interests.

Suzhou Suxin Qikang Venture Capital Partnership (Limited Partnership) (蘇州市蘇信啟康創業投資合夥企業(有限合夥)) (“**Suxin Qikang**”) is a limited partnership incorporated under the laws of the PRC, with its general partner being Yihe Private Fund, and is ultimately controlled by the Finance Bureau of Suzhou. The single largest limited partner of Suxin Qikang is Suzhou International Development Group Co., Ltd. (蘇州國際發展集團有限公司), holding approximately 43.43% partnership interests in it and is an Independent Third Party. None of the other partners of Suxin Qikang hold one-third or more of the partnership interests.

Suxin Guokang, Suxin Junnuo and Suxin Qikang are investment funds of Yihe Private Fund, which focuses on the medical and health sector, investing in new drug research and development and the import substitution of high-end medical devices, centering on advancements in bioscience cognition and application technology, the investment portfolio in the medical and healthcare and related industries of which include, among others, Agibot Biotechnology (Suzhou) Co., Ltd. (敏捷醫療科技(蘇州)有限公司), Eluminex Biosciences (Suzhou) Limited (典晶生物醫藥科技(蘇州)有限公司) and Nanjing Delova Biotech Co., Ltd. (南京清普生物科技有限公司).

Lake Ventures

Hangzhou Jingxin Venture Capital Partnership (Limited Partnership) (杭州鏡心創業投資合夥企業(有限合夥)) (“**Hangzhou Jingxin**”) is a limited partnership established under the laws of the PRC. The general partner of Hangzhou Jingxin, Ningbo Zehong Ziyue Investment Management Co., Ltd. (寧波澤泓子悅投資管理有限公司), is owned as to 70.00% by an Independent Third Party to the Company, Lyu Xiaoxiang (呂曉翔). The largest limited partner of Hangzhou Jingxin is Guizhou Xinbang Pharmaceutical Co., Ltd. (貴州信邦製藥股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002390), which holds 40.00% of the partnership interests. None of the other partners of Hangzhou Jingxin holds one-third or more of the partnership interests.

Hangzhou Jingxin has invested in various companies engaged in medical, pharmaceutical and related industries including, among others, Shanghai Zhimeng Biopharma Co., Ltd. (上海摯盟醫藥科技有限公司) and Hangzhou Highlight Pharma Co., Ltd. (杭州高光製藥有限公司).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CSPC

CSPC NBP Pharmaceutical Co., Ltd. (石藥集團恩必普藥業有限公司) (“**CSPC NBP**”) is a limited liability company established in China and is principally engaged in the manufacture and sales of pharmaceutical products. CSPC NBP is a wholly-owned subsidiary of CSPC Pharmaceutical Group Limited (石藥集團有限公司), a company listed on the Hong Kong Stock Exchange (stock code: 1093).

Shanjin Capital

Jiaxing Runji Equity Investment Partnership (Limited Partnership) (嘉興潤濟股權投資合夥企業(有限合夥)) (“**Jiaxing Runji**”) is a limited partnership incorporated under the laws of the PRC and filed as an equity investment fund with the Asset Management Association of China (中國證券投資基金業協會), with the fund number being: SNB034. Its general partner is Shanghai Shanjin Private Fund Management Co., Ltd. (上海善金私募基金管理有限公司) (“**Shanjin Capital**”), which is ultimately controlled and held as to 36.00% equity interests by Liu Jing (劉婧), an Independent Third Party to the Company. Jiaxing Runji has more than 30 partners, and none of any of the partners holds one-third or more of the partnership interests.

Qingdao Shanjin Anjia Equity Investment Partnership (Limited Partnership) (青島善金安嘉股權投資合夥企業(有限合夥)) (“**Shanjin Anjia**”) is a limited partnership incorporated under the laws of the PRC and is also a venture capital fund filed with the Asset Management Association of China, with the fund number being: SSA028. Its general partner is Shanjin Capital (善金資本) and is ultimately controlled by Liu Jing (劉婧), an Independent Third Party. Shanjin Anjia has a total of 19 partners, and none of any of the partners holds one-third or more of the partnership interests.

Shanjin Capital focuses its investment on two major lines: hard technology and medical health, specializing in investments in areas such as new energy, advanced technology, as well as research and development of biopharmaceutical, the investment portfolio of which include, among others, TINAVI Medical Technologies Co., Ltd. (北京天智航醫療科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688277) and Suzhou Zelgen Biopharmaceuticals Co., Ltd. (蘇州澤璟生物製藥股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688266).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pu'en Guoxin

Shijiazhuang High-Tech Zone Pu'en Guoxin Equity Investment Centre (Limited Partnership) (石家莊高新區普恩國新股權投資中心(有限合夥)) (“**Pu'en Guoxin**”) is a limited partnership and private equity fund incorporated under the laws of China. Guoxin Sichuang Investment Fund Management (Beijing) Co., Ltd. (國新思創投資基金管理(北京)有限公司), the general partner of Pu'en Guoxin, is ultimately controlled by Wang Hongjie (王宏傑), an Independent Third Party to the Company. Pu'en Guoxin has four limited partners, and Shijiazhuang High-tech Capital Industry Investment Co., LTD (石家莊高新資本產業投資有限公司) as its largest limited partner holds approximately 30.00% of the partnership interests. None of the other partners of Pu'en Guoxin holds one-third or more of the partnership interests.

Shanghai Taiyi

Shanghai Taiyi Venture Capital Partnership (Limited Partnership) (上海泰沂創業投資合夥企業(有限合夥)) (“**Shanghai Taiyi**”) is a limited partnership established under the laws of the PRC, with Shanghai Taiyou Investment Management Center (Limited Partnership) (上海泰有投資管理中心(有限合夥)) as its general partner, of which general partner is Shanghai Taifu Venture Capital Management Co., Ltd. (上海泰甫創業投資管理有限公司) (“**Shanghai Taifu**”). Shanghai Taifu is ultimately controlled by Liu Junjun (劉軍軍), an Independent Third Party to the Company. The single largest limited partner of Shanghai Taiyi is Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司) (a company listed on the Shenzhen Stock Exchange (stock code: 002399) and the Hong Kong Stock Exchange (stock code: 9989)), holding approximately 49.58% partnership interests and is an Independent Third Party. None of the other partners of Shanghai Taiyi hold one-third or more of the partnership interests.

Shanghai Taiyi is an investment fund controlled by Shanghai Taifu, which focuses on venture capital in the life sciences sector, primarily investing in promising companies in early and growth stage, the investment portfolio of which include, among others, Shanghai Rendu Biotechnology Co., Ltd. (上海仁度生物科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688193).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shanghai Yuhan

Shanghai Yuhan Equity Investment Fund Partnership (Limited Partnership) (上海譽瀚股權投資基金合夥企業(有限合夥)) (“**Shanghai Yuhan**”) is a limited partnership incorporated under the laws of the PRC, with its general partner being Shanghai Qianlong Yuhan Investment Management Co., Ltd. (上海潛龍譽瀚投資管理有限公司), and is ultimately controlled by Zhang Hanhong (張漢宏), an Independent Third Party to the Company. The largest partner of Shanghai Yuhan is Shenxian Yuzhong Enterprise Management Consulting Center (Limited Partnership) (莘縣譽中企業管理諮詢中心(有限合夥)), which holds 36.00% of the partnership interests in Shanghai Yuhan. The de facto controller of Shenxian Yuzhong Enterprise Management Consulting Center (Limited Partnership) is Guo Leifeng (國磊峰), an Independent Third Party to the Company. None of the other partners of Shanghai Yuhan holds one-third or more of the partnership interests.

Shanghai Yuhan focuses on investments in the healthcare sector, concentrating on innovative pharmaceuticals and devices, research and development services and other sectors, the investment portfolio of which include, among others, Shanghai Xihua Scientific Co., Ltd. (上海熙華檢測技術服務股份有限公司) and Changchun Zhuoyi Biological Co., Ltd. (長春卓誼生物股份有限公司).

Huimei Capital

Huimei Jiankang Haihe (Tianjin) Private Equity L.P. (惠每健康海河(天津)股權投資基金合夥企業(有限合夥)) (“**Huimei Jiankang**”) is a limited partnership incorporated under the laws of the PRC. The general partner of Huimei Jiankang is Beijing Huimei Private Equity Fund Management Partnership L.P. (北京惠每私募基金管理合夥企業(有限合夥)) (“**Huimei Capital**”). The general partner and the largest partner of Huimei Capital is Huimei Huakang Health Management (Beijing) Co., Ltd. (惠每華康健康管理(北京)有限公司), holding 60.00% of the partnership interests in Huimei Capital. Huimei Huakang Health Management (Beijing) Co., Ltd. is held as to 66.00% equity interests by Luo Rushu (羅如澍), an Independent Third Party to the Company. None of the partners holds one-third or more interest in Huimei Jiankang.

Huimei Jiankang is a private equity fund managed by Huimei Capital (惠每資本), which has extensive experiences in medical and healthcare investments. The investment portfolio of Huimei Capital in the medical and healthcare and related industries include, among others, Suzhou NanoMicro Technology Co., Ltd. (蘇州納微科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688690), SMO ClinPlus Co., Ltd. (普蕊斯(上海)醫藥科技開發股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 301257), and PharmaResources (Shanghai) Co., Ltd. (上海泓博智源醫藥股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 301230).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Lake Bleu Capital

LBC Sunshine Healthcare Fund II L.P. (“**LBC Sunshine II**”) is managed by Lake Bleu Capital (Hong Kong) Limited (“**Lake Bleu Capital**”). LBC Sunshine II is an exempted limited partnership registered in the Cayman Islands engaged in investing in medical companies in Asia and Greater China with an investment scope covering pharmaceuticals, biotechnology, medical devices and healthcare services. An Independent Third Party to the Company, LBC GP II Limited, is an exempted company incorporated in the Cayman Islands and acts as the general partner of LBC Sunshine II. LBC GP II Limited is ultimately owned by an Independent Third Party. None of the partners of LBC Sunshine II hold one-third or more of the partnership interests.

LBC Sunshine II is an investment fund managed by Lake Bleu Capital (清池資本), which is an investment platform focusing on the healthcare, pharmaceutical, and technology innovation sectors. The investment portfolio of Lake Bleu Capital in the medical and healthcare and related industries include, among others, Duality Biotherapeutics, Inc. (a company listed on the Hong Kong Stock Exchange, stock code: 9606), Akeso, Inc. (a company listed on the Hong Kong Stock Exchange, stock code: 9926), RemeGen Co., Ltd. (a company listed on the Hong Kong Stock Exchange, stock code: 9995), Zylox-Tonbridge Medical Technology Co., Ltd. (a company listed on the Hong Kong Stock Exchange, stock code: 2190), Jiangsu Hansoh Pharmaceutical Group Co., Ltd. (江蘇豪森藥業集團有限公司), Pharmaron Beijing Co., Ltd. (a company listed on the Shenzhen Stock Exchange (stock code: 300759) and Hong Kong Stock Exchange (stock code: 3759)) and JD Health International Inc. (a company listed on the Hong Kong Stock Exchange, stock code: 6618).

Qiaojing Capital

Suzhou Jingtian Medical Investment Partnership (Limited Partnership) (蘇州景天醫療投資合夥企業(有限合夥)) (“**Suzhou Jingtian**”) is a limited partnership established in the PRC, whose general partner is Suzhou Qiaojing Investment Management Consulting Co., Ltd. (蘇州喬景投資管理諮詢有限公司), which is ultimately controlled and held as to 80.00% equity interests by Jin Dan (金澹), an Independent Third Party to the Company. Suzhou Jingtian has 11 limited partners and none of any of the partners holds one-third or more of the partnership interests.

Suzhou Jingtian is an investment fund of Qiaojing Capital (喬景資本), which has focused on investments in medical and consumer industries, including Allgens Medical Science & Technology Co., Ltd. (奧精醫療科技股份有限公司) (a company listed on the Shanghai Stock Exchange; stock code: 688613), Leto Laboratories Co., Ltd. (北京志道生物科技有限公司) and Xiamen Spacegen Co., Ltd. (廈門飛朔生物技術有限公司).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Dyee Evergreen

Xiamen Dyee Evergreen Venture Capital Partnership (Limited Partnership) (廈門德屹長青創業投資合夥企業(有限合夥)) (“**Dyee Evergreen**”) is a limited partnership incorporated under the laws of the PRC and is mainly engaged in private equity investments. Focusing on modern service industries, Dyee Evergreen mainly invested in medical, healthcare, biopharmaceutical, information technology and services business, including, among others, Shanghai Zhimeng Biopharma Co., Ltd. (上海摯盟醫藥科技有限公司), Genepoint Biotechnology (Shanghai) Co., Ltd. (基點生物科技(上海)有限公司) and Shanghai Ark Biopharmaceutical Co., Ltd. (上海愛科百發生物醫藥技術股份有限公司).

The general partner of Dyee Evergreen is Xiamen Derong Investment Partnership (Limited Partnership) (廈門德嶸投資合夥企業(有限合夥)), holding 1.00% of the partnership interests whose general partner is Xiamen Dyee Evergreen Equity Investment Management Partnership (Limited Partnership) (廈門德屹長青股權投資管理合夥企業(有限合夥)) (“**Dyee Evergreen Equity**”). Xiamen Zhisheng Investment Management Co., Ltd. (廈門至昇投資管理有限公司) (“**Xiamen Zhisheng**”) acts as the general partner of Dyee Evergreen Equity and Zhu Qiuzhen (朱秋貞), an Independent Third Party, held 80.0% equity interest in Xiamen Zhisheng. Dyee Evergreen had seven limited partners, with the largest limited partner, Xiamen Delihong Investment Partnership (Limited Partnership) (廈門德利泓投資合夥企業(有限合夥)) holding approximately 50.00% partnership interest and each of the remaining limited partners holding less than one-third of the partnership interest.

Linden Asset

Suqian Lingdao Shengming Changqing Equity Investment Partnership (Limited Partnership) (宿遷領道生命常青股權投資合夥企業(有限合夥)) (“**Suqian Lingdao**”) is a limited partnership established in China, primarily engaged in equity investment. The general partner of Suqian Lingdao is Suzhou Lingdao Investment Management Co., Ltd. (蘇州領道投資管理有限公司), the de facto controller of which is Sun Yurong (孫玉蓉), an Independent Third Party to the Company. None of any of Suqian Lingdao’s partners holds one-third or more of the partnership interests. Suqian Lingdao is engaged in investments in the medical technology and related industries including, among others, AIM Vaccine Co., Ltd. (艾美疫苗股份有限公司) (a company listed on the Hong Kong Stock Exchange, stock code: 6660), BrioHealth Technologies, Inc. (蘇州同心醫療科技股份有限公司) and Singlera Genomics Inc. (江蘇鵬遠生物科技股份有限公司).

BOCOM International

BOCOM Sci-Tech Innovation Equity Investment Fund (Shanghai) Partnership (Limited Partnership) (交銀科創股權投資基金(上海)合夥企業(有限合夥)) (“**BOCOM Sci-Tech**”) is a limited partnership established under the laws of the PRC, with its general partner being Shanghai Boli Investment Co., Ltd. (上海博禮投資有限公司). Shanghai Boli Investment Co., Ltd. is controlled by BOCOM International Holdings Company Limited, a company listed on the Hong Kong Stock Exchange (stock code: 3329). None of the partners of BOCOM Sci-Tech holds one-third or more of the partnership interests.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

BOCOM Sci-Tech is principally engaged in equity investment business and have invested in companies including, among others, Shanghai Xukang Gene Technology Co., Ltd. (上海序康基因科技股份有限公司), Hangzhou Sumgen Biotechnology Co., Ltd. (杭州尚健生物技術有限公司), and Guangdong Raynovent Biotech Co., Ltd. (廣東眾生睿創生物科技有限公司).

Baidu Ventures

BV Fund II L.P. (“**Baidu Ventures**”) is an exempted limited partnership validly established and legally existing under Cayman law, and is set up as a venture capital institution by Baidu, Inc. Baidu, Inc. is listed on the Nasdaq Global Market (stock code: BIDU) and the Hong Kong Stock Exchange (stock code: 9888). The general partner of Baidu Ventures is Baidu Ventures GP II, L.P., which is ultimately controlled by Baidu, Inc., each of which is an Independent Third Party to the Company. The other partner of Baidu Ventures is Fresco Mobile Limited, holding approximately 99.99% of the partnership interests in Baidu Ventures.

Baidu Ventures concentrates on early-stage AI-based technology innovation companies and devoting to several major fields, including but not limited to, technology innovation and life sciences. The investment portfolio of Baidu Ventures and its related parties in the life sciences related industries include, among others, Beijing DP Technology Co., Ltd. (北京深勢科技有限公司), BCIFlex Medical Technology Co., Ltd. (北京智冉醫療科技有限公司) and Beijing MoleculeMind Technology Co., Ltd. (北京分子之心科技有限公司).

Wenzhou Junzhe

Zhuzhou Wenzhou Junzhe Venture Capital Partnership (Limited Partnership) (株洲市文周君喆創業投資合夥企業(有限合夥)) (“**Wenzhou Junzhe**”) is a limited partnership incorporated under the laws of the PRC and is managed by its general partner Shanghai Wenzhou Investment Management Co., Ltd. (上海文周投資管理有限公司), which in turn is ultimately controlled by Wang Shuguang (王曙光), an Independent Third Party to the Company. None of the limited partners of Wenzhou Junzhe holds one-third or more of the partnership interests in Wenzhou Junzhe.

Wenzhou Junzhe focuses on investment in biopharmaceutical-related areas. Its investment portfolio includes other pharmaceutical companies such as Ab&B Bio-Tech Co., Ltd. JS (江蘇中慧元通生物科技股份有限公司), Zhejiang Zhida Pharmaceutical Co., Ltd. (浙江智達藥業有限公司) and uBriGene Biosciences Co., Ltd. (宜明(北京)生物醫藥有限公司).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Jiangmen Qishun

Jiangmen Qishun Technology Partnership (Limited Partnership) (江門啓順科技合夥企業(有限合夥)) (“**Jiangmen Qishun**”) is a limited partnership incorporated under the laws of the PRC, with its general partner being Li Songsheng (李松勝), an Independent Third Party to the Company. The single largest partner of Jiangmen Qishun is Jing Hao (Shenzhen) Equity Investment Fund Partnership (Limited Partnership) (晶浩(深圳)股權投資基金合夥企業(有限合夥)), which holds approximately 99.80% partnership interests in Jiangmen Qishun. The general partner of Jing Hao (Shenzhen) Equity Investment Fund Partnership (Limited Partnership) is Qian Hai Wan Hui Equity Investment Fund Management (Shenzhen) Co., Ltd. (前海萬匯股權投資管理(深圳)有限公司), an Independent Third Party to the Company. None of the other partners of Jiangmen Qishun hold one-third or more of the partnership interests. Jiangmen Qishun is engaged in investments in medical companies including Hangzhou Sumgen Biotechnology Co., Ltd. (杭州尚健生物技術有限公司).

ABCI

Faithful Way Investment Limited (信運投資有限公司) (“**Faithful Way Investment**”) is a limited liability company incorporated in Hong Kong and is wholly-owned by ABCI Investment Management Limited, which is a wholly-owned subsidiary of Agricultural Bank of China Limited (a company listed on the Hong Kong Stock Exchange (stock code: 1288) and the Shanghai Stock Exchange (stock code: 601288)).

Zhineng Capital

Nantong Ruiyi Equity Investment Partnership (Limited Partnership) (南通瑞宜股權投資合夥企業(有限合夥)) (“**Nantong Ruiyi**”) is a limited partnership incorporated under the laws of the PRC, with the general partner being Nantong Zhineng Private Fund Management Co., Ltd. (南通知能私募基金管理有限公司), which is ultimately controlled and held as to 58.75% equity interests by Guo Yihong (郭奕紅), an Independent Third Party to the Company. None of any of Nantong Ruiyi’s partners holds one-third or more of the partnership interests.

Hangzhou Yantong

Hangzhou Yantong Investment Partnership (Limited Partnership) (杭州岩桐投資合夥企業(有限合夥)) (“**Hangzhou Yantong**”) is a limited partnership registered under the laws of the PRC, with Xie Li (謝力), an Independent Third Party to the Company, being its general partner. Huang Dongdong (黃冬冬), an Independent Third Party to the Company, serves as the single largest partner of Hangzhou Yantong and holds 82.96% of the partnership interests. None of the other partners of Hangzhou Yantong hold one-third or more of the partnership interests.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Hangzhou Yantong is engaged in investments in the biotechnology, medical devices, and information technology industries. The investment portfolio of Hangzhou Yantong include, among others, Hangzhou SynRx Therapeutics Co., Ltd. (杭州聖域生物醫藥科技有限公司) and Zhejiang Curaway Medical Technology Co., Ltd. (浙江伽奈維醫療科技有限公司).

Qingding Beijing

Qingding (Beijing) Management Consulting Partnership (Limited Partnership) (擎鼎(北京)管理諮詢合夥企業(有限合夥)) (“**Qingding Beijing**”) is a limited partnership established in accordance with Chinese law and serves as a joint employee investment plan of GF Qianhe. It is managed by the general partner Mr. He Kuanhua (何寬華), who is the chairman of GF Qianhe and an Independent Third Party. None of the partners of Qingding Beijing hold one-third or more of the partnership interests.

Shanghai Shengcheng

Shanghai Shengcheng Investment Management Partnership (Limited Partnership) (上海聖成投資管理合夥企業(有限合夥)) (“**Shanghai Shengcheng**”) is a limited partnership established under the laws of the PRC. Wu Aimin, an Independent Third Party to the Company, serves as its general partner, single largest partner, and the de facto controller, holding 58.00% of partnership interests in Shanghai Shengcheng. None of the other partners of Shanghai Shengcheng holds one-third or more of the partnership interests. The investment portfolio of Shanghai Shengcheng in the medical and healthcare and related industries include, among others, Puzhong Discovery Medical Technology (Shanghai) Co., Ltd. (普眾發現醫藥科技(上海)有限公司) and Shanghai Chengyi Biotechnology Co., Ltd. (上海誠益生物科技有限公司).

PUBLIC FLOAT

Following the conversion of the Unlisted Shares into H Shares and upon completion of the [REDACTED] (taking into account the [REDACTED] and assuming that the [REDACTED] and the [REDACTED] are not exercised):

- (a) GenFleet HK, Shanghai Kunjin and Auspicious Delight, each of which is a close associate of Dr. Lu and Dr. Lan (our Directors and members of the Single Largest Group of Shareholders), are our core connected persons and a total of [REDACTED] H Shares (taking into account the [REDACTED]) held by them will not be counted towards the public float, representing [REDACTED]% of our issued share capital in aggregate;
- (b) a total of [REDACTED] Unlisted Shares (taking into account the [REDACTED]) held by our Shareholders (including Hongyong Bingde, Sinopharm, Huajin Lingjian, CSPC NBP, Pu'en Guoxin, BOCOM Sci-Tech, Suzhou Jingtian, Wenzhou Junzhe, Nantong Ruiyi and Shanghai Shengcheng) will not be converted into H Shares and [REDACTED] on the Stock Exchange, and therefore will not be counted as part of the public float, representing [REDACTED]% of our issued share capital in aggregate;

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (c) a total of [REDACTED] Unlisted Shares (taking into account the [REDACTED]) held by our Shareholders who are not our core connected persons (nor are accustomed to take instructions from core connected persons of the 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 the Company) will be converted into H Shares and [REDACTED] on the Stock Exchange, and therefore will be counted as part of the public float, representing [REDACTED]% of our issued share capital in aggregate; and
- (d) a total of [REDACTED] H Shares (taking into account the [REDACTED]) issued pursuant to the [REDACTED] will be counted as part of the public float, representing [REDACTED]% of our issued share capital in aggregate.

Based on the above, it is expected that immediately following completion of the [REDACTED], a total of [REDACTED] H Shares (taking into account the [REDACTED]), representing [REDACTED]% of our total share capital upon the completion of the [REDACTED] (assuming that the [REDACTED] and the [REDACTED] are not exercised) will be counted as part of the public float, which is higher than the prescribed percentage of H Shares required to be held in public hands of approximately (i) [REDACTED]% (on the basis of the low-end of the indicative [REDACTED] of HK\$[REDACTED] per H Share); (ii) [REDACTED]% (on the basis of the mid-point of the indicative [REDACTED] of HK\$[REDACTED] per H Share); and (iii) [REDACTED]% (on the basis of the high-end of the indicative [REDACTED] of HK\$[REDACTED] per H Share) under Rule 8.08(1) of the Listing Rules (assuming that the [REDACTED] and the [REDACTED] are not exercised). Immediately following the completion of the [REDACTED], based on the mid-point of the indicative [REDACTED] of HK\$[REDACTED] per H Share, assuming that the [REDACTED] and the [REDACTED] are not exercised and [without taking into account [REDACTED] that may be subscribed by [REDACTED] who will be subject to [REDACTED] requirement pursuant to the respective [REDACTED]], the expected market value of the H Shares being held by the public and not subject to any disposal restrictions at the time of [REDACTED] under Rule 8.08A of the Listing Rules would amount to approximately HK\$[REDACTED]. The Company is expected to satisfy the free float requirement under Rule 8.08A(2) 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 Latest Practicable Date and the [REDACTED]:

	As of the Latest Practicable Date without taking into account the [REDACTED]		Immediately upon completion of the [REDACTED] (taking into account the [REDACTED] and assuming the [REDACTED] and the [REDACTED] are not exercised)		
	Number of Unlisted Shares Held	Approximate ownership percentage	Number of Unlisted Shares Held	Number of H Shares Held	Approximate ownership percentage
Single Largest Group of Shareholders					
– GenFleet HK ^(Note 1)	4,372,465	16.33%	[REDACTED]	[REDACTED]	[REDACTED]%
– Shanghai Kunjin ^(Note 1)	1,383,607	5.17%	[REDACTED]	[REDACTED]	[REDACTED]%
– Auspicious Delight ^(Note 1)	1,000,000	3.73%	[REDACTED]	[REDACTED]	[REDACTED]%
Subtotal	6,756,072	25.23%	[REDACTED]	[REDACTED]	[REDACTED]%
Ourea Biotech	2,241,889	8.37%	[REDACTED]	[REDACTED]	[REDACTED]%
Long Star	1,509,115	5.64%	[REDACTED]	[REDACTED]	[REDACTED]%
Huagai Capital					
– Huagai Xincheng	746,755	2.79%	[REDACTED]	[REDACTED]	[REDACTED]%
– Capital Health	746,755	2.79%	[REDACTED]	[REDACTED]	[REDACTED]%
Subtotal	1,493,510	5.58%	[REDACTED]	[REDACTED]	[REDACTED]%
Hongyong Bingde ^(Note 2)	1,317,182	4.92%	[REDACTED]	[REDACTED]	[REDACTED]%
Shenzhen Capital					
– Shenzhen Hongtu	896,012	3.35%	[REDACTED]	[REDACTED]	[REDACTED]%
– Shenzhen Capital	149,335	0.56%	[REDACTED]	[REDACTED]	[REDACTED]%
Subtotal	1,045,347	3.90%	[REDACTED]	[REDACTED]	[REDACTED]%
Cherami Sun Tour					
– Guangzhou Chenhui	564,325	2.11%	[REDACTED]	[REDACTED]	[REDACTED]%
– Chentu No. 14	280,017	1.05%	[REDACTED]	[REDACTED]	[REDACTED]%
– Chentu No. 15	140,021	0.52%	[REDACTED]	[REDACTED]	[REDACTED]%
Subtotal	984,363	3.68%	[REDACTED]	[REDACTED]	[REDACTED]%
Sinopharm ^(Note 2)	947,615	3.54%	[REDACTED]	[REDACTED]	[REDACTED]%
Suzhou Apricot	776,199	2.90%	[REDACTED]	[REDACTED]	[REDACTED]%
Ningbo Hongjia	887,187	3.31%	[REDACTED]	[REDACTED]	[REDACTED]%
Northern Light Venture Capital					
– Beta Achieve	406,919	1.52%	[REDACTED]	[REDACTED]	[REDACTED]%
– Jichuang Xinyuan	290,557	1.09%	[REDACTED]	[REDACTED]	[REDACTED]%
– Jichuang Fengyuan	116,362	0.43%	[REDACTED]	[REDACTED]	[REDACTED]%
Subtotal	813,838	3.04%	[REDACTED]	[REDACTED]	[REDACTED]%
Panlin Capital					
– Shanghai Panlong	448,006	1.67%	[REDACTED]	[REDACTED]	[REDACTED]%
– Hangzhou Panlin	186,695	0.70%	[REDACTED]	[REDACTED]	[REDACTED]%
– Qingdao Panlin	174,394	0.65%	[REDACTED]	[REDACTED]	[REDACTED]%
Subtotal	809,095	3.02%	[REDACTED]	[REDACTED]	[REDACTED]%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	As of the Latest Practicable Date without taking into account the [REDACTED]		Immediately upon completion of the [REDACTED] (taking into account the [REDACTED] and assuming the [REDACTED] and the [REDACTED] are not exercised)		
	Number of Unlisted Shares Held	Approximate ownership percentage	Number of Unlisted Shares Held	Number of H Shares Held	Approximate ownership percentage
Haibang Venture Capital					
– Shaoxing Haibang	348,788	1.30%	[REDACTED]	[REDACTED]	[REDACTED]%
– Haibang Talent	322,129	1.20%	[REDACTED]	[REDACTED]	[REDACTED]%
<i>Subtotal</i>	670,917	2.51%	[REDACTED]	[REDACTED]	[REDACTED]%
GF Qianhe	476,496	1.78%	[REDACTED]	[REDACTED]	[REDACTED]%
Huajin Lingjian ^(Note 2)	470,271	1.75%	[REDACTED]	[REDACTED]	[REDACTED]%
Hangzhou Taikun	470,271	1.75%	[REDACTED]	[REDACTED]	[REDACTED]%
Yihe Fund					
– Suxin Guokang	186,695	0.70%	[REDACTED]	[REDACTED]	[REDACTED]%
– Suxin Junnuo	186,695	0.70%	[REDACTED]	[REDACTED]	[REDACTED]%
– Suxin Qikang	93,347	0.35%	[REDACTED]	[REDACTED]	[REDACTED]%
<i>Subtotal</i>	466,737	1.74%	[REDACTED]	[REDACTED]	[REDACTED]%
Hangzhou Jingxin	448,006	1.67%	[REDACTED]	[REDACTED]	[REDACTED]%
CSPC NBP ^(Note 2)	441,176	1.65%	[REDACTED]	[REDACTED]	[REDACTED]%
Shanjin Capital					
– Jiaxing Runji	232,525	0.87%	[REDACTED]	[REDACTED]	[REDACTED]%
– Shanjin Anjia	186,695	0.70%	[REDACTED]	[REDACTED]	[REDACTED]%
<i>Subtotal</i>	419,220	1.57%	[REDACTED]	[REDACTED]	[REDACTED]%
Pu'en Guoxin ^(Note 2)	395,607	1.48%	[REDACTED]	[REDACTED]	[REDACTED]%
Shanghai Taiyi	339,919	1.27%	[REDACTED]	[REDACTED]	[REDACTED]%
Shanghai Yuhan	331,702	1.24%	[REDACTED]	[REDACTED]	[REDACTED]%
Huimei Jiankang	307,213	1.14%	[REDACTED]	[REDACTED]	[REDACTED]%
LBC Sunshine II	294,024	1.10%	[REDACTED]	[REDACTED]	[REDACTED]%
Dyee Evergreen	280,017	1.05%	[REDACTED]	[REDACTED]	[REDACTED]%
Suqian Lingdao	192,661	0.72%	[REDACTED]	[REDACTED]	[REDACTED]%
BOCOM Sci-Tech ^(Note 2)	189,048	0.70%	[REDACTED]	[REDACTED]	[REDACTED]%
Suzhou Jingtian ^(Note 2)	186,695	0.70%	[REDACTED]	[REDACTED]	[REDACTED]%
Baidu Ventures	186,695	0.70%	[REDACTED]	[REDACTED]	[REDACTED]%
Wenzhou Junzhe ^(Note 2)	186,695	0.70%	[REDACTED]	[REDACTED]	[REDACTED]%
Jiangmen Qishun	149,335	0.56%	[REDACTED]	[REDACTED]	[REDACTED]%
Faithful Way Investment	118,354	0.44%	[REDACTED]	[REDACTED]	[REDACTED]%
Nantong Ruiyi ^(Note 2)	93,347	0.35%	[REDACTED]	[REDACTED]	[REDACTED]%
Hangzhou Yantong	58,131	0.22%	[REDACTED]	[REDACTED]	[REDACTED]%
Qingding Beijing	11,223	0.04%	[REDACTED]	[REDACTED]	[REDACTED]%
Shanghai Shengcheng ^(Note 2)	8,891	0.03%	[REDACTED]	[REDACTED]	[REDACTED]%
[REDACTED] taking part in the [REDACTED]	–	–	[REDACTED]	[REDACTED]	[REDACTED]%
Total	26,774,063	100.00%	[REDACTED]	[REDACTED]	100.00%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

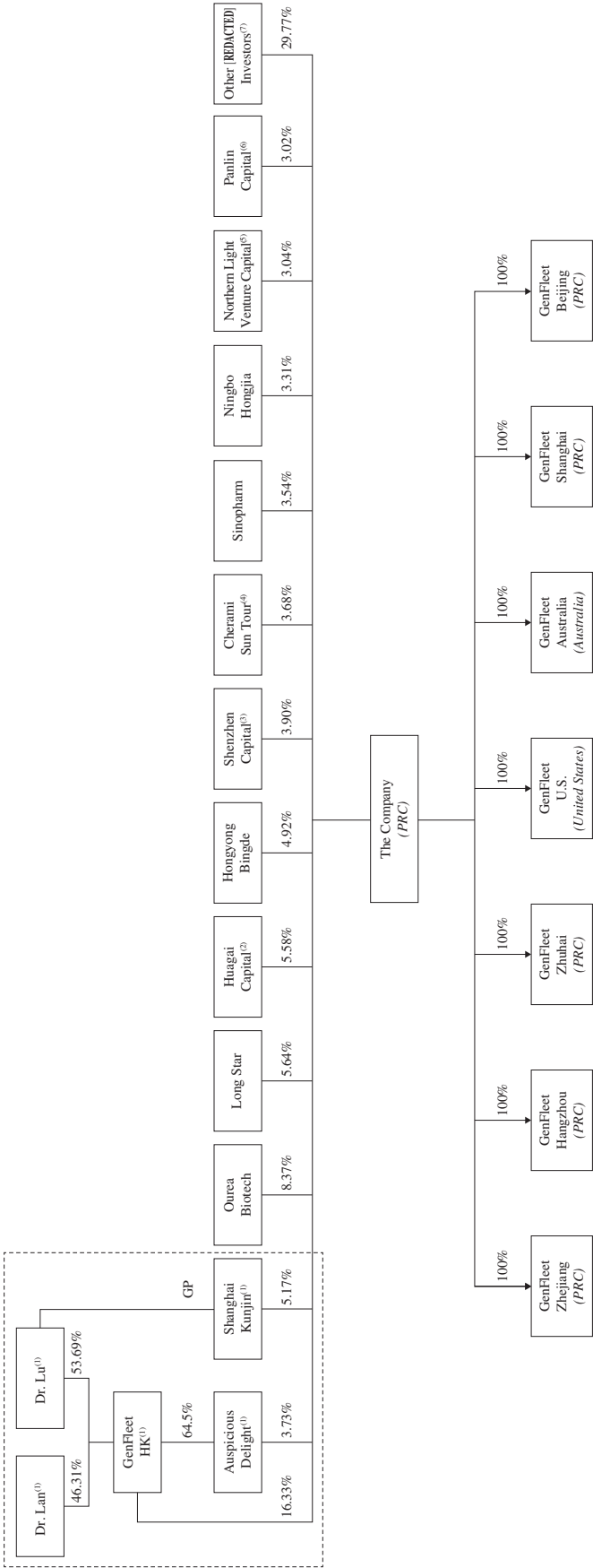
Notes:

- (1) Such Shareholders are close associates of Dr. Lu and Dr. Lan (our Directors and members of the Single Largest Group of Shareholders), and therefore are our core connected persons. Hence, Shares held by such Shareholders will not be counted towards the public float.
- (2) Unlisted Shares held by such Shareholders will not be converted into H Shares and [REDACTED] on the Stock Exchange, and therefore will not be counted as part of the public float.
- (3) Save as otherwise indicated in Note 1 and Note 2 above, H Shares held by other Shareholders and the H Shares to be held by [REDACTED] taking part in the [REDACTED] will be counted as part of the public float.

HISTORY, DEVELOPMENT 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]:



HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

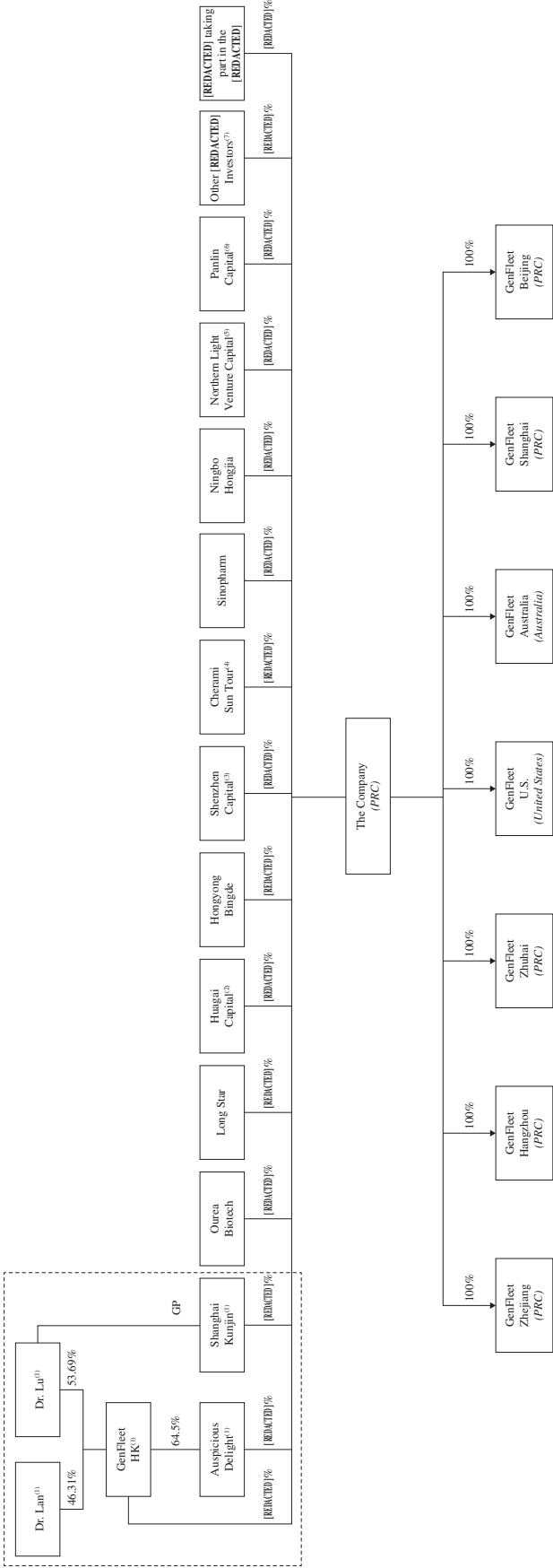
Notes:

1. Shanghai Kunjin and Auspicious Delight are our ESOP Platforms. Dr. Lu, Dr. Lan, GenFleet HK, Shanghai Kunjin and Auspicious Delight are our Single Largest Group of Shareholders and they have entered into a concert party agreement on March 25, 2022. See “— Concert Party Agreement” above for details.
2. Includes Shares held by Huagai Xincheng and Capital Health. See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Huagai Capital” above for details.
3. Includes Shares held by Shenzhen Hongtu and Shenzhen Capital. See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Shenzhen Capital” above for details.
4. Includes Shares held by Chentu No. 14, Chentu No. 15 and Guangzhou Chenhui. See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Cherami Sun Tour” above for details.
5. Includes Shares held by Beta Achieve, Jichuang Xinyuan and Jichuang Fengyuan. See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Northern Light Venture Capital” above for details.
6. Includes Shares held by Shanghai Panlong, Qingdao Panlin and Hangzhou Panlin. See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Panlin Capital” above for details.
7. Other [REDACTED] Investors include other Shareholders, each holding less than 3% shareholding interests in our Company immediately before completion of the [REDACTED]. See “— [REDACTED] Investments” and “— Capitalization of our Company” above for details.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CORPORATE STRUCTURE IMMEDIATELY FOLLOWING COMPLETION OF THE [REDACTED]

The chart below sets out the shareholding structure of our Company immediately following completion of the [REDACTED] (assuming the [REDACTED] and the [REDACTED] are not exercised):



Note: For notes (1) to (7), please see “— Corporate Structure Immediately Before Completion of the [REDACTED]” above. For the Unlisted Shares and H Shares held by each of the Shareholders, please see “— Capitalization of our Company” above.

BUSINESS

OVERVIEW

Who We Are

We are a biopharmaceutical company based in China, featuring a global vision, international collaborations and operations. We adhere to an innovative development strategy, with a vision to propel ourselves with the advancement of science and technology to build a globally competitive biopharmaceutical company.

Upholding the mission of addressing unmet medical needs around the globe, we aspire to bring new and effective treatment options in the fields of oncology, autoimmune and inflammatory diseases. During our endeavor, we have established and leveraged a proven, integrated research and development platform spanning target discovery, molecular discovery and evaluation, translational science and clinical development, as well as key CMC aspects including formulation research, process development and quality analysis. Our technological capabilities include discovery of new molecular entities, novel molecular modalities, investigation of molecular process routes and quality standards, as well as exploration of differentiated clinical development strategy and pathway. Combining these internally accumulated capabilities and external resources of our collaborators and service providers, we have rendered our pipeline products among the frontrunners in both China and the global market, resulting in potentially significant market opportunities and commercial value.

Inspired by scientific advancements and driven by our in-depth research and development capabilities, we had established an evolving product pipeline consisting of eight product candidates, with five under clinical development, as of the Latest Practicable Date. The in-house discovered new drug product, GFH925 (fulzerasib, marketed under the brand name Dupert[®]), has been approved for commercialization in China for the treatment of advanced non-small cell lung cancer (“NSCLC”). We view our pipeline programs as competitive, innovative and market oriented. In total, we possessed 72 issued patents and 117 patent applications (including 8 PCT applications), of which 12 issued patents and 61 patent applications (including 2 PCT applications) are related to our Core Products, as of the Latest Practicable Date, which collectively cover key inventions undergirding our product pipeline. The following chart summarizes the development status of our pipeline products as of the same date.

BUSINESS

Compound	Target	Route of administration	Indication	Pre-Clinical	IND	Phase I	Phase II	Phase III	NDA	Key Regulatory Authority	Expected Upcoming Milestone	Commercial Rights	Partnership
Oncology: RAS-Focused													
★GFH925	KRAS G12C	Oral	advanced stage NSCLC (1 st line, combo) ^(b)							FDA, EMA ⁽²⁾	2025Q4 Enter Phase III	Global (outside of Greater China)	Innovent 信达生物制药
★GFH375	KRAS G12D	Oral	advanced stage PDAC, NSCLC and CRC ⁽³⁾							NMPA	2025Q4 Enter Pivotal trials	Greater China	VERASTEM oncology
GFH276	Pan-Ras	Oral	advanced stage Solid tumors							/	2025H2 IND Approval	Global	
GF5784	ADC (new payload)	Injection	advanced stage Solid tumors							/	2026Q1 IND submission	Global	
Oncology: Others													
GF520A	GDF15 / IL-6	Injection	Cachexia							NMPA	2026H2 Enter Phase II	Global	
GFH009	CDK9	Injection	advanced stage AML ⁽⁴⁾							NMPA	2025H2 Enter Pivotal Trial	Greater China	SELLAS pharmaceuticals
GFH018	TGF-βR1	Oral	advanced stage Various solid tumors							NMPA, Taiwan FDA, TGA ⁽⁵⁾	*	Global	
Immunology													
GFH312	RIPK1	Oral	PBC							NMPA	2026H1 Enter Phase II ⁽⁶⁾	Global	
			PAD with PC							TGA, FDA ⁽⁷⁾	*	Global	

★ = Core Products

NSCLC: non-small cell lung cancer
CRC: colorectal cancer
AML: acute myeloid leukemia

PAD: peripheral artery disease
IC: intermittent claudication
PBC: primary biliary cholangitis

ADC: antibody drug conjugate
PDAC: pancreatic ductal adenocarcinoma

*: Currently assessing the competitive landscape and formulating future clinical development plan.

BUSINESS

Notes:

- (1) Cetuximab used in the clinical trials of GFH925/cetuximab combination is provided by Merck at no cost, pursuant to the Merck Agreement. For additional information, please see “Business — Major Collaboration and Licensing Arrangements — Merck Agreement.” The Merck Agreement only provided for supply of cetuximab used in the EU clinical trials. Cetuximab received regulatory approval for the treatment of patients with EGFR- expressing, RAS wild-type metastatic CRC in the U.S. and EU in 2004. Cetuximab received regulatory approval for the treatment of patients with squamous cell cancer of the head and neck in the U.S. in 2006 and EU in 2004.
- (2) Phase Ib and II clinical trials of the GFH925/cetuximab combination were conducted in the EU. We plan to apply for a Phase III clinical trial of the GFH925/cetuximab combination in the United States and had a pre-IND meeting with the FDA in February 2025 regarding our planned IND application. We also plan to submit a clinical trial application for a Phase III clinical trial of the GFH925/cetuximab combination in selected member states within the jurisdiction of the EMA.
- (3) We granted Verastem an option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China within the specified option exercise period. In January 2025, Verastem exercised the option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China.
- (4) We granted SELLAS an exclusive (even to ourselves), sublicensable and royalty-bearing right and license to develop, manufacture and commercialize GFH009 across all therapeutic and diagnostic uses worldwide outside of Greater China.
- (5) The clinical trial of GFH018 was a single trial with a single protocol conducted at different locations.
- (6) We have completed a Phase I clinical trial for GFH312 in healthy participants in China. We submitted an IND application for a Phase II clinical trial of GFH312 for the treatment of PBC to the NMPA in March 2025 and obtained NMPA’s approval in May 2025. We plan to initiate a Phase II clinical trial of GFH312 for the treatment of PBC in the first half of 2026.
- (7) We have completed a Phase I clinical trial for GFH312 in healthy participants in Australia, and we have no plans for subsequent clinical trials in Australia. In July 2022, we submitted an IND application including results of the Phase I clinical trial in Australia to the FDA for a Phase II clinical trial of GFH312 in patients with PAD with IC. The FDA granted our IND application in August 2022, based on the results of the Phase I clinical trial in Australia.

BUSINESS

Our Diverse Pipeline — Comprehensive Innovative Drug Portfolio Addressing RAS

A substantial part of our pipeline programs revolves around therapies targeting RAS family members, including KRAS, HRAS and NRAS, which are binary switches cycling between “on” (GTP-bound) and “off” (GDP-bound) states during cellular signaling transduction to stimulate or silence downstream proteins to effectuate regulation on cell growth, differentiation and survival. Mutations that result in excessive “on” signal from RAS thus may lead to uncontrolled cell division and growth and ultimately generation of tumor. Indeed, RAS genes are among the most frequently mutated oncogenes, and mutations of RAS family members appear in approximately 30% of all human cancers. RAS-targeting therapies therefore present a potentially significant market opportunity, according to Frost & Sullivan.

However, selective inhibitors against RAS family members remained elusive for decades and RAS proteins earned the reputation of being “undruggable.” The seemingly unsurmountable difficulty was primarily due to the usually smooth shape of RAS proteins, their high affinity for GTP/GDP and the absence of known allosteric sites for small molecule binding. A breakthrough in 2013, when a compound was developed that could bind to a small pocket in the mutant KRAS G12C protein, reinvigorated the field and inspired us to embark on our journey to pursue RAS-targeting therapies. We anchored the breakthrough of RAS-targeting therapies and endeavored to develop related targeted therapies.

GFH925, also known as **fulzerasib** and marketed in China under the brand name **Dupert[®]**, is an in-house discovered, small molecule selective inhibitor of the KRAS G12C protein. It is our lead pipeline product in the RAS-targeting therapies under development. GFH925 is China’s first and globally the third KRAS G12C selective inhibitor approved for marketing, having recently obtained the NDA approval from the NMPA as a Class 1 new drug in August 2024 for second or later-line treatment of advanced NSCLC in China. Clinical results of GFH925 as a monotherapy for NSCLC have demonstrated potentially favorable safety and efficacy profile. For instance, in the single arm registrational Phase II clinical trial that supported the NDA approval, GFH925 was generally well tolerated and demonstrated encouraging antitumor activity in NSCLC patients harboring the KRAS G12C mutation. According to its approved label in China, as of the data cut-off date of December 13, 2023, the confirmed objective response rate (“**ORR**”) was 49.1%, and the median progression-free survival (“**PFS**”) was 9.7 months. While no head-to-head clinical trials were conducted, these values appear to outperform those of the other two FDA-approved selective KRAS G12C inhibitors (sotorasib and adagrasib) in treating NSCLC, for which the ORR was 37.1% and 42.9% and the median PFS was 6.8 months and 6.5 months, respectively.

We are advancing overseas clinical development of GFH925, including a Phase Ib/II clinical trial for the first-line treatment of advanced NSCLC as a combination therapy with cetuximab in countries within the EMA jurisdiction. The FDA also approved our IND application for a Phase III clinical trial of GFH925 for a later-line treatment of refractory metastatic colorectal cancer (“**CRC**”) as a monotherapy. In China, we oversaw preclinical studies of GFH925 and obtained IND approval from the NMPA in July 2021. Innovent is the marketing authorization holder (“**MAH**”) of GFH925 in Greater China, pursuant to an

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agreement between Innovent and our Company entered into in September 2021. We are entitled to an upfront fee, development and regulatory milestone payments, commercial milestone payment, and royalty payments ranging from a single-digit percentage to a low teen percentage of GFH925 annual net sales achieved by Innovent, its affiliates and its sublicensees (although we are not aware of any such sublicensees as of the Latest Practicable Date) upon the achievement of specific thresholds.

GFH375 is an in-house discovered orally bioavailable, potent and selective small molecule inhibitor targeting both the “on” GTP-bound and “off” GDP-bound states of KRAS protein with G12D mutation. According to Frost & Sullivan, GFH375 was among the most advanced orally bioavailable KRAS G12D inhibitors in the world in terms of development status as of the Latest Practicable Date. We are conducting a Phase I/II clinical trial of GFH375 in China to evaluate its safety and efficacy in treating advanced solid tumors with the KRAS G12D mutation. In addition, we have initiated a separate Phase II clinical of GFH375 as a second-line treatment of PDAC. As of the Latest Practicable Date, the Phase I clinical data demonstrated good oral bioavailability and anti-tumor activities of GFH375, with potentially encouraging efficacy in treating multiple tumor types including PDAC and NSCLC.

Leveraging our deep understanding of RAS family members and the experience gained from developing GFH925 and GFH375 in drug design, molecular mechanism and CMC, we have gradually broadened our horizon to build a product candidate matrix that not only covers commonly seen mutant RAS proteins, such as KRAS G12D that similarly features a potentially significant market potential, but also seeks to dampen excessive activities of RAS proteins in a pan-RAS manner. These RAS-targeting therapies under development by us not only include small molecules, such as molecular glue **GFH276**, but also functional antibody synergistic conjugate (“**FAScon**”) **GFS784**, a differentiated type of conjugate of an antibody and a small molecule designed to achieve synergistic effects of both components. The versatility of modalities that we are exploring to address RAS both shows our commitment to fully address this challenging target and potentially enables sequential therapies to overcome drug resistance to mutant-specific treatment options, which we believe would help us maintain a solid footing in the field, and evidences our research and development capabilities in mastering cutting-edge technologies. Our RAS-targeting product candidate matrix also renders us one of the companies with the most comprehensive innovative drug portfolio addressing the RAS proteins in the world, according to Frost & Sullivan.

Our in-depth research and development capabilities, accumulated know-how and acumen in the industry also enable us to pursue a diversified pipeline portfolio, which reaches beyond RAS family members to other therapeutic areas, such as other tumor and adjunctive therapy (a supplementary form of treatment used in conjunction with traditional therapies) and autoimmune and inflammatory diseases. For instance, our product candidate **GFH312** is an in-house developed inhibitor of the kinase RIPK1, a key mediator of cell death and inflammation that potentially allows a broad application in autoimmune, inflammatory and neurodegenerative diseases. We completed a Phase I clinical trial for GFH312 in healthy participants in Australia and China, achieving the predefined safety and pharmacokinetic objectives. GFH312 has also demonstrated differentiation in penetrating the blood-brain barrier

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and its pharmacodynamic profile. After reviewing results from the Australian Phase I clinical trial, the FDA has allowed us to commence a Phase II clinical trial of GFH312 for peripheral artery disease (“**PAD**”) with intermittent claudication (“**IC**”). We are also planning to investigate GFH312 for the treatment of primary biliary cholangitis (“**PBC**”) in China and have obtained NMPA’s approval to conduct a Phase II clinical of GFH312 targeting PBC in May 2025. According to Frost & Sullivan, we are globally the first company that not only has advanced an RIPK1 inhibitor to the Phase II clinical trial-ready stage for the treatment of PAD with IC but also seeks to explore PBC as a potential indication.

We are also developing **GFS202A**, a novel bispecific antibody targeting both GDF15 and IL-6, for the treatment of cachexia, a condition experienced by the majority of patients with malignant tumors and various other chronic diseases, which significantly affects their treatment tolerability, quality of life, and poses life-threatening risks. In multiple preclinical pharmacologic models, once-weekly administration of GFS202A has shown statistically significant improvement in cachexia. As of the Latest Practicable Date, the Phase I clinical trial was ongoing, and there was no FDA- or NMPA-approved drug specifically for the treatment of cachexia. GDF15 has been recently recognized as a key target for treating cachexia, and reported positive data from clinical study of ponesegromab, a monoclonal antibody directed against GDF15 developed by Pfizer, underscored its therapeutic potential. We believe that GFS202A represents a promising treatment of cachexia with the similar mechanism of action and demonstrates a substantial market potential.

Our Collaborations

To maximize the commercial potential and improve the development efficiency of our pipeline products, we actively pursue diversified global business development opportunities. We strategically choose our collaborators to not only allow our strengths to supplement and reinforce each other to create value, but also ensure that development programs of our pipeline products will be among the top priorities in our collaborations. In the past, we have entered into collaborations with Innovent that enabled GFH925 to be smoothly developed and approved for commercialization in China. We also forged collaborations with SELLAS, which has significant expertise in hematological malignancies and solid tumors, on GFH009, a small molecule selective inhibitor of CDK9 designed for the treatment of AML and certain lymphomas, as well as with Verastem, a company focused on RAS pathway-driven cancers, on certain of our RAS-targeting pipeline products. As a testament of its confidence in our clinical development program, we have also secured supplies of cetuximab from Merck for our clinical trials of GFH925 in combination with cetuximab for the first-line treatment of advanced NSCLC. We view our track record of forming beneficial collaborations as a critical driver and validation of our pipeline development.

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Our Management

Our development to date has been guided by an experienced management team comprised of seasoned industry veterans. Our achievements have been enabled under the leadership of our co-founders, Dr. Lu and Dr. Lan, both with decades of experience and successful track records in the pharmaceutical industry, including serving leading roles in Novartis in the United States and Yangtze River Pharmaceutical in China. Dr. Lu also equipped himself with abundant experience in start-up companies such as CStone Pharmaceuticals. With leaders who “know the drill,” we have constantly been steered in the right direction. Other key members of the management team also synergized their efforts and made indispensable contributions to our achievements over time. We have built a well-rounded team to effectuate smooth functioning, consisting of members with in-depth hands-on experience in every key aspect of our business, spanning early-stage discovery, clinical development, CMC and business development.

Our Path Forward

Building on our established research and development capabilities and the extensive progress we have made to date, we aim to accelerate the clinical development of our Core Products, rapidly advance our innovative product pipeline to later stages of development, and expand our portfolio in other oncology, autoimmune and inflammatory diseases. We also aim to continue our global strategy through broad and diverse collaborations to maximize the commercial value of pipelines, internalize certain aspects of drug manufacturing by establishing GMP-compliant facilities, and expand our professional team to continuously propel ourselves ahead as a globally competitive biopharmaceutical company.

OUR STRENGTHS

The first approved selective inhibitor of KRAS G12C in China with a favorable safety and efficacy profile and considerable market potential

Our Core Product GFH925, also known as fulzerasib and marketed in China under the brand name Dupert[®], is an in-house discovered, small molecule selective inhibitor of the KRAS G12C protein. Having received the NDA approval from the NMPA as a Class 1 new drug in August 2024 for the second or later-line treatment of NSCLC harboring the KRAS G12C mutation, it is China’s first and globally the third approved selective inhibitor of KRAS G12C. GFH925 was designated as a breakthrough therapy (“**BTD**”) for advanced NSCLC and was conferred the priority review status by the NMPA, and received marketing approval in merely approximately three years after the NMPA cleared the IND approval in July 2021, underscoring its recognized competitive advantages over existing therapeutic options. We anticipate that GFH925 would qualify for negotiation for inclusion in 2026 National Reimbursement Drug List. GFH925 also received the BTD from the NMPA in May 2023 as a third-line treatment for advanced CRC harboring the KRAS G12C mutation. With over 15 years of patent term remaining for GFH925 as of the Latest Practicable Date, we anticipate to realize commercial returns from GFH925 to fuel our future growth.

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Clinical results of GFH925 as a monotherapy have demonstrated promising safety and efficacy profile. For instance, in the single arm registrational Phase II clinical trial that supported the NDA approval, GFH925 was generally well tolerated and demonstrated encouraging antitumor activity in NSCLC patients harboring the KRAS G12C mutation. According to its approved label in China, as of the data cut-off date of December 13, 2023, the confirmed objective response rate (“**ORR**”) was 49.1%, and the disease control rate (“**DCR**”) was 90.5% in 116 patients. The median progression-free survival (“**PFS**”) was 9.7 months, and the median overall survival (“**OS**”) was 13.3 months. The median duration of response (“**DoR**”) was not reached. While no head-to-head clinical trials were conducted, these values appear to outperform those of the other two FDA-approved selective KRAS G12C inhibitors (sotorasib and adagrasib) in treating NSCLC, for which the ORR was 37.1% and 42.9% and the median PFS was 6.8 months and 6.5 months, respectively. GFH925 also demonstrated a favorable overall safety profile with absence of Grade 3 or above QT interval prolongation or renal impairment observed in the FDA-approved KRAS G12C inhibitors based on reported data, which are critical measurements for cardiac safety and drug clearance.

We are advancing overseas clinical development of GFH925 to unleash its therapeutic potential, including a Phase Ib/II clinical trial for the first-line treatment of advanced NSCLC as a combination therapy with cetuximab, an antibody drug targeting epidermal growth factor receptor (“**EGFR**”), in countries within the EMA jurisdiction. As EGFR is situated upstream of RAS proteins in the signaling pathway and involved in switching on RAS proteins, we reasoned the combination therapy may achieve synergistic effects in damping the EGFR-RAS pathway, which is critical for cell growth.

Interim results from the Phase Ib/II clinical trial in Europe provide preliminary evidence of the synergetic effect of GFH925 and cetuximab, which leads to promising antitumor efficacy compared to GFH925 as a monotherapy or to the current treatment regimens with chemotherapy drugs or PD-(L)1 drugs alone or in combination with chemotherapy. Following completion of the Phase Ib safety confirmation trial and pursuant to the clinical trial protocol, all data review team members, consisting of principal investigators, the CRO medical monitor and we as the clinical trial sponsor, collectively reviewed the clinical data from the Phase Ib trial, and collectively confirmed that the selected dosage of GFH925 is safe, and collectively agreed that the Phase II trial may proceed. As of the 2024 ASCO Cut-off Date, in a cohort of 33 patients who received the combination therapy and received at least one post-treatment tumor assessment, the ORR was 81.8% and the DCR was 100%. In addition, the GFH925/cetuximab combination therapy also led to partial response (“**PR**”) in seven out of ten patients (70.0%) with brain metastasis, demonstrating its promising potential in addressing this challenging medical condition, considering that brain metastasis is a common and lethal complication in NSCLC and typically associated with a poor prognosis. The primary endpoints of the Phase Ib were reached and safety confirmation of Phase Ib trial was completed by the data review team, as required by the clinical trial protocol. We anticipate completing the Phase II trial in the fourth quarter of 2025.

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Updated Phase II data of GFH925’s Phase Ib/II clinical trial in Europe was presented at the 2025 European Lung Cancer Conference (“**ELCC**”) annual meeting. As of January 14, 2025, a total of 47 patients were enrolled and 45 of them received at least one post-treatment tumor assessment: the ORR reached 80% and the DCR reached 100%. The post-treatment evaluation revealed 3 patients achieved complete response; 33 others reached partial response, including one with 100% tumor shrinkage; 57.8% of patients exhibited $\geq 50\%$ tumor shrinkage. As the data cut-off date, the median follow-up time was 12.8 months, and the median progression-free survival was 12.5 months. 34% of enrolled patients had baseline brain metastasis, and the ORR was 71.4% per RECIST 1.1 among brain-metastatic patients who received at least one post-treatment tumor assessment; all non-target lesions of brain-metastatic patients disappeared or remained stable in the course, and brain target lesions of 5 patients exhibited shrinkage. As of January 14, 2025, the combination therapy presented a favorable safety/tolerability profile. TRAEs occurred in 87.2% of patients and the majority of the TRAEs were graded 1-2; 14.9% of patients experienced at least one grade 3 TRAEs; no grade 4-5 TRAEs. 2 patients had treatment-related serious adverse events (“**TRSAE**”) and the TRSAEs were assessed to be merely related with cetuximab; 3 patients experienced TRAEs, unrelated to fulzerasib, leading to dose discontinuation. The KROCUS study demonstrated a relatively low occurrence of dose discontinuation or reduction among different first-line G12C-mutant NSCLC combo studies. No new safety signals were identified compared with fulzerasib or cetuximab as single agent.

We plan to leverage the clinical results in Europe to apply for a Phase III clinical trial in the United States and Europe to evaluate the safety and efficacy of the GFH925/cetuximab combination therapy. We had a pre-IND meeting with the FDA in February 2025, where the FDA provided guidance on the clinical development pathway for fulzerasib in combination with cetuximab as a first-line treatment for patients with locally advanced or metastatic KRAS G12C-mutated NSCLC. Subject to the IND approval by the FDA, we subsequently plan to initiate the Phase III trials in United States in the fourth quarter of 2025. We also intend to submit a clinical trial application for a Phase III clinical trial of the GFH925/cetuximab combination in selected member states within the jurisdiction of the EMA in the second half of 2025.

Beyond NSCLC, we view GFH925 as potentially a valuable therapeutic option in other challenging cancers, such as advanced CRC. The Phase I results of GFH925X1101 and Phase Ib results of a Phase Ib/III clinical trial conducted by Innovent in China for GFH925 in advanced CRC patients revealed an ORR of 45.8% and a DCR of 89.6% for the 600 mg twice-daily dosing regimen. For the patients who had received at least two lines of prior treatment, the ORR was 63.0% and the DCR was 88.9% with the same dosing regimen. A majority of treatment-related adverse events (“**TRAEs**”) were classified as Grade 1 or 2. Overall, the Phase Ib results demonstrated an encouraging efficacy and safety profile in advanced CRC patients with KRAS G12C mutation. We plan to investigate the safety and efficacy of GFH925 monotherapy as a later-line treatment for refractory metastatic CRC harboring the KRAS G12C mutation in the United States. The FDA approved our IND application for a Phase III clinical trial in April 2024.

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Both NSCLC and CRC present large addressable markets, and we view GFH925 as well-positioned to capture the considerable market opportunities. NSCLC is the most common subtype of lung cancer and represents approximately 85% of all lung cancer cases globally. According to Frost & Sullivan, the global incidence of NSCLC increased from 1.9 million cases in 2019 to 2.2 million cases in 2023 and is projected to reach 2.7 million cases by 2032. The KRAS G12C mutation appears in approximately 13% of the NSCLC incidence, however there were only five approved KRAS G12C selective inhibitor drugs globally as of the Latest Practicable Date, including GFH925. The global KRAS G12C inhibitor drug market reached US\$318.9 million in 2023 and is anticipated to reach US\$2,748.4 million in 2032, according to the same source. Given the scarcity of selective inhibitor for KRAS G12C and the prevalence of the mutation, we anticipate GFH925 to establish a solid footing in the market soon after its commercial launch. According to Frost & Sullivan, KRAS G12C mutation appears in approximately 3-4% of the CRC incidence and the global incidence of CRC increased from 1.8 million cases in 2019 to 2.0 million in 2023, and is expected to reach 2.5 million by 2032, we anticipate GFH925 to generate a significant return for us in its application to treat advanced CRC.

A diverse set of innovative RAS-targeting product candidates to harness the therapeutic potential of the RAS pathway

Leveraging our deep understanding of RAS family members and the experience gained from developing GFH925 in drug design, molecular mechanism and CMC, we have gradually broadened our horizon to build a diverse set of innovative RAS-targeting product candidates, which collectively are dubbed our “RAS matrix.” Our RAS matrix not only covers other RAS mutations, such as KRAS G12D addressed by GFH375, but also includes product candidates that are designed to dampen excessive activities of RAS proteins in a pan-RAS manner, including GFH276 and GFS784, which potentially enable sequential therapies to overcome drug resistance to mutant-specific treatment options. Besides particular targets, the breadth and diversity of our RAS matrix is reflected in the modalities we have deployed — from small molecule chemical drug to molecular glue and conjugation of large and small molecules. Overall, we are at the forefront of harnessing the therapeutic potential of the RAS pathway and have become one of the companies with the most comprehensive innovative drug portfolio addressing the RAS proteins in the world, according to Frost & Sullivan.

GFH375, an orally bioavailable small molecule inhibitor of KRAS G12D

KRAS G12D is the most prevalent oncogenic KRAS variant that lacks approved treatment options. It is found in various cancer types, including approximately 35% of pancreatic cancers, 12% of CRC and 4% of NSCLC. In 2023, the incidence of pancreatic cancers, CRC and NSCLC reached 0.5 million, 2.0 million and 2.2 million worldwide, respectively, according to Frost & Sullivan. Therefore, we believe that the addressable patient population and market opportunity for drugs targeting KRAS G12D could be substantial.

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However, development of selective KRAS G12D inhibitors has faced significant challenges. As compared with KRAS G12C protein, the GTPase activity of KRAS G12D protein is further impaired, which makes the “on” to “off” state conversion proceed in a very slow rate and thus keeping KRAS G12D predominantly in the “on” state in tumor cells. Therefore, solely trapping KRAS G12D in its “off”, similar to the action of KRAS G12C inhibitors on KRAS G12C mutant, state may not be able to achieve sufficient target inhibition and thus targeting “on” activity is required for a KRAS G12D inhibitor.

We have overcome the technical challenges to discover GFH375, a small molecule inhibitor that targets KRAS G12D in both “on” and “off” states with a low nanomolar-level binding affinity, as demonstrated in our preclinical studies. GFH375 has also demonstrated preclinical antitumor activity in controlling tumor growth in different animal models. As of the Latest Practicable Date, the Phase I clinical data of GFH375 demonstrated good oral bioavailability and anti-tumor activities, with potentially encouraging efficacy in treating multiple tumor types including PDAC and NSCLC. Furthermore, GFH375 differentiates itself from many other product candidates currently under development for KRAS G12D in terms of route of administration. Formulated as a once-daily, orally available treatment instead of requiring infusions, we believe GFH375 can potentially ease repeated drug administration, improve patient compliance, and therefore potentially increase the overall efficacy of the treatment regimen.

We are conducting a Phase I/II clinical trial of GFH375 in China to evaluate its safety and efficacy in treating advanced solid tumors with the KRAS G12D mutation. We received IND approval from the NMPA in June 2024. We have initiated Phase II part in February 2025. According to Frost & Sullivan, GFH375 was among the most advanced orally bioavailable KRAS G12D inhibitors in the world in terms of development status as of the Latest Practicable Date.

GFH276, a pan-RAS (on) molecular glue

Pan-RAS approaches, which inhibit most oncogenic RAS mutant and wild-type RAS isoforms, have theoretical advantages over their mutant-specific counterparts. First, pan-targeting approaches have the potential to block compensatory activation of wild-type RAS proteins and overcome the acquired resistance to mutant-specific inhibitors. Second, pan-RAS may also have potentially broad applications and enduring therapeutic benefits in various types of cancers, such as pancreatic cancer, which feature significant medical needs and substantial market opportunities. Third, we believe that the pan-RAS approaches may also offer tools applicable to the development of emerging modalities, including our in-house developed bioconjugates, FAScon, featuring a combination of antibody and small molecule drug targeting separate components of the same signaling pathway.

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We believe pan-RAS approaches are differentiated from pan-KRAS approaches that aim to address multiple KRAS mutations at the same time. As of the Latest Practicable Date, a few pan-KRAS inhibitors with publicly available information targeted solely the “off” state of KRAS protein, generally sparing the NRAS and HRAS proteins, according to Frost & Sullivan. Thus, these pan-KRAS “off” state inhibitors are vulnerable to adaptive resistance caused by mitogen-activated protein kinase (“**MAPK**”) reactivation via upstream receptor tyrosine kinase signaling, which drives the resynthesis of KRAS in its “on” state, or through signaling bypass via wild-type NRAS and HRAS proteins. Moreover, pan-KRAS “off” state inhibitors have been found ineffective against certain KRAS mutants, such as KRAS G12R or KRAS Q61X, which exhibit nearly complete impairment of GTPase activity in tumor cells. Therefore, an inhibitor that targets both multiple KRAS mutants and wild-type RAS variants in their active states, termed a pan-RAS “on” state inhibitor, would potentially encompass a larger patient population and yield better clinical outcomes compared to existing pan-KRAS “off” state inhibitors.

GFH276 is our flagship product candidate exploring pan-RAS approaches. It acts as a molecular glue by forming a binary complex with the chaperone protein cyclophilin A (“**CypA**”), which in turn interacts with RAS in the “on” state, regardless of the particular RAS variants. Formation of the tricomplex of GFH276, CypA and RAS leads to steric occlusion and prevents the binding of downstream effector proteins to RAS, therefore disrupting signaling pathways that drive tumor cell growth.

GFH276 demonstrated potential anti-proliferative activity in tumor cell lines that harbor various mutations in the RAS family members or in KRAS G12C mutated cell lines with acquired resistance to sotorasib and adagrasib due to various mechanisms. In addition, the activity of GFH276 was not affected by the upstream receptor tyrosine kinase (“**RTK**”) activation that results in adaptive resistance to covalent inhibitors of KRAS G12C. While exhibiting an inhibitory activity in preclinical studies on par with that of RMC-6236, globally the only Phase III clinical-stage pan-RAS product candidate with a similar mechanism of action, GFH276 demonstrated potentially enhanced bioavailability, lower efficacious dose and less distribution in normal tissues compared to RMC-6236. We believe these features suggest that GFH276 may exhibit a potentially lower efficacious dose and better tolerability in human, which underscore the competitiveness of GFH276 as a pan-RAS inhibitor and its potential to benefit the patient population in need. In June 2025, we submitted to the NMPA an IND application to conduct a Phase I/II clinical of GFH276.

GF5784, a new molecular modality leveraging synergistic effect of large and small molecules

The biopharmaceutical industry has witnessed notable success with bioconjugates, exemplified by antibody-drug conjugates (“**ADCs**”), in the treatment of cancers, resulting in improved treatment outcomes, offering precise delivery of drugs to cancer cells while minimizing damage to healthy tissues. ADCs are typically designed with an antibody that functions to recognize diseased cells and a cytotoxic, small molecule payload to kill that recognized cell.

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We aimed to push the boundary further and explore bioconjugates that realize both precise targeting and synergistic effects of the large and small molecules. To that end, we are developing a class of bioconjugates, which we call “FAScon,” featuring a combination of antibody and small molecule drug targeting separate components of the same signaling pathway. The design of FAScon also incorporates a highly hydrophilic linker, which is sufficiently stable to prevent premature release of payload in the blood and enables conjugation of hydrophobic small molecules at a high drug-to-antibody ratio.

GFS784 is our leading FAScon candidate, consisting of an antibody that blocks EGFR, an upstream cell surface receptor of RAS signal pathway, and a small molecule pan-RAS inhibitor. We believe this design has the potential to deliver promising clinical benefits, given the encouraging results of our clinical development of the GFH925/cetuximab combination, which also targets EGFR and a RAS variant. GFS784 may even outperform the GFH925/cetuximab combination, as it addresses RAS not in a mutant-specific manner but with a broader coverage that is less vulnerable to drug resistance. In our preclinical studies, GFS784 demonstrated durable antitumor activity measured by tumor volume in mice models regardless of their sensitivity to Dxd, a commonly deployed cytotoxic payload in ADCs.

Differentiated clinical programs and market potential beyond our RAS matrix

Our research and development efforts extend beyond the RAS family to build a diversified pipeline portfolio. This is exemplified by GFH312, an in-house developed inhibitor of the kinase RIPK1, and GFS202A, an in-house developed bispecific antibody targeting GDF15 and IL-6. GFH312 is designed to address certain autoimmune and inflammatory diseases, and GFS202A is a potential treatment for cachexia.

GFH312, a small molecule inhibitor of RIPK1

RIPK1 is a master regulator of the cellular decision between pro-survival signaling and death in response to inflammatory and pro-death stimuli. The unique hydrophobic pocket in the allosteric regulatory domain of RIPK1 has enabled the development of highly selective small molecules of its kinase activity. As RIPK1 plays an important role in driving cell death and inflammation, RIPK1 inhibitors potentially possess broad therapeutic applications for the treatment of a wide range of human diseases, such as autoimmune diseases, inflammatory disorders and neurodegenerative conditions. RIPK1 inhibitors thus feature a potentially significant market opportunity. According to Frost & Sullivan, the global addressable patient number of the RIPK1 inhibitor drugs reached 313.2 million in 2023 and is anticipated to reach 367.9 million in 2032.

From the outset, we have been developing GFH312 with an innovative development strategy in mind. In contrast to the majority of other RIPK1-targeting drugs under clinical development, which are focused on central nervous system disorders, such as amyotrophic lateral sclerosis, multiple sclerosis, or Alzheimer’s disease, or autoimmune diseases, like inflammatory bowel disease and psoriasis, we pursue differentiated clinical programs of GFH312 that target diseases that may seriously affect patients’ quality of life yet lack much

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needed attention. To that end, we aim to be an early-mover to investigate application of RIPK1 inhibitors for the treatment of PAD with IC and PBC. In that regard, GFH312 is the first RIPK1 inhibitor drug candidate developed by a Chinese company that has entered the clinical stage, and we are among the world’s earliest drug developers that apply a RIPK1 inhibitor to the treatment of PAD with IC and PBC, according to Frost & Sullivan. For details, see “Industry Overview — Overview of Ripk1 Drug Market — Competitive Landscape of RIPK1 Drug Market.”

PAD is a common condition in which atherosclerosis causes narrowed arteries that reduce blood flow to the arms or legs. Atherosclerosis, the gradual buildup of plaque inside the arteries, is closely linked to inflammation. PAD is estimated to affect over 300 million people worldwide, according to Frost & Sullivan. The classic symptom of PAD, IC, is characterized by exertional leg pain that resolves with rest and is estimated to affect approximately 5.5% of the newly diagnosed patients with PAD and 12.6% of the patients with a prior diagnosis of PAD, according to Frost & Sullivan. Patients with PAD with IC have impaired walking ability, poor functional outcomes, and a reduced quality of life. However, few pharmacological therapy options are available to address the inflammatory mechanisms of PAD. According to Frost & Sullivan, the size of the global PAD drug market is anticipated to reach US\$13.4 billion in 2032.

PBC is a chronic, slowly progressive autoimmune, cholestatic liver disease. It is characterized by progressive inflammation and destruction of small bile ducts, resulting in fibrosis, cirrhosis, and eventually leading to complications of end-stage liver disease and death. The prevalence of PBC reached 1.2 million globally and 287.3 thousand in China in 2023, according to Frost & Sullivan. The four approved treatments for PBC as of the Latest Practicable Date are each with their own limitations. For instance, while ursodeoxycholic acid (“UDCA”) is prescribed for patients with PBC as the current first-line therapy, up to 40% of PBC patients do not achieve a complete response to UDCA as a monotherapy, leaving considerable unmet medical need for novel treatments of PBC, according to Frost & Sullivan.

We believe GFH312 has therapeutic potential to alleviate the root cause of PAD with IC and PBC. In both diseases, inflammation plays a critical role in disease progression and/or manifestation, and GFH312 is demonstrated in our preclinical studies to exhibit not only potent and selective inhibition of RIPK1 but also an anti-inflammatory effect. For instance, in the systemic inflammatory response model, mice administered with GFH312 at dosages of 0.1 mg/kg or 1 mg/kg survived while all mice in the control group deceased in 48 hours. Pharmacodynamic biomarkers of our clinical trial suggest that GFH312 is able to inhibit RIPK1 activation from doses as low as 5 mg to the highest tested dose of 500 mg, which potentially enables a wide therapeutic window. In addition, GFH312 has also demonstrated an ability to penetrate blood-brain barrier, making it suitable for addressing both central nervous system diseases and peripheral diseases.

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We completed a Phase I clinical trial for GFH312 in healthy participants in Australia and China, achieving the predefined safety and pharmacokinetic objectives. After reviewing results from the Australian Phase I clinical trial, the FDA has granted us approval to commence a Phase II clinical trial of GFH312 for PAD with IC. We are also planning to investigate GFH312 for the treatment of PBC in China and have obtained NMPA’s approval to conduct a Phase II clinical of GFH312 targeting PBC in May 2025. According to Frost & Sullivan, we are globally the first company that not only has advanced an RIPK1 inhibitor to the Phase II clinical trial-ready stage for the treatment of PAD with IC but also seeks to explore PBC as a potential indication. We believe our clinical program design potentially paves the way for us to capture opportunities in those and other blue ocean markets where approved RIPK1 inhibitor drugs are scarce.

GFS202A, a novel bispecific antibody for cachexia

GFS202A is a novel bispecific antibody targeting both GDF15 and IL-6, two important cytokines that play crucial roles in inflammatory processes, metabolic regulation, cancer progression and cachexia. Cachexia is a common, life-threatening wasting condition that can significantly impact quality of life in affected patients with cancer or other types of chronic diseases. More than 50% of patients with malignant tumors experience cancer cachexia, characterized by decreased appetite and accelerated catabolism of muscle and adipose tissue during tumor progression, resulting in significant weight loss. These debilitating symptoms not only impact patient tolerability to treatment but also significantly deteriorate their quality of life, with approximately 30% of cancer related death linked to cancer cachexia, according to Frost & Sullivan. As of the Latest Practicable Date, there had been no FDA- or NMPA-approved drug specifically for the treatment of cachexia, according to Frost & Sullivan.

Targeting GDF15 for the treatment of cachexia has been demonstrated as a promising approach, as reflected in the recently announced Phase II results of onsegregromab, a GDF15 antibody under development by Pfizer, in improving body weight, appetite, physical activity and muscle mass in cancer patients. As overexpression of GDF15 and IL-6 is associated with cachexia development and poor survival, we believe a dual neutralization of GDF15 and IL-6 may potentially achieve a better activity compared to targeting GDF15 alone. In multiple preclinical pharmacologic models, once-weekly administration of GFS202A at doses as low as 1.5-4 mg/kg has shown significant improvement in cachexia with weight loss. GFS202A has also demonstrated good tolerability profile in preclinical studies.

We have filed IND application with the NMPA in December 2024 and received the IND approval in March 2025. We initiated Phase I clinical trials for GFS202A monotherapy for the treatment of cachexia in April 2025. We believe that GFS202A represents a potent treatment of cachexia and has the potential to capture a substantial market share.

BUSINESS

A powerhouse with a suite of integrated research and development platforms, CMC expertise and proven business development capabilities

Strong R&D capabilities driven by a suite of integrated technology platforms

Our diversified pipeline portfolio is a natural outcome of our integrated research and development platforms, spanning target discovery, molecular discovery and evaluation, translational science and clinical development, augmented by our expertise in key CMC aspects including formulation research and quality analysis. These research and development capabilities organically constitute our drug development framework, which enables us to efficiently advance pipeline programs through different developmental stages.

- **Target Discovery Platform** is rooted in our endeavor to develop differentiated therapeutic options based on clinical needs. We focus on addressing clinical needs by analyzing disease-related factors such as geographical variations, underlying biological mechanisms, primary or secondary drug resistance, and the specifics of medical treatment modalities. We also consider the mechanisms of drug action and the global clinical strategy landscape. We deploy computational biology, bioinformatics, and artificial intelligence to systematically track, discover and evaluate new drug targets based on clinical needs. By analyzing literature and ongoing research in the field, we are able to identify and prioritize novel and potentially druggable targets. After integrating insights from the developments and future projections of the industry as a whole, our target discovery platform crafts differentiated clinical development strategies tailored to specific disease contexts and therapeutic areas.
- **Molecular Discovery and Evaluation Platform** is a critical component in our new drug development process, which is designed to enhance the efficiency and success rate of our drug discovery efforts. The platform includes integrated molecular design, synthesis and optimization technology, high-quality molecular discovery, efficient drug metabolism and pharmacokinetics research technology, comprehensive biological and drug mechanisms evaluation technology, which together not only accelerate the molecular investigation phase but also significantly increase the likelihood of successful drug development.
- **Translational Science and Clinical Development Platform** encompasses our biomarker clinical translation technology, precision medicine technology for the entire project lifecycle, clinical development technology based on data science and quantitative analysis.

Our accumulated research and development capabilities, as exemplified by the establishment, continuous refinement, and application of these technology platforms, have empowered us to pursue innovative and diversified drug development opportunities. In addition to the pipeline products described above, our pipeline products include GFH018, an oral small molecule inhibitor targeting the receptor TGF- β R1, and GFH009, a highly selective CDK9 inhibitor, both of which have been advanced to the clinical stage.

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We also distinguish ourselves through our ability to strategize and execute multicenter clinical trials across a global scale. We have adopted the strategy to develop many of our pipeline products by conducting global multicenter clinical trials, which significantly enhances the efficiency and effectiveness of advancing our product pipeline. We strategically design and implement clinical plans tailored to the unique needs of each pipeline product based on our profound understanding of the product targets and indications, as well as our deep knowledge of clinical and regulatory environments in major jurisdictions worldwide. We are able to maintain effective communication and collaboration with competent regulatory authorities across various countries and regions and have successfully conducted clinical trials in the multiple jurisdictions.

Differentiated CMC expertise to accelerate drug development and facilitate cost control

Since inception, we have strived to build reliable internal CMC capabilities, so that we are able to continuously optimize the CMC aspects to establish the best practice during product development. Over the years, we have established integrated CMC capabilities covering key aspects from the design of synthetic routes for preclinical candidates to process development and quality control in clinical development and commercial supply of drugs. We have accumulated in-depth expertise in areas including small molecule process development, dosage form selection, formulation determination, formulation process development, drug quality control strategies, development and validation of quality control methodologies, non-GMP kilogram-scale pilot production, and NDA-stage process validation. Such internal and differentiated CMC expertise allows us to accelerate the drug development cycle and better control costs at every stage of drug development.

- ***Accelerate drug development.*** Our CMC functions facilitate a smooth drug development to potentially reduce the overall development timeline. In particular, we develop suitable process and ensure quality control according to applicable drug registration regulations at early stages of product development. This strategy enables us to avoid detours in subsequent development stage resulted from CMC issues that could have been addressed earlier in the process, therefore may improve the overall efficiency of our research and development efforts. We believe our meticulous CMC development for GFH925 since the start of the program facilitated GFH925 to receive marketing approval in China in merely approximately three years after it obtained IND approval. Our CMC functions also undergirds our swift development of the comprehensive RAS matrix in merely seven years since our inception.
- ***Facilitate cost control.*** Our CMC process development capabilities allow us to device efficient synthetic routes and establish measures to ensure consistent and reliable production, thereby contribute to cost control and efficient use of resources. We are able to significantly lower the manufacturing cost of GFH925 by approximately 30-fold primarily through optimizing the process route and production scaling up. Evidencing our reliable capabilities, we will work with Innovent to secure commercial supply of GFH925 in China. We intend to further optimize the CMC aspects of GFH925 and view the ability to substantially reduce the cost of goods, in particular for commercial drug supply, not only as a critical factor for achieving commercial success, but also as our social responsibility to lower the burden for patients in need.

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Diversified collaboration to maximize value of our pipeline programs

To maximize the commercial potential and improve the development efficiency of our pipeline products, we actively pursue diversified global business development opportunities. We strategically choose our collaborators to not only allow our strengths to supplement and reinforce each other to create value, but also ensure that development programs of our pipeline products will be among the top priorities in our collaborations. In the past, we have entered into collaborations with Innovent that enabled GFH925 to be smoothly developed and approved for commercialization in China, as we recognized the advantages of Innovent to advance clinical trials, their established commercialization team as well as extensive marketing channel. We also forged collaborations with SELLAS, which has significant expertise in hematological malignancies and solid tumors, on GFH009, a small molecule selective inhibitor of CDK9 designed for the treatment of AML and certain lymphomas, as well as with Verastem, a company focused on RAS pathway-driven cancers, on certain of our RAS-targeting pipeline products. As a testament of its confidence in our clinical development program, we have also secured supplies of cetuximab from Merck for our clinical trials of GFH925 in combination with cetuximab for the first-line treatment of advanced NSCLC. These collaborations are strategically designed to leverage the strengths of each party, combining our own research and development capabilities with the extensive commercial and development expertise of such collaborators. We view our track record of forming beneficial collaborations as a critical driver of our pipeline development.

Seasoned Discovery and Development Leadership Team with Successful First-to-Market Drug Experience

In addition to their complimentary technical skillsets, our founders, Dr. Lu and Dr. Lan, share the same vision of building a world-class research and development team that is capable of providing and delivering first-to-market drugs candidates with significant global market value.

The leadership experiences of our Chairman and co-founder, Dr. Lu, span from early-stage research and development projects and technology platform building to executing pipeline strategy, as well as corporate fundraising. Prior to founding our Company, Dr. Lu led the inception of CStone Pharmaceuticals as the senior vice president for operation and spearheaded its initial pipeline advancement. Before that, he served as the chief scientific officer for Yangtze River Pharmaceuticals and Gloria Pharmaceutical, responsible for the portfolio strategy and execution. Dr. Lu served as a founder of the biology business unit for WuXi AppTec, part of which later became WuXi Biologics in China. Dr. Lu started his career as a project team lead at Wyeth Pharmaceuticals, and then moved to Novartis to build up a novel technical platform for the lead optimization and compound profiling in the United States.

As an experienced chemist and our co-founder and Chief Executive Officer, Dr. Lan is instrumental in our operation, project execution and organizational buildup. Dr. Lan brings to us a wealth of cross-border research and development experience spanning a number of large pharmaceutical companies such as Novartis in the United States and Jiangsu Hengrui Pharmaceuticals in China. Dr. Lan had a longstanding working relationship with Dr. Lu at Yangtze River Pharmaceuticals in China, and more importantly, they share a common vision of building up a globally competitive innovative biotech company in China.

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Since our inception, our core team has grown and excelled along with the maturation of our key pipeline programs. Notably, our Core Product GFH925 (fulzerasib), the first-in-China KRAS G12C inhibitor, advanced from project initiation to NDA approval in merely six years, including the time from IND to NDA approval within two and a half years after collaborating with Innovent. We have integrated our team well within our proprietary development system, which encompasses all the way from research and development to commercialization. This is also a reflection of the pursuit of corporate excellence focusing on cross-functional collaboration and continued process optimization.

We have built a well-rounded discovery and development leadership team consisting of members with strong technical expertise in every key aspect of the drug development process, spanning from early-stage discovery to clinical development, and CMC.

OUR STRATEGIES

Advance our Core Products and leading product candidates through global clinical development

Leveraging our strong in-house clinical and development capabilities, we aim to continue to efficiently advance our Core Products through various clinical development programs. We also plan to maximize the therapeutic value of our assets by expanding the number of indications and combinations for our product candidates. We anticipate achieving significant development milestones for our Core Products and other leading product candidates.

- **GFH925.** We are conducting a Phase Ib/II clinical trial of the GFH925/cetuximab combination therapy in Europe and anticipate completing that trial in the fourth quarter of 2025. We plan to leverage clinical results of the European trial to apply for a Phase III clinical trial in the United States for the same combination therapy. We had a pre-IND communication with the FDA in February 2025 regarding our potential IND application for a Phase III clinical trial for the combination therapy. Once approved, we intend to commence the Phase III trial in the United States in the fourth quarter of 2025. Furthermore, the FDA also approved our IND application for a Phase III clinical trial of GFH925 for a later-line treatment for refractory metastatic CRC harboring the KRAS G12C mutation.
- **GFH375.** We are conducting a Phase I/II clinical trial of GFH375 in China to evaluate its safety and efficacy in treating advanced solid tumors with the KRAS G12D mutation. We received IND approval from the NMPA in June 2024. We completed the Phase I part of the clinical trial in January 2025 and initiated the Phase II part in February 2025. In addition, we have initiated a separate Phase II clinical of GFH375 as a second-line treatment of PDAC.

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- **GFH312.** We have completed a Phase I clinical trial for GFH312 in healthy participants in Australia and China, respectively. We received the IND approval for one Phase II clinical trial of GFH312 for the treatment of PAD with IC in the United States and expect to initiate the Phase II clinical trial to evaluate safety and efficacy of GFH312 monotherapy in patients with PAD with IC. In addition, we have submitted the Phase II trial application of GFH312 for the treatment of PBC to the NMPA in November 2024 and obtained NMPA’s approval in May 2025. We plan to initiate the clinical trial in the the first half of 2026.

Advancing and replenishing our other innovative product pipeline with a focus on the comprehensive RAS pathway product matrix

We strive to achieve and deliver major development milestones for our RAS matrix pipeline products in the coming years. We believe the anticipated milestones will help us solidify our position and competitive advantage in the field of RAS-targeting therapies.

As our other RAS matrix product candidates were currently in the preclinical stage as of the Latest Practicable Date, we intend to advance them to the clinical stage and submit IND applications once ready.

We will closely monitor the development of market landscape and technology advancements to formulate or adjust future clinical development plans for other pipeline products, including GFH009 and GFH018. For additional information, see “— Our Product Pipeline” and “Future Plans and Use of [REDACTED].” We will also explore additional drug development opportunities that bear significant market potential, particularly in the fields of oncology, autoimmune disorders and inflammatory diseases, to replenish our product pipeline. Once our pipeline products approach commercialization in markets where we retain exclusive commercialization rights, we will determine the commercialization arrangement and, if warranted, enter into strategic alliances to conduct adequate promotion and achieve smooth market penetration.

Execute global strategy through broad and diverse collaborations in commercialization arrangements, business development and pipeline development

To maximize the unique value of our product candidates and fully realize their clinical potential, we will continue to actively collaborate with both existing and prospective partners to explore potential opportunities for indication expansion and combination therapies among our pipeline product candidates and with other potential treatments.

Going forward, we plan to continue and further establish strategic partnerships with leading international and domestic pharmaceutical companies to expand our geographic coverage, actively explore the global business layout, and accelerate the global development of our product candidates, with the ultimate objective to maximize the value of our product pipeline. We may also explore future collaboration opportunities for the research and development of some of our product candidates to improve the chance of successful product development and the efficient usage of our resources.

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We plan to adopt multi-level development strategies keyed to the development status of product candidates. We may seek and establish strategic partnerships with leading international and domestic pharmaceutical companies to leverage their experience in early-stage drug discovery, clinical development and manufacturing to expediently advance product development. As our product candidates move towards later-stage of clinical trial and/or near commercialization, we may pursue out-licensing arrangements with large multinational companies or prestigious local pharmaceutical companies to realize the commercial value of our product candidates at a potentially earlier stage.

We anticipate our overall business development efforts to revolve around and eventually lead to gaining favorable brand image and name recognition for our Company, realizing the global market potential of our products, and maximizing the commercial value of our product portfolio.

Establish a GMP-compliant formulation manufacturing facility

We have a diverse pipeline of products, including small molecules, functional antibody synergetic conjugates, as well as molecular glues. As a biopharmaceutical company, we focus on a comprehensive and balanced development across the value chain of the entire biopharmaceutical industry. The clinical development and commercialization of our pipeline products require significant formulation production. To leverage our established CMC capabilities, including drug product and formulation production, reduce our operational costs and cover the full cycle of the clinical development process, besides continuing to cooperate with existing CMOs or CDMOs, we plan to commence the construction of a GMP-compliant formulation manufacturing facility that meets international standards and would enhance our manufacturing capabilities especially in preparing the formulations for our pipeline products.

We believe constructing such a facility and strengthening our in-house manufacturing capabilities would ensure that our products meet the clinical and marketing approval requirements of regulatory authorities and could further establish our advantages in the development of challenging products. As of the Latest Practicable Date, we were in the process of detailing the plan for the facility construction.

Attract, retain and motivate high-caliber talents across our business functions

We are a biopharmaceutical company dedicated to development and commercialization of drug products. Our employees are key to our growth strategy and ability to develop and commercialize innovative drugs, and hence we will continue to recruit, train, promote and retain talents with relevant background and experience in the pharmaceutical and biotech industries. To fully support our continued growth, we will continue to invest in attracting and retaining top talents in various aspects of our operations around the world, including discovery, research and development, manufacture and commercialization. This initiative is a key part of our strategy to enrich our talent pool. In addition, we will continue to cultivate our culture of collaboration and efficiency and refine our organizational structure to empower our leaders and team members to take ownership of their work and reward their contributions. Accordingly, by

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investing in the advanced education of our staff, we not only enhance their expertise and skills but also foster a culture of continuous learning and innovation within our organization. This approach ensures that our team remains at the forefront of industry knowledge and expertise, significantly benefiting our research, development, and overall business performance.

OUR PRODUCT PIPELINE

As of the Latest Practicable Date, we had established a diverse and innovative pipeline featuring eight pipeline products. A substantial part of our pipeline programs revolves around therapies targeting RAS family members, which are key regulators during cellular signaling transduction to stimulate or silence downstream proteins to effectuate regulation on cell growth, differentiation and survival. In particular, one of our Core Products, GFH925 (fulzerasib, marketed under the brand name Dupert[®]), has been approved for commercialization in China for the treatment of NSCLC. Another Core Product of ours, GFH375, is one of the most advanced orally bioavailable inhibitors of KRAS G12D in terms of development status as of the Latest Practicable Date. In addition to RAS, we also explore treatment options for autoimmune and inflammatory diseases, including our product candidate GFH312, and other cancer-related therapies. We believe that this diverse range of pipeline products reflects our commitment to innovation and addressing various medical needs through advanced therapeutic approaches. The following chart summarizes the development status of our pipeline product candidates as of the Latest Practicable Date.

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Compound	Target	Route of administration	Indication	Pre-Clinical	IND	Phase I	Phase II	Phase III	NDA	Key Regulatory Authority	Expected Upcoming Milestone	Commercial Rights	Partnership
Oncology: RAS-Focused													
★GFH925	KRAS G12C	Oral	advanced stage NSCLC (1 st line, combo) ⁽¹⁾							FDA, EMA ⁽²⁾	2025Q4 Enter Phase III	Global (outside of Greater China)	Innovent 信达生物制药
★GFH375	KRAS G12D	Oral	advanced stage PDAC, NSCLC and CRC ⁽³⁾							NMPA	2025Q4 Enter Pivotal trials	Greater China	VERASTEM ONCOLOGY
GFH276	Pan-Ras	Oral	advanced stage Solid tumors							/	2025H2 IND Approval	Global	
GF5784	ADC (new payload)	Injection	advanced stage Solid tumors							/	2026Q1 IND submission	Global	
Oncology: Others													
GF520A	GDF15 / IL-6	Injection	Cachexia							NMPA	2026H2 Enter Phase II	Global	
GFH009	CDK9	Injection	advanced stage AML ⁽⁴⁾							NMPA	2025H2 Enter Pivotal Trial	Greater China	ΣELLAS CELLS
GFH018	TGF-βR1	Oral	advanced stage Various solid tumors							NMPA, Taiwan FDA, TGA ⁽⁵⁾	*	Global	
Immunology													
GFH312	RIPK1	Oral	PBC							NMPA	2026H1 Enter Phase II ⁽⁶⁾	Global	
			PAD with PC							TGA, FDA ⁽⁷⁾	*	Global	

★ = Core Products

NSCLC: non-small cell lung cancer
CRC: colorectal cancer
AML: acute myeloid leukemia

PAD: peripheral artery disease
IC: intermittent claudication
PBC: primary biliary cholangitis

ADC: antibody drug conjugate
PDAC: pancreatic ductal adenocarcinoma

*: Currently assessing the competitive landscape and formulating future clinical development plan.

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Notes:

- (1) Cetuximab used in the clinical trials of GFH925/cetuximab combination is provided by Merck at no cost, pursuant to the Merck Agreement. For additional information, please see “Business — Major Collaboration and Licensing Arrangements — Merck Agreement.” The Merck Agreement only provided for supply of cetuximab used in the E.U. clinical trials. Cetuximab received regulatory approval for the treatment of patients with EGFR- expressing, RAS wild-type metastatic CRC in the U.S. and EU in 2004. Cetuximab received regulatory approval for the treatment of patients with squamous cell cancer of the head and neck in the U.S. in 2006 and EU in 2004.
- (2) Phase Ib and II clinical trials of the GFH925/cetuximab combination were conducted in the EU. We plan to apply for a Phase III clinical trial of the GFH925/cetuximab combination in the United States and had a pre-IND meeting with the FDA in February 2025 regarding our planned IND application. We also plan to submit a clinical trial application for a Phase III clinical trial of the GFH925/cetuximab combination in selected member states within the jurisdiction of the EMA.
- (3) We granted Verastem an option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China within the specified option exercise period. In January 2025, Verastem exercised the option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China.
- (4) We granted SELLAS an exclusive (even to ourselves), sublicensable and royalty-bearing right and license to develop, manufacture and commercialize GFH009 across all therapeutic and diagnostic uses worldwide outside of Greater China.
- (5) The clinical trial of GFH018 was a single trial with a single protocol conducted at different locations.
- (6) We have completed a Phase I clinical trial for GFH312 in healthy participants in China. We submitted an IND application for a Phase II clinical trial of GFH312 for the treatment of PBC to the NMPA in March 2025 and obtained NMPA’s approval in May 2025. We plan to initiate a Phase II clinical trial of GFH312 for the treatment of PBC in the first half of 2026.
- (7) We have completed a Phase I clinical trial for GFH312 in healthy participants in Australia, and we have no plans for subsequent clinical trials in Australia. In July 2022, we submitted an IND application including results of the Phase I clinical trial in Australia to the FDA for a Phase II clinical trial of GFH312 in patients with PAD with IC. The FDA granted our IND application in August 2022, based on the results of the Phase I clinical trial in Australia.

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OUR RAS MATRIX PIPELINE PRODUCTS

Core Product GFH925: A Small Molecule Inhibitor of KRAS G12C

Overview

GFH925, also known as fulzerasib and marketed in China under the brand name Dupert[®], is an in-house discovered, potent and highly selective small molecule inhibitor of KRAS protein glycine-to-cysteine mutation at position 12 (“**G12C**”). It demonstrates substantial activity against KRAS G12C mutant tumors. KRAS is one of the most frequently mutated oncogenes in human cancers, and G12C is a very common mutation in the KRAS gene, accounting for 40% of all KRAS mutations in NSCLC according to Frost & Sullivan.

The GFH925 monotherapy received two BTDs for treating advanced KRAS G12C-mutant NSCLC and CRC patients from the NMPA in January 2023 and May 2023, respectively. In August 2024, the NMPA approved the NDA for GFH925 for the treatment of NSCLC, making it the first KRAS inhibitor approved in Mainland China and the third globally. Innovent commenced the commercial sales of GFH925 in Mainland China shortly after the approval in the same month. Innovent is the MAH of GFH925 in Greater China, pursuant to an agreement between Innovent and our Company. For additional information, see “— Licenses, Rights and Obligations.” We are advancing the clinical development of GFH925 in overseas regions to unleash its therapeutic potential, including as a combination therapy with cetuximab for the first-line treatment of advanced NSCLC harboring KRAS G12C mutation, currently in a Phase Ib/II clinical trial in Europe.

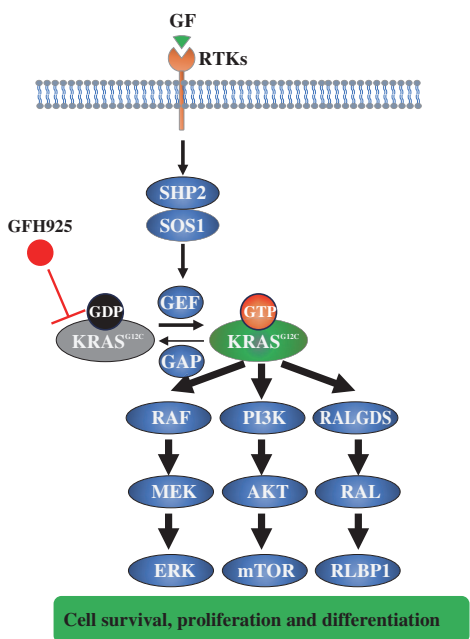
Mechanism of Action

RAS exhibits a guanosine triphosphatase (“**GTPase**”) activity. A GTPase binds to the nucleotide guanosine triphosphate (“**GTP**”) and removes one phosphate group from the GTP in a process called hydrolysis to generate guanosine diphosphate (“**GDP**”). RAS cycles between “on” (GTP-bound) and “off” (GDP-bound) states during cellular signaling transduction to stimulate or silence downstream proteins to effectuate regulation on cell growth, differentiation and survival. Three RAS genes encode for protein isoforms, namely KRAS, Harvey Ras (“**HRAS**”) and Neuroblastoma Ras (“**NRAS**”). KRAS is one of the most frequently mutated oncogenes in human cancers. KRAS mutations are detected in nearly 90% of pancreatic cancer, 30-40% of colon cancer, and 15-20% of lung cancer patients according to Frost & Sullivan. These mutations are often associated with resistance to targeted therapies and poor outcomes in cancer patients. G12C is one of the most common mutations in KRAS gene, accounting for approximately 15% of all KRAS mutations, and it is also the most prevalent variant of KRAS mutations in NSCLC according to Frost & Sullivan. The KRAS G12C variant leads to enhanced proliferation and survival of tumor cells.

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GFH925 is a small molecule that exhibits a highly selective inhibitory effect on the KRAS G12C mutation site, through covalent, irreversible modification of cysteine residues in the KRAS G12C protein. Different from reversible inhibitors, GFH925 functions by forming a chemical bond with the mutated cysteine residue, which cannot be broken apart in the cell once formed. In this manner, GFH925 impedes the GTP/GDP exchange, an essential step in pathway activation, and disrupts the mutant KRAS protein from interacting with downstream proteins. By down-regulating the activation level of the KRAS protein, GFH925 results in subsequent down-regulation of the downstream signaling pathways, effectively inducing apoptosis in tumor cells and arresting the cell cycle, leading to an efficient antitumor effect.

The diagram below illustrates the mechanism of action of GFH925:



1. In normal cells, wild type KRAS cycles between active and inactive states, serves as a molecular switch to transmit upstream signaling to downstream pathways and thus regulates cell survival, proliferation and differentiation.
2. KRAS G12C mutation impairs GAP-mediated GTP hydrolysis process, hyperactivates downstream pathway, leads to uncontrolled cell proliferation and ultimately promotes tumorigenesis.
3. GFH925 traps KRAS G12C in its inactive state via covalent modification, blocks downstream pathway signaling and inhibits tumor growth.

Source: Company information

Abbreviations: ERK: extracellular signal-regulated kinase; GAP: GTPase-Activating Protein; GER: Guanine Exchange Factor; GF: growth factor; MEK: MAPK/ERK; mTOR: mechanistic target of rapamycin; PI3K: phosphoinositide 3-kinases; RAF: rapidly accelerated fibrosarcoma; RALGDS: Ral guanine nucleotide dissociation stimulator; RLBPI: retinaldehyde-binding protein 1; RTK: receptor tyrosine kinase; SHP2: Src homology 2 domain-containing phosphatase 2; SOS1: son of sevenless 1

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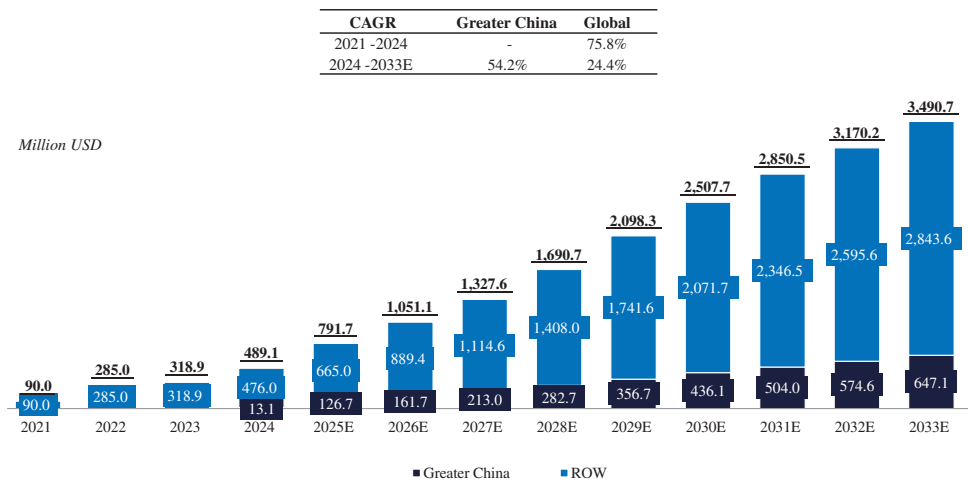
Market Opportunity and Competition¹

RAS drug market is increasingly competitive with major players such as Mirati (acquired by Bristol Myers Squibb (NYSE: BMY) in 2024) and Revolution Medicines (NASDAQ:RVMD) actively expanding their RAS matrix. One of the most common mutations in the KRAS gene is G12C, accounting for approximately 15% of all KRAS mutations, and it is also the most prevalent variant of KRAS mutations in NSCLC. The KRAS G12C mutation occurs in approximately 13% of NSCLC, in 3% to 4% of CRC, and other solid tumors.

GFH925 (fulzerasib) was the first KRAS G12C inhibitor drug that received approval for commercialization in China. Globally, there were four other KRAS G12C inhibitor (adagrasib, sotorasib, garsorasib and glecirasib) drugs that have been approved as of the Latest Practicable Date. Among them, garsorasib, glecirasib and fulzerasib received received approval for commercialization in China as of the same date. As of Latest Practicable Date, there were more than 20 KRAS G12C inhibitor candidates being clinically developed globally.

With the continuous market penetration of the commercialized KRAS G12C inhibitor drugs and development of new drugs, the global KRAS G12C inhibitor drug market is expected to grow rapidly from US\$489.1 million in 2024 to US\$3,490.7 million in 2033 with a CAGR of 24.4%. The diagram below sets forth the historical and projected global market size of KRAS G12C inhibitor drugs from 2021 to 2033.

Global KRAS G12C Inhibitor Drug Market, 2021-2033E



Source: Frost & Sullivan Analysis

Note

1. Market information and statistics set out in this subsection have been extracted from an report prepared by Frost & Sullivan.

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We are advancing overseas clinical development of GFH925 to unleash its therapeutic potential, including a Phase Ib/II clinical trial for the first-line treatment of advanced NSCLC as a combination therapy with cetuximab and as a later-line treatment of refractory metastatic CRC as a monotherapy.

Among the common driver genes identified in NSCLC, KRAS mutations are one of the most prevalent mutations, accounting for approximately 20% of cases, and KRAS G12C mutation alone is present in approximately 13% of all NSCLC cases. The global incidence of NSCLC increased from 1,937.6 thousand in 2019 to 2,203.5 thousand in 2024, and is expected to further increase to 2,743.2 thousand in 2032. In China, the incidence of NSCLC increased from 830.2 thousand in 2019 to 946.7 thousand in 2024, and is expected to further increase to 1,119.3 thousand in 2033. The 5-year survival rate for lung cancer in China is comparable to that in the United States, both standing at approximately 20%, which is significantly lower than that of other major cancers. The low survival rate and deficient treatment underscore the critical need for improved therapeutic options. With the existing treatment regimen, many patients experience rapid disease progression and unsatisfied outcomes, and there is a lack of targeted therapies for KRAS mutations in NSCLC. GFH925 (fulzerasib) became the first commercially available KRAS G12C inhibitor drug in China, which offers novel solution for patients with KRAS G12C mutations, and potentially addresses the gap in targeted therapies for this mutation. However, GFH925, as a KRAS G12C inhibitor, is not designed or expected to eliminate drug resistance or certain side effects, such as gastrointestinal toxicity, associated with other approved KRAS G12C inhibitor drugs. See “Industry Overview — Overview of KRAS G12C Drugs — The impact on the market potential and acceptance of GFH925” for comparison of GFH925 with other approved KRAS G12C inhibitor drugs.

RAS is one of the most frequently mutated oncogenes in CRC, and KRAS G12C mutation alone appears in approximately 3-4% of the CRC incidence. The global incidence of CRC increased from 1,849.1 thousand in 2019 to 2,005.2 thousand in 2024, and is expected to further increase to 2,472.6 thousand in 2033. In China, the incidence of CRC increased from 477.1 thousand in 2019 to 542.4 thousand in 2024, and is expected to further increase to 642.0 thousand in 2033. CRC ranks as the second most lethal and the third most commonly-diagnosed cancer globally. The incidence of CRC among the younger population has also been rising. We view GFH925 as potentially a valuable therapeutic option in advanced CRC.

Advantages of GFH925

GFH925 (fulzerasib) is the first approved KRAS G12C inhibitor for the treatment of NSCLC in China. We believe that GFH925 has the following advantages:

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Highly selective inhibition of the KRAS G12C protein mutant

In preclinical studies evaluating the binding of GFH925 to human KRAS recombinant proteins, selective covalent modification of GFH925 to the cysteine site at position 12 on the KRAS G12C protein was observed. Notably, no covalent modification was detected on cysteine sites other than G12C in KRAS G12C or for any cysteines on the KRAS wild-type proteins. Furthermore, GFH925 dose-dependently inhibited nucleotide exchange in human KRAS G12C recombinant proteins, with a half-inhibitory concentration (“IC₅₀”) of 29 ± 3 nM. Importantly, GFH925 did not exhibit inhibitory activity against KRAS wild-type protein. We believe that GFH925 selectively targets the KRAS G12C mutant protein with high potency in such preclinical studies.

Favorable safety profile

GFH925 has demonstrated favorable safety profiles in clinical trials. For instance, in the clinical trial in China that supported the NDA approval of GFH925, there were no Grade 3 or above QT interval prolongation or renal impairment observed in the FDA-approved KRAS G12C inhibitors, which are critical measurements for cardiac safety and drug clearance. There was also lower incidence of treatment-related adverse events than those of another FDA-approved KRAS G12C inhibitor based on reported data, although no head-to-head comparisons were conducted in the clinical trial.

In preclinical studies using Sprague-Dawley rat and Beagle dog models, GFH925 also demonstrated a favorable safety profile. In particular, GFH925 had no impact on the central nervous system or the respiratory system of Sprague-Dawley rats. It also had no impact on cardiovascular parameters or affect electrocardiographic parameters in a 28-day repeated dose toxicity test in Beagle dogs.

Validated antitumor effect

GFH925 has also demonstrated the antitumor effect in NSCLC patients harboring the KRAS G12C mutation. For instance, in the single arm registrational Phase II clinical trial that supported the NDA approval, the confirmed ORR was 49.1%, and the DCR was 90.5% in 116 patients as of the data cut-off date of December 13, 2023. As of the same date, the median PFS was 9.7 months, and the median OS was 13.3 months. The median DoR was not reached. While no head-to-head trials were conducted, these values appear to outperform those of the other two FDA-approved selective KRAS G12C inhibitors (sotorasib and adagrasib) in treating NSCLC, for which the ORR was 37.1% and 42.9% and the median PFS was 6.8 months and 6.5 months, respectively.

In preclinical mouse xenograft tumor models, GFH925 demonstrated clear activities in controlling tumor growth as measured by the size of tumor. In preclinical studies, the tumor inhibitory effects of GFH925 were similar to or better than those of an FDA-approved KRAS G12C inhibitor.

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Potential for combination therapy to realize better clinical outcomes

While RAS is a critical component in its associated cellular signaling pathways, there are other potentially druggable targets in those pathways that, once addressed in combination with RAS, may lead to better inhibitory effect of the pathways and result in potentially more favorable clinical outcomes. For instance, in an ongoing Phase Ib/II trial that we are conducting in Europe to evaluate the safety and efficacy of the GFH925/cetuximab combination therapy as a first line treatment for advanced NSCLC harboring KRAS G12C mutation, the ORR was 81.8% and the DCR was 100% in a cohort of 33 patients as of the 2024 ASCO Cut-off Date. In addition, the combination therapy also exhibited a favorable safety profile, further suggesting its potential as a competitive and potentially advantageous treatment option. These results provide preliminary evidence of the synergetic effect of GFH925 and cetuximab, which leads to promising antitumor efficacy compared to GFH925 as a monotherapy or to the current treatment regimens with PD-(L)1 drugs alone or in combination with chemotherapy. According to Frost & Sullivan, the combination therapy of GFH925 and cetuximab for the treatment of NSCLC that we are investigating is among the first of its kind to co-target KRAS G12C and EGFR in terms of the clinical development status.

Summary of Clinical Trials

We retain all rights of GFH925 in jurisdictions outside of Greater China, and we were conducting clinical development of GFH925 in combination with cetuximab in Europe, as of the Latest Practicable Date. In Greater China, we have exclusively out-licensed the development, manufacturing and commercialization rights of GFH925 to Innovent. Innovent is the MAH of GFH925 in Greater China. However, Innovent does not have any role or involvement in the clinical trials of GFH925 in EU and the U.S. For additional information, see “— Licenses, Rights and Obligations.” The following table sets forth an overview of the ongoing clinical trial of GFH925 that we are conducting, as well as the completed clinical trial of GFH925 in China that supported the NDA approval:

<u>Study Number</u>	<u>Phase</u>	<u>Study Design</u>	<u>Sites</u>	<u>Subjects</u>	<u>Status</u>	<u>Actual Patient Enrollment</u>
GFH925X0201 (sponsored by us)	Ib/II	Evaluate safety, tolerance and PK and efficacy of GFH925 in combination with cetuximab	Sites within the jurisdiction of EMA (Greece, Italy, Spain)	Patients with advanced NSCLC harboring KRAS G12C mutation	Phase II trial is ongoing ¹	Six in the Phase Ib trial, 41 in the Phase II trial as of April 25, 2024 ²

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Study Number	Phase	Study Design	Sites	Subjects	Status	Actual Patient Enrollment
GFH925X1101 (initiated by us and subsequently sponsored by Innovent) . .	I/II	Evaluate the safety, tolerability and efficacy, and PK of GFH925	Mainland China	Patients with advanced solid tumors with KRAS G12C mutation	Completed	No less than 293 (based on the label of fulzerasib)

Note:

- (1) The data review team reviewed the Phase Ib data, confirmed safety of the selected dose and allowed Phase II to proceed in October 2023, in accordance with the approved clinical trial protocol.
- (2) For the purpose of 2024 American Society of Clinical Oncology (“ASCO”) abstract, six patients were enrolled in the Phase Ib trial and 40 patients were enrolled in the Phase II trial as of April 19, 2024, the 2024 ASCO Cut-off Date.

The following sets forth an overview of the key clinical trials of GFH925:

GFH925X0201 (KROCUS): A Phase Ib/II trial to evaluate the safety, tolerability, PK, and efficacy of GFH925 in combination with cetuximab in patients with previously untreated advanced NSCLC harboring KRAS G12C mutation sponsored by us

This trial is a multi-center, open-label Phase Ib/II clinical trial. The trial consists of two parts: the Phase Ib part and the Phase II part. The two parts are separate clinical trials with different designs, objectives and endpoints, while the designs and the mechanism on how to proceed to the Phase II part (after the safety of the combination of GFH925 and cetuximab is confirmed by the Phase Ib part) are included in the same clinical trial protocol, which is approved by relevant health authorities in countries within the jurisdiction of the EMA.

The Phase Ib part is a safety confirmation trial to evaluate the safety and tolerability of GFH925 at certain dosage level combining with cetuximab. The safety data generated in the Phase Ib part shall be reviewed by a data review team, consisting of principal investigators, CRO medical monitor and we as the clinical trial sponsor, to confirm safety before the Phase II part is commenced. Once safety of the combination in the Phase Ib is confirmed, the enrollment of Phase II will be initiated.

Phase Ib Trial

Trial Design. In the Phase Ib trial, six patients were enrolled to receive a combination treatment of GFH925 and cetuximab to confirm safety. Cetuximab is administered at a dose of 500 mg/m² once every two weeks, as recommended by its FDA-approved prescribing information. GFH925 was administered at a dose of 600 mg, twice daily (“**BID**”), which has been established as the recommended Phase II dose (“**RP2D**”) of GFH925 monotherapy based on the first-in-human GFH925X1101 clinical trial. The treatment cycle is defined as 28 days.

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The safety data generated in the first cycle are designed to be reviewed by the data review team. According to the clinical trial protocol of the KROCUS Study approved by the relevant health authorities of the MSCs, this Phase Ib trial, is a standalone complete trial equivalent to a typical Phase I clinical trial regulated by the Competent Authority.

While results of a previous clinical trial as a single agent facilitated our initial dose selection of GFH925 for the combination therapy, the clinical trial protocol provides that the dose level of GFH925 shall be adjusted lower should the safety results of this Phase Ib trial suggests. In particular, should the safety of GFH925 at the dose level of 600 mg BID not be confirmed, one or more dose levels of GFH925 lower than 600 mg BID may be explored in the combination therapy, prior to the commencement of the Phase II trial. Therefore, we view this Phase Ib trial, as a safety confirmation trial, also serving a dose finding/confirmation purpose.

The primary objective of Phase Ib trial is to evaluate the safety and tolerability of GFH925 in combination with cetuximab in patients with advanced KRAS G12C mutant NSCLC. The secondary objectives of Phase Ib trial are to evaluate PK and preliminary efficacy of GFH925 in combination with cetuximab.

The primary endpoints of Phase Ib trial are to evaluate incidence of adverse events (“**AEs**”), serious adverse events (“**SAEs**”), and changes in laboratory parameters, vital signs, physical examinations, and electrocardiogram. The secondary endpoints of Phase Ib trial are to evaluate plasma concentration and PK parameters of GFH925, and best overall response (“**BOR**”), duration of response (“**DoR**”), time to response (“**TTR**”), progression free survival (“**PFS**”), and overall survival (“**OS**”).

The key inclusion criteria for the trial include but not limited to: (i) male or female patients aged 18 years or older; (ii) patients with a life expectancy greater than three months judged by the investigator; (iii) patients with histologically or cytologically confirmed advanced KRAS G12C-mutated NSCLC; (iv) patients with sufficient organ functions; and (v) patients whose toxicities from prior antitumor therapy have resolved to baseline levels or Common Terminology Criteria for Adverse Events Grade 1 (with neurotoxicity or alopecia not greater than Grade 2). The key exclusion criteria for the trial include but not limited to: (i) patients with clinically significant cardiovascular diseases; (ii) patients with active central nervous system metastases and/or carcinomatous meningitis; (iii) patients with clinically significant gastrointestinal diseases; (iv) patients with uncontrolled systemic diseases; or (v) patients that have undergone major surgery within four weeks prior to the initiation of the treatment.

Scope of IND Approval. The KROCUS study — a Phase Ib/II trial of GFH925 in combination with cetuximab for patients with previously untreated advanced NSCLC harboring the KRAS G12C mutation in Italy, Spain, and Greece — was approved by the respective regulatory authorities in February 2023 (Italy), February 2023 (Spain), and June 2023 (Greece). Under the approved trial protocol, the combination therapy was intended to be evaluated as a first-line treatment. However, the Competent Authorities did not require, and the protocol did not include, a head-to-head comparison in this Phase Ib/II study. We intend to conduct such a head-to-head study in the planned pivotal trial.

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Trial Status. The Phase Ib trial was initiated in April 2023. The first patient was dosed in April 2023. All six enrolled patients completed one 28-day treatment cycle in September 2023, and all six patients were safety-evaluable. In October 2023, the primary endpoints of the Phase Ib were reached and safety confirmation of Phase Ib trial was completed by the data review team, as required by the clinical trial protocol.

The following summary outlines the safety data reviewed by the data review team as stipulated in the clinical trial protocol.

Safety Data. In the first treatment cycle, one patient experienced Grade 3 asthenia related to both of GFH925 and cetuximab, meeting the criteria of predetermined toxicity listed in the clinical trial protocol. No other predetermined toxicity occurred. As of the data cut-off date October 10, 2023, no fatal treatment-emergent adverse events or treatment-related serious adverse events occurred. Four patients (66.7%) experienced at least one treatment-related adverse events, and most of the adverse events were Grade 1 or Grade 2. There were one reported Grade 3 asthenia and one Grade 3 rash related to both GFH925 and cetuximab. A Grade 3 skin fissures was not assessed as related to GFH925. Other than those Grade 3 treatment-related adverse events, no other Grade 3 or more severe treatment-related adverse events were reported. There were no unexpected safety signals from the Phase Ib trial. Overall, the results demonstrate a favorable safety profile of the combination therapy.

No Objection to the Commencement of Phase II Trial

Pursuant to the clinical trial protocol approved by the relevant health authorities within the jurisdiction of the EMA, in October 2023, the data review team, consisting of a majority-independent parties, including five principal investigators, one representative of the CRO medical monitor and two representatives from us as the medical and biostatistical representative, reviewed the results of the Phase Ib trial, confirmed the safety of the selected dose of the combination therapy, and agreed that the Phase II trial may proceed. All data review team members are required to vote. If the decision isn’t unanimous, it will be determined by majority vote, with the leading principal investigator casting two votes to break a tie when there’s an even number of members. We believe the data review team is competent with relevant experience to conclude on the completion of a clinical trial under the EMA regulatory framework. Authorities of similar data review team or data monitoring committee are acknowledged under the ICH E6 (R3) Guideline on good clinical practice and EU Clinical Trials Regulation. See “Regulation — Overview of EU Laws and Regulations.” The clinical trial protocol and all subsequent amendments have been authorized by relevant health authorities, and under the authorized clinical trial protocol, the data review team is authorized to review the safety data and to confirm RP2D. As such, the authority of the data review team is acknowledged by relevant authorities.

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The approved clinical trial protocol does not require us to communicate with the relevant health authorities or the EMA prior to the commencement of the Phase II trial, and therefore we did not conduct such communications, in line with the common practice in similar situations, according to Frost & Sullivan. In June 2024, we submitted a substantial modification application to the Clinical Trials Information System (“CTIS”) maintained by the EMA, in which we included an updated investigator’s brochure for GFH925 that contains (1) the PK data from the Phase Ib trial and (2) the latest results, including the safety results, of 27 patients who had received treatment of the GFH925/cetuximab combination as of January 31, 2024. The said 27 patients included the 6 patients enrolled in the completed Phase Ib trial. As of the Latest Practicable Date, the modifications had been authorized, and we had not received any objections to the ongoing Phase II trial from the relevant healthcare authorities or the EMA, and we have not received any objection or rejection from the MSCs via the CTIS to commence the Phase II trial.

Phase II Trial

Trial Design. Up to 45 patients are designed to receive GFH925 at a dose of 600mg BID, which has been confirmed as safe in the Phase Ib trial, in combination with cetuximab at dose of 500 mg/m² once every two weeks in a 28-day cycle to evaluate efficacy. The primary endpoint of Phase II trial is to evaluate overall response rate (“**ORR**”). The secondary endpoints are to evaluate (i) disease control rate (“**DCR**”), DoR, TTR, PFS, and OS, (ii) incidence of AEs and SAEs; (iii) changes in laboratory parameters, vital signs, physical examinations, and electrocardiogram; (iv) trough concentration of GFH925 and (v) concentration of GFH925 near the time of maximum concentration (“**T_{max}**”).

The key inclusion criteria for the trial include but not limited to: (i) male or female patients aged 18 years or older; (ii) patients with a life expectancy greater than three months judged by the investigator; (iii) patients with histologically or cytologically confirmed advanced KRAS G12C-mutated NSCLC; (iv) patients with sufficient organ functions; and (v) patients whose toxicities from prior antitumor therapy have resolved to baseline levels or Common Terminology Criteria for Adverse Events Grade 1 (with neurotoxicity or alopecia not greater than Grade 2). The key exclusion criteria for the trial include but not limited to: (i) patients with clinically significant cardiovascular diseases; (ii) patients with active central nervous system metastases and/or carcinomatous meningitis; (iii) patients with clinically significant gastrointestinal diseases; (iv) patients with uncontrolled systemic diseases; or (v) patients that have undergone major surgery within four weeks prior to the initiation of the treatment.

Trial Status. The Phase II trial was initiated in October 2023. As of the 2024 ASCO Cut-off Date, a total of 40 patients received the GFH925/cetuximab combination treatment. We anticipate completing the Phase II trial in the fourth quarter of 2025.

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Efficacy Data. Most patients (95.0%) were diagnosed with stage IV diseases, and 13 (32.5%) were with brain metastases. As of the 2024 ASCO Cut-off Date, a total of 33 patients had at least one available post-treatment tumor assessment. Among these 33 patients, the ORR was 81.8% with one complete response and the DCR was 100%. Seven out of ten patients (70.0%) with brain metastases achieved partial responses. The results demonstrate a promising efficacy profile of GFH925 in combination with cetuximab as the first line treatment for KRAS G12C mutated NSCLC.

As of January 14, 2025, a total of 47 patients were enrolled and 45 of them received at least one post-treatment tumor assessment: the ORR reached 80% and the DCR reached 100%. The post-treatment evaluation revealed 3 patients achieved complete response; 33 others reached partial response, including one with 100% tumor shrinkage; 57.8% of patients exhibited $\geq 50\%$ tumor shrinkage. As of the data cut-off date, the median follow-up time was 12.8 months, and the median progression-free survival was 12.5 months. 34% of enrolled patients had baseline brain metastasis, and the ORR was 71.4% per RECIST 1.1 among brain-metastatic patients who received at least one post-treatment tumor assessment; all non-target lesions of brain-metastatic patients disappeared or remained stable in the course, and brain target lesions of 5 patients exhibited shrinkage. The data also showcased the combination therapy’s superior therapeutic potential over immunotherapy or chemo-immunotherapy in first-line KRAS-mutant NSCLC treatment: consistent response rates were observed in KROCUS study across subgroups with varied PD-L1 expressions; since STK11 and KEAP1 have been identified as associated with a lower response to immunotherapy and with poor prognosis for first-line NSCLC SOC, it’s noteworthy that similar responses were discovered in KROCUS study between STK11 or KEAP1 wild-type patients and those with STK11 or KEAP1 co-mutations. The above results of the Phase II trial were presented in a late-breaking abstract at the mini oral presentation of the 2025 ELCC annual meeting.

Safety Data. As of the 2024 ASCO Cut-off Date, among the 40 patients who received the GFH925/cetuximab combination therapy, TRAEs of any grade occurred in 35 patients (87.5%). Seven patients (17.5%) experienced Grade 3 TRAEs and the only treatment-related serious adverse event of the combination therapy was assessed as not related to GFH925. The Grade 3 TRAEs included rash, asthenia, pruritus, eye infection, dry skin, skin fissures and infusion-related reaction. One (2.1%) and four patients (10.0%), respectively, required dose reductions or temporary interruptions of GFH925 treatment due to TRAEs but no patients permanently discontinued GFH925 treatment. Three patients (7.5%) discontinued cetuximab treatment due to TRAEs. Overall, the results demonstrate a favorable safety profile of the combination therapy. The above results of the Phase II trial were presented as a late-breaking oral presentation at the 2024 American Society of Clinical Oncology (“ASCO”) annual meeting.

As of January 14, 2025, the combination therapy presented a favorable safety/tolerability profile, with a lower incidence of TRAEs than that of fulzerasib monotherapy for second-line and above NSCLC treatment; grade 3 or higher TRAEs occurred at a considerably lower rate than that of fulzerasib monotherapy. TRAEs occurred in 87.2% of patients and the majority of the TRAEs were graded 1-2; 14.9% of patients experienced at least one grade 3 TRAEs; no

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grade 4-5 TRAEs. 2 patients had treatment-related serious adverse events (“TRSAE”) and the TRSAEs were assessed to be merely related with cetuximab; 3 patients experienced TRAEs, unrelated to fulzerasib, leading to dose discontinuation. The KROCUS study demonstrated a relatively low occurrence of dose discontinuation or reduction among different first-line G12C-mutant NSLCL combo studies. No new safety signals were identified compared with fulzerasib or cetuximab as single agent. The above results of the Phase II trial were presented in a late-breaking abstract at the mini oral presentation of the 2025 ELCC annual meeting.

GFH925X1101: A Phase I/II clinical trial to evaluate safety, tolerability, PK and efficacy in patients with advanced solid tumors with KRAS G12C mutations in Mainland China sponsored by Innovent and originally initiated by us

Overview. This trial is a multicenter, non-randomized, open-label, single-arm Phase I/II clinical trial. The primary objective of the Phase Ia trial is to evaluate safety and tolerability of GFH925 in patients with advanced solid tumors harboring KRAS G12C mutations, and to determine the maximum tolerated dose (“MTD”) and/or RP2D of GFH925. The primary objective of the Phase Ib trial is to evaluate efficacy of GFH925 in patients with advanced colorectal cancer or other tumors with KRAS G12C mutations. The primary objective of the Phase II trial is to evaluate efficacy of GFH925 in patients with advanced NSCLC with KRAS G12C mutations.

We led and were responsible all preclinical development of GFH925 and obtained an IND approval addressed to our Company for GFH925X1101 from the NMPA in July 2021. In preparation for the clinical trial and prior to entering into the GFH925 License Agreement, we proactively identified and finalized the arrangement details with the lead principal investigator. We also arranged eight clinical sites in multiple provinces in China, submitted materials for ethics committee approvals for a number of these clinical sites, and activated one clinical trial site in August 2021. Innovent later supported the clinical collaboration by expanding the trial from eight clinical sites we initially arranged to a total of 55 clinical sites.

After signing of the GFH925 License Agreement, Innovent became the sponsor of the GFH925X1101 trial in China and is thereafter solely responsible for the development and commercialization of GFH925 in the Greater China region. However, we retain a critical role in managing the CMC-related processes, including overseeing process development, finalizing agreements with key stakeholders, and selecting suitable vendors to ensure smooth trial execution. Innovent will pay our Company for the drug supply on an ongoing basis, with payments determined by the quantity required to support the trial’s development needs. For additional information about the Innovent Agreement, see “— Licenses, Rights and Obligations” below.

Clinical results from the Phase II trial supported the NDA approval of GFH925 in China for the treatment of advanced NSCLC harboring KRAS G12C.

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Design of the Phase II Trial. The Phase II trial enrolled a total of 116 patients with advanced NSCLC with KRAS G12C mutations. All patients were treated with GFH925 at a dose of 600 mg orally twice daily until intolerable toxicity or disease progression occurred.

The primary endpoint of the Phase II trial is ORR. The secondary endpoints include (i) DCR, DoR, TTR, PFS, and OS, disease progression-free rate at six and 12 months, and survival rate at 12 months; (ii) incidence and severity of AEs, SAEs, AEs leading to treatment suspension, and AEs leading to treatment discontinuation; and (iii) plasma concentrations of patients after multiple doses, including trough concentrations.

The key inclusion criteria for the trial include but not limited to: (i) patients aged 18 years or older at the time of signing the informed consent form; (ii) patients with at least one measurable lesion; and (iii) patients with an expected survival time of 12 weeks or more. The key exclusion criteria for the trial include but not limited to: (i) patients with significant cardiovascular system disease; (ii) patients with brain metastases judged unstable by the investigators; (iii) patients with significant gastrointestinal disease; (iv) patients with significant acute or chronic infections; or (v) patients that are allergic to the drug or any component of its formulation.

Efficacy Data of the Phase II Trial. As of the data cut-off date of December 13, 2023, the confirmed ORR was 49.1%, and the DCR was 90.5% in 116 patients. The median DoR was not reached, and 75.8% and 53.7% patients had DoR at six months and 12 months, respectively. The median of TTR was 1.38 months and the median PFS was 9.7 months. The median OS was 13.3 months, with six-month OS and 12-month OS of 81.8% and 54.4%, respectively.

Safety Data of GFH925. Results of 301 patients were used for the safety analysis of GFH925. TRAEs occurred in 92.2% of patients. Most TRAEs are Grade 1 to 2. The most common TRAEs included anemia, increased alanine aminotransferase, increased aspartate aminotransferase, elevated blood bilirubin, asthenia, proteinuria, hypoproteinemia, pruritus, edema, and elevated gamma-glutamyl transferase. The common AEs of Grade 3 and higher include anemia, elevated gamma-glutamyl transferase, asthenia, hepatic dysfunction, elevated blood alkaline phosphatase, and decreased lymphocyte counts. 14.0% of patients has SAE, and 2.7% of patients experienced AEs leading to drug discontinuation. 32.6% and 18.3% of patients experienced AEs resulting in drug suspension and dose reduction, respectively.

The above clinical efficacy and safety data are included in the label of GFH925 in China.

Clinical Development Plan

Our overseas clinical development of GFH925 has been focused on the GFH925/cetuximab combination therapy as a first-line treatment of NSCLC, instead of GFH925 as a monotherapy. This is because, when we started the clinical development of GFH925, in multiple regions outside China, such as the U.S., certain drugs (e.g., sotorasib and adagrasib) as monotherapies targeting the KRAS G12C mutation had received regulatory approval for treating NSCLC as a standard of care in the second or later line treatment, and the medical need for the first line treatment was not met.

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We chose to conduct the KROCUS trial in EU where the population is considered representative to the global-wise population and the trial is relatively cost-effective. The planned Phase III clinical trial in the U.S. was designed to be part of a multi-regional study in U.S. and EU, and may support future global registration in multiple regions. Conducting the Phase III clinical trial in the U.S. would enable us to benefit from the fast and straightforward U.S. IND process and to initiate communications with FDA to receive FDA’s inputs on the study design. The FDA’s inputs may support further communications with the regulatory authorities in EU and other regions. In EU, we plan to conduct the Phase III trial in Spain, Italy and Greece. We would also consider conducting the Phase III trial in other EU member states where there are extensive experience in conducting clinical trials and KRAS testing capacity for lung cancers. Innovent will not be involved or co-lead this Phase III clinical trial as sponsors.

We will continue to advance the clinical development of our Core Product GFH925 for cancer treatment. We anticipate completing the KROCUS Phase II trial in the fourth quarter of 2025. We plan to leverage the clinical results of the KROCUS trial to apply for a Phase III clinical trial in the United States to evaluate the safety and efficacy of the GFH925/cetuximab combination therapy as a first-line treatment for NSCLC harboring the KRAS G12C mutation. We had a pre-IND meeting with the FDA in February 2025 regarding our planned IND application for a Phase III clinical trial. In the meeting, the FDA provided guidance on the clinical development pathway for fulzerasib/cetuximab combination therapy as a first-line treatment for NSCLC harboring the KRAS G12C-mutation. In particular, the FDA provided requests and recommendations regarding the study protocol. Specifically, the FDA advised us to, as part of the proposed Phase III clinical trial, (i) further optimize the dosages and (ii) assess the contribution of each of GFH925 and cetuximab within the combination regimen in light of the strong efficacy observed in GFH925 monotherapy trials. We expect to incorporate the FDA’s requests and recommendations and prepare a revised study protocol for the planned Phase III clinical trial. We expect to submit an IND application to the FDA for the Phase III clinical trial in the third quarter of 2025 and initiate the trial in the fourth quarter of 2025. Based on our communication with the FDA, we do not expect the guidance on “*Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases*” released by the FDA in August 2024 will have material impact on the development of GFH925/cetuximab combination therapy in the U.S.. We expect to submit to the FDA an NDA for the GFH925/cetuximab combination therapy in the fourth quarter of 2028 and obtain the NDA approval in the fourth quarter of 2029. We also intend to submit a clinical trial application for a Phase III clinical trial of the GFH925/cetuximab combination in selected member states within the jurisdiction of the EMA in the second half of 2025.

Beyond NSCLC, we view GFH925 as a potentially valuable therapeutic option in other challenging cancers, such as advanced CRC. The FDA approved our IND application for a Phase III clinical trial of GFH925 monotherapy as a later-line treatment for refractory metastatic CRC harboring the KRAS G12C mutation in April 2024, based on the revised protocol, informed consent document, and Investigator’s Brochure that we submitted in March 2024. However, because of commercial considerations of GFH925 in the CRC drug market and the potential significant costs for further R&D, we are not currently actively pursuing the clinical development of GFH925 as a potential treatment of CRC for commercial considerations. We are currently assessing the competitive landscape and formulating future clinical development plan of GFH925.

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We independently designed and conducted the clinical trials of GFH925 in the EU and U.S. Specifically, before the KROCUS trial, we conducted two preclinical studies in China to test the antitumor effects of the GFH925/cetuximab combination on xenograft mouse models of human NSCLC and PDAC cell lines, between December 2021 and March 2022. Both preclinical studies showed good tolerability and considerable synergistic effect of the GFH925/cetuximab combination compared with monotherapy. We are the sole sponsor of the KROCUS study in the EU and expect to be sole sponsor of the planned Phase III clinical trial of the GFH925/cetuximab combination therapy in the U.S. Innovent does not and will not have any involvement in the two overseas studies. We retain the right to develop and commercialize GFH925 in the overseas markets, and Innovent does not possess such a right. Also, we, not Innovent, possess patents that cover GFH925. Therefore, our R&D and commercialization efforts in the EU and/or U.S. are independent without any reliance on Innovent.

In our clinical trial application for the KROCUS study, we included a summary of the clinical data generated from the GFH925X1101 study as required under the relevant regulations, including the reference to the dosage and patient selection. The initial dosage of GFH925 at 600 mg BID in the Phase Ib part of the KROCUS study was derived from the RP2D determined in the Phase I part of Innovent’s GFH925X1101 study. As advised by Frost & Sullivan, a study’s sponsor normally will review available clinical or non-clinical research data relating to the investigational therapy to design its own study protocol, including the dosage and patient selection. The Phase I clinical data of the GFH925X1101 study and the dosage regimen of cetuximab at 500 mg/m² once every two weeks based on its prescribing information approved by the FDA were such existing knowledge for the KROCUS study at its planning stage. The RP2D that derived from the GFH925X1101 study provided a starting point for the dosage selection of GFH925 in the KROCUS study. Since the safety of GFH925 in combination with cetuximab was confirmed at 600 mg BID for GFH925 and 500 mg/m² once every two weeks for cetuximab, we did not need to test other dosage levels per the dose de-escalating design of the Phase Ib part, thereby saving considerable time and costs in dosage selection.

We are currently focused on the research and development of GFH925 in the Ex-China Territory and have not yet formulated a detailed commercialization plan. However, we currently expect GFH925 to be positioned with a competitive pricing strategy in the overseas markets with other approved KRAS G12C inhibitor drugs, leveraging production cost efficiencies anticipated from our second-generation manufacturing process. For information on the regulatory pathways to marketing authorization in the EU and U.S., please refer to “Regulations — Overview of EU Laws and Regulations” and “Regulations — Overview of U.S. Laws and Regulations.”

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Licenses, Rights and Obligations

Innovent Agreement

On September 1, 2021, we entered into a license and option agreement (the “**GFH925 License Agreement**”) with Innovent. According to the GFH925 License Agreement, we grant to Innovent (i) an exclusive, royalty-bearing and sublicensable license to develop and commercialize GFH925 for the treatment, prevention or diagnosis of any disease in humans in Mainland China, Hong Kong, Macau and Taiwan (the “**Greater China**”); and (ii) an exclusive option (the “**Ex-China Option**”) to develop and commercialize GFH925 in the all countries and regions in the world other than Greater China (the “**Ex-China Territory**”). Prior to entering into the GFH925 License Agreement, we proactively identified and finalized the arrangement details with the lead principal investigator. Innovent later supported the clinical collaboration by expanding the trial from the eight sites we initially arranged to a total of 55 clinical sites. After signing of the GFH925 License Agreement, Innovent became the sponsor of the GFH925X1101 trial in China and is thereafter solely responsible for the development and commercialization of GFH925 in the Greater China region. However, we retain a critical role in managing the CMC-related processes, including overseeing process development, finalizing agreements with key stakeholders, and selecting suitable vendors to ensure smooth trial execution. Innovent will pay our Company for the drug supply on an ongoing basis, with payments determined by the quantity required to support the trial’s development needs. On January 11, 2024, we further entered into a supplementary agreement (the “**GFH925 Supplementary Agreement**,” together with the GFH925 License Agreement, the “**Innovent Agreement**”) with Innovent. According to the GFH925 Supplementary Agreement, both parties agreed to terminate the Ex-China Option under the GFH925 License Agreement. We have the exclusive rights to develop, manufacture and commercialize GFH925 for any indication in the Ex-China Territory. For more details, please see “— Major Collaboration and Licensing Arrangements — Innovent Agreement.”

We collaborated with Innovent to facilitate the swift development and approval of GFH925 for commercialization in China. This collaboration leveraged Innovent’s development expertise in advancing clinical trials, as well as their leadership position in China, which includes an established commercialization team and an extensive marketing network.

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The table lists the chronology on the material clinical development of GFH925 conducted by us and Innovent in different regions.

	GenFleet			Innovent
	China	Europe	U.S.	China
2018	Commenced the endeavor to discover and develop GFH925			
2021	July: Received the IND approval from the NMPA for GFH925 for a Phase I/II clinical trial in patients with advanced solid tumors with the KRAS G12C mutation;			September: Entered into collaboration agreement with the Company in relation to the clinical development and commercialization of GFH925;
	September: Entered into collaboration agreement with Innovent in relation to the clinical development and commercialization of GFH925			September: Completed the first patient dosed for Phase I/II clinical trial of GFH925 in Chinese patients with solid tumors
2022	March: completed preclinical studies of the antitumor effects of the GFH925/cetuximab combination on xenograft models of human NSCLC and PDAC cell lines;	June: Entered into a clinical trial collaboration and supply agreement with Merck Healthcare KGaA to secure cetuximab for the KROCUS trial; October: Submitted the investigational medicinal product dossier to the CTIS maintained by the EMA for the KROCUS trial, which is a Phase Ib/II trial of GFH925 in combination with cetuximab to assess the combination therapy as a first-line treatment of advanced NSCLC		June: The Phase I dose-escalation study results of GFH925 as monotherapy were released at the ASCO Annual Meeting 2022; H2: Initiated Phase Ib studies for GFH925 combination therapy for KRAS G12C mutated cancers; H2: Initiated the pivotal Phase II study for GFH925 for the treatment of 2L KRAS G12C mutated NSCLC

BUSINESS

	GenFleet			Innovent
	China	Europe	U.S.	China
2023		March: Initiated the KROCUS trial in Italy, Spain and Greece; October: The Phase Ib trial of KROCUS reached the primary endpoints, and there was no objection from the data review team or relevant health authorities to the commencement of the Phase II trial		January and May: The GFH925 monotherapy received two Breakthrough Therapy Designations from the NMPA for treating advanced KRAS G12C-mutant NSCLC and CRC patients; June: Entered into a clinical trial collaboration and supply agreement with Merck KGaA for the combination therapy of GFH925 with cetuximab (ERBITUX[®]) for KRAS G12C-mutated NSCLC in a Phase Ib study in China; November: The NMPA accepted the NDA and granted Priority Review Designation for GFH925 monotherapy in patients with previously treated advanced NSCLC harboring KRAS G12C mutation who have received at least one systemic therapy

BUSINESS

	GenFleet			Innovent
	China	Europe	U.S.	China
2024		June: Reported the results of the KROCUS trial for GFH925 as a late-breaking oral presentation at the 2024 American Society of Clinical Oncology annual meeting	April: The FDA approved the Phase III clinical trial of GFH925 for the treatment of refractory metastatic CRC patients	Initiated a Phase Ib/III clinical trial to investigate GFH925/cetuximab combination therapy in patients with previously untreated advanced NSCLC harboring KRAS G12C mutation; August: GFH925 (marketed under the name Dupert®) was approved by NMPA for the treatment of patients with advanced NSCLC harboring KRAS G12C mutation who have received at least one systemic therapy
2025		March: Reported the results of the latest phase II data of the KROCUS trial for GFH925 in a late-breaking abstract at the mini oral presentation of the 2025 European Lung Cancer Conference annual meeting		

Merck Agreement

On June 30, 2022, we entered into a clinical trial collaboration and supply agreement (the “**Merck Agreement**”) with Merck Healthcare KGaA in relation to the clinical development of the GFH925/cetuximab combination therapy for a Phase Ib/II clinical trial (i.e., GFH925X0201) in the EU. According to the Merck Agreement, Merck is obligated to provide cetuximab for the use in the clinical trial to us with a maximum number of 3,500 vials and schedule specified in the Merck Agreement according to the clinical trial status and subject to mutual agreement between Merck and our Company. Our Company shall bear all other costs associated with the subject clinical trial. The Merck Agreement does not affect our status as the sole sponsor of or our sole responsibility to conduct the KROCUS trial. The Merck Agreement does not provide for a JSC.

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The Merck Agreement stipulates that all rights to all inventions that are directed to the combination therapy and variants thereof, except those inventions solely relating to GFH925 or cetuximab, shall be jointly owned by Merck and our Company. Those inventions solely relating to GFH925 or cetuximab shall be solely owned by GenFleet or Merck, respectively. The Merck Agreement allows us to freely exploit such joint inventions and does not provide for payment obligations in connection with any licensing arrangement or Merck's provision of cetuximab. Where a license is required, Merck grants to us a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license under Merck's right, title and interest in and to all joint inventions to use such inventions for any use, and vice versa. Accordingly, if a joint invention is developed through potential future collaboration with Merck, each party (i.e. we and Merck) is permitted to use and freely exploit such joint invention without any costs and without written consent from the other party in accordance with the Merck Agreement. The Merck Agreement granted us the first right (but not the obligation) to file, maintain and defend the patents that cover the joint inventions. However, if we do not want to file or share expenses for a patent application that covers the joint inventions, Merck may at its own expenses continue to file, maintain and defend such a patent application. Also, under the Merck Agreement, we need Merck's consent in making disclosures to the patent authority regarding jointly inventions. The Merck Agreement does not otherwise affect our existing ownership of intellectual property rights over GFH925. As of the Last Practicable Date, neither party has obtained any patent or filed any patent application for the joint inventions under the Merck Agreement.

Each party agreed to customary indemnification to the other party in relation to losses attributable to such party's product and, in case of Company, arising from the trial of GFH925/cetuximab combination therapy.

Merck and we agreed to attempt in good faith to settle all disputes arising out of the Merck Agreement in an amicable manner. If such disputes cannot be so resolved, they shall be finally settled at the competent courts of Geneva, Switzerland. During the Track Record Period, we did not have any unresolvable dispute with Merck.

The term of the Merck Agreement shall continue until completion of all of the obligations of the parties. Either party may terminate the Merck Agreement (i) when the other party commits a material breach and fail to remedy in a specified period, (ii) when the party reasonably determines in good faith, after a review of relevant information, that the trial may unreasonable affect patient safety, (iii) by providing written notice in specified events, including regulatory action or manufacturing or supply chain disruption, (iv) by providing advance written notice in case the study fails to reach any of its endpoints. Merck may terminate the Merck Agreement if it reasonably and in good faith believes that the supplied cetuximab is being used in the trial in an unsafe manner or there is imminent danger to patients, and we fail to promptly incorporate appropriate changes to address such issues after we receive notification from Merck.

BUSINESS

Material Communications with Competent Authorities

Regarding the KROCUS Trial

EMA

The EMA is a decentralized agency of the EU and is responsible for the scientific evaluation, supervision and safety monitoring of medicines. It plays a key role in ensuring that the standards of good clinical practice are applied in cooperation with EU member states and manages clinical trial databases, including CTIS, for clinical trials that are carried out in the EU. The CTIS serves to implement the EU Clinical Trials Regulation, Regulation (EU) No 536/2014, and supports interactions between clinical trial sponsors and regulatory authorities in the EU member states throughout the lifecycle of a clinical trial. The EMA evaluates the marketing authorization applications (“**MAAs**”) submitted through the centralized procedure and its evaluation provides the basis for the authorization of medicines in Europe.

According to EMA, it does not evaluate applications for the authorization of clinical trials. Instead, such authorization occurs at EU member state level. The Clinical Trials Regulation enables sponsors to submit one online application via the CTIS maintained by the EMA, through which regulators and authorities of each state can collaboratively process clinical trial applications, request further information, authorize or refuse a trial and oversee an authorized trial. The evaluation process of an initial clinical trial application includes three main phases: validation, assessment and decision. The assessment phase includes two parts: Part I and Part II.

- Part I consists in a joint assessment by the member states concerned (“**MSCs**”) led by the reporting member state (“**RMS**”) on aspects primarily related to scientific documentation, manufacturing and importing requirements, labeling requirements and completeness and adequateness of the investigator’s brochure.
- Part II consists in a separate assessment performed by each MSC, each of which results in the submission of an individual conclusion. The scope of the Part II assessment is set out in the Clinical Trial Regulation and primarily relate to aspects such as informed consent, compensation, protection of data and samples, patient recruitment and suitability of clinical trial sites.

Request for information (“**RFIs**”) may be raised by RMS for Part I or by the MSC for Part II. Each MSC decides if the application is complete and adequate, and therefore if the clinical trial can be conducted in its territory.

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On October 14, 2022, pursuant to the Clinical Trials Regulation (EU) No. 536/2014CTR, we independently prepared and submitted to the CTIS a clinical trial application for the KROCUS study. The application included IMPD, Investigator’s Brochure (“IB”), clinical study protocol (the “Protocol”) and informed consents of clinical trial participants. The IMPD presented the detailed data of GFH925 regarding its manufacturing and formulation. The IB presented detailed data generated in the prior non-clinical and clinical studies of GFH925, and the only clinical study mentioned therein was the GFH925X1101 study. The Protocol elaborated the design, procedure and data analysis planned for the KROCUS study. The introduction part of the Protocol, which explained the scientific basis of the study, summarized the clinical data generated from the GFH925X1101 study (including the dosage and safety profile of GFH925 in the study). In addition, we take the initiative and are responsible for drafting and leading the annual updates of the IB.

On November 14, 2022, our clinical trial application was validated. On February 20, 2023, the Italian health authority submitted the part I evaluation report, including a favorable conclusion. The Italian and Spanish health authorities submitted the part II evaluation report with a favorable conclusion on February 20, 2023 and January 12, 2023, respectively. Subsequently, both countries’ health authorities authorized the KROCUS study in their respective jurisdictions on February 23, 2023. On June 20, 2023, Greece agreed to be added as an MSC.

The French authority declined to authorize our clinical trial application in June 2023, noting a lack of clinical data at the time that may guarantee a favorable benefit/risk balance of the GFH925/cetuximab combination therapy in the KROCUS study. The decision of the French authority would not have any adverse or knock-on impact on the ongoing clinical development, market registration application, and commercialisation plans of the GFH925 in other member states under the EMA regime. The marketing authorization application of the GFH925/cetuximab combination therapy, as a new active substance indicated for the treatment of cancer, is expected to follow the centralised procedure. Accordingly, we expect to submit via the CTIS a single marketing application for the combination therapy. Under the EMA centralised procedure, if the GFH925/cetuximab combination therapy is approved by the European Commission, we will obtain a single marketing authorization valid in all E.U. member states, including France and other member states, even though the clinical trial of the GFH925/cetuximab combination therapy has not been conducted in France and such other member states or France declined to authorize clinical trial application of the GFH925/cetuximab combination therapy. For more details, please refer to “Regulations — Overview of EU Laws and Regulations.”

We initially selected Greece, Italy, France, and Spain as the sites for the KROCUS study because these EU member states have relatively large populations, well-developed healthcare systems, and extensive experience in conducting clinical trials. These factors facilitated patient recruitment and enabled the smooth execution of the study at local hospitals. In addition, these countries have relatively greater openness to innovative trial designs within the EU, such as the combination study we are conducting. We have successfully recruited a sufficient number of patients from Greece, Italy, and Spain to meet the requirements set forth in the approved trial protocol. Accordingly, we believe the selection of the participating member states in the E.U. is sufficient for the approved clinical development purpose.

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Following the authorization of the KROCUS trial, we made five substantial modifications (“SM”) through the CTIS, with two of them involving the Part I (SM-3 and SM-4 below). According to the EU Clinical Trials Regulation, a substantial modification is any change to any aspect of a clinical trial, which is likely to either have a substantial impact on subjects’ safety or rights or on the reliability and robustness of the data generated in the clinical trial. A substantial modification may only be implemented if it has been authorized by the MSCs through CTIS maintained by the EMA. Through these modifications, we have ongoing communications via CTIS with the EMA and MSCs by updating information, including the investigator’s brochure that contains updated clinical trial results, about the ongoing KROCUS trial. As of the Latest Practicable Date, we had not received any objections to the ongoing Phase II trial from the relevant healthcare authorities, any relevant MSC, or the EMA, and we do not expect to make further SMs.

The following table sets out information about those five substantial modifications, which had all been authorized by the relevant MSCs.

	Primary purpose/ Major changes	Initial submission date	Status
SM-1	We added six new clinical trial sites in Spain.	March 17, 2023	The proposed modifications were authorized on April 27, 2023, by Spain through CTIS maintained by the EMA. There were no other comments/feedbacks from CTIS maintained by the EMA after the submission of evaluation reports by each relevant MSC.
SM-2	We added four new clinical trial sites in Italy.	April 26, 2023	The proposed modifications were authorized on June 21, 2023, by Italy through CTIS maintained by the EMA. There were no other comments/feedbacks from CTIS maintained by the EMA after the submission of evaluation reports by each relevant MSC.

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	Primary purpose/ Major changes	Initial submission date	Status
SM-3	We updated the protocol for GFH925 to include (1) new preclinical data and (2) changes on definition of the end of the trial and eligibility criteria. We changed the definition from “the time when the last enrolled patient has been under study treatment for at least 1 year or discontinued for any reason (whichever is earlier)” to “the time when the last on treatment patient has been under study treatment for at least 1 year or discontinued for any reason (whichever is earlier),” because, during the KROCUS study, we found the revised definition is more reasonable than the previous one and therefore submitted SM-3 to reflect the same. We also updated nonclinical and clinical data regarding GFH925 and its combination therapies (including the clinical data from the KROCUS study, as well as dosage and safety profile of GFH925 in the GFH925X1101 study), as well as reference safety information in the investigator’s brochure for GFH925.	September 1, 2023	The proposed modifications were authorized to be made to the protocol and investigator’s brochure on November 6, 2023, November 2, 2023, and November 7, 2023, by Italy, Spain and Greece, respectively, through CTIS maintained by the EMA. There were no other comments/feedbacks from CTIS maintained by the EMA after the submission of evaluation reports by each relevant MSC.

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	Primary purpose/ Major changes	Initial submission date	Status
SM-4	We updated the investigator’s brochure for GFH925 to include, among others, (1) the PK data from the Phase I trial, (2) the latest results, including the safety results, of 27 patients who had received treatment of the GFH925/cetuximab combination as of January 31, 2024, and (3) the latest safety and efficacy results of the GFH925X1101 study as of December 13, 2023. We also updated the informed consent form, which mentioned updated safety data of the KROCUS study, in line with the new investigator’s brochure. SM-4 represented a routine process of updating the investigator’s brochure annually on the clinical and non-clinical study results of the study drug. We made the updates without any health authorities’ request.	June 20, 2024	The proposed modifications were authorized to be made to the investigators’ brochure and the informed consent form on September 11, 2024, August 27, 2024, and September 12, 2024, respectively, by Italy, Spain and Greece through CTIS maintained by the EMA. There were no other comments/feedbacks from CTIS maintained by the EMA after the submission of evaluation reports by each relevant MSC. In particular, as of the date of the Document, we have not received further updates from the member states of Italy, Spain and since the submission of SM-4.
SM-5	We changed a principal investigator for a clinical trial site in Spain, because the previous principal investigator left that principal investigator position on July 30, 2024.	October 3, 2024	The proposed modification was authorized on October 23, 2024, by Spain through CTIS maintained by the EMA. There were no other comments/feedbacks from CTIS maintained by the EMA after the submission of evaluation reports by each relevant MSC.

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Regarding the GFH925X1101 Trial in China

We conducted all preclinical development of GFH925 and submitted an IND application for the first-in-human GFH925X1101 trial to the NMPA in May 2021. We were responsible for the trial design that resulted in the NMPA’s approval in July 2021, addressed to our Company without any significant inquiries or objections. In preparation for the clinical trial and prior to entering into the GFH925 License Agreement, we proactively identified and finalized the arrangement details with the lead principal investigator. We also arranged eight clinical sites in multiple provinces in China, submitted materials for ethics committee approvals for a number of these clinical sites, and activated one clinical trial site in August 2021. Innovent later supported the clinical collaboration by expanding the trial from the eight sites we initially arranged to a total of 55 clinical sites.

After signing of the GFH925 License Agreement, Innovent became the sponsor of the GFH925X1101 trial in China and is thereafter solely responsible for the development and commercialization of GFH925 in the Greater China region. However, we retain a critical role in managing the CMC-related processes, including overseeing process development, finalizing agreements with key stakeholders, and selecting suitable vendors to ensure smooth trial execution. Innovent will pay our Company for the drug supply on an ongoing basis, with payments determined by the quantity required to support the trial’s development needs. For additional information about the Innovent Agreement, see “— Licenses, Rights and Obligations” above.

On August 20, 2024, the NMPA approved GFH925 for the treatment of patients with advanced NSCLC harboring KRAS G12C who have received at least one systemic therapy.

In the United States

We submitted an IND application to the FDA on March 18, 2024 for a Phase III clinical trial to investigate the safety and efficacy of GFH925 monotherapy as a later-line treatment for refractory metastatic CRC harboring the KRAS G12C mutation in the United States. The FDA communicated with us their comments and requests for additional clinical information on April 4, 2024. In their letter dated April 4, 2024, the FDA requested us to (i) modify the protocol to require a treatment hold for Grade 3 nausea, vomiting, or diarrhea and treatment discontinuation for Grade 4 vomiting or diarrhea; (ii) modify the protocol to include AEs that would not require permanent discontinuation for a Grade 4 event; and (iii) submit the most recent copy of the protocol for the dose finding study conducted in China. We submitted our responses to the FDA on April 11, 2024, which included dosage and safety data of GFH925 in the Phase I part of the GFH925X1101 study. There were no material inquiries or comments that we were unable to address. Thereafter, the FDA issued the “study may proceed” letter on April 17, 2024, allowing us to conduct the proposed Phase III clinical trial. However, because of commercial considerations of GFH925 in the CRC drug market and the potential significant costs for further R&D, we are not currently actively pursuing the clinical development of GFH925 as a potential treatment of CRC for commercial considerations. We are currently assessing the competitive landscape and formulating future clinical development plan of GFH925. Accordingly, we have not conducted R&D activities of GFH925 as a potential treatment for CRC after the FDA issued the “study may proceed” letter, and we have not initiated the Phase III clinical trial of GFH925 targeting CRC.

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We are aware of the guidance on “*Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases*” released by the FDA in August 2024. Given we received the “study may proceed” letter prior to the release of such guidance and our Phase III clinical trial in the U.S. is not a dose finding trial, we do not expect such guidance will have material impact on the development of GFH925 in the U.S. 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 GFH925 SUCCESSFULLY.

Core Product GFH375: A Small Molecule Inhibitor of KRAS G12D

Overview

GFH375 is an orally bioavailable, potent and selective small molecule inhibitor targeting both the “on” GTP-bound and “off” GDP-bound states of KRAS protein with G12D mutation. KRAS G12D mutation is the most prevalent oncogenic KRAS variant found in human cancers that lacks approved treatment options. Preclinical results demonstrate low-nanomolar binding affinity, favorable safety, oral bioavailability and potent activity for GFH375 in solid tumor models. We are currently conducting a Phase I/II trial to evaluate safety and tolerability, PK, and efficacy of GFH375 in patients with advanced solid tumors harboring the KRAS G12D mutation in China. PDAC has emerged as the lead indication of GFH375. As of the Latest Practicable Date, no drugs targeting the KRAS G12D mutation had been approved for marketing globally, and GFH375 was among the most advanced orally bioavailable KRAS G12D inhibitors in the world in terms of development status, according to Frost & Sullivan. We believe that GFH375 has the potential to be an effective treatment for cancer harboring KRAS G12D mutation.

Mechanism of Action

KRAS is the most commonly mutated oncogene in human cancers. The KRAS G12D mutation accounts for approximately 29% of all KRAS mutations, making it the most prevalent variant in human cancers. The KRAS G12D mutation is particularly frequent in pancreatic cancer (approximately 35%), CRC (approximately 12%) and NSCLC (approximately 4%).

In comparison to the KRAS G12C mutation, the KRAS G12D mutation causes a more significant disruption of intrinsic GTPase activity, resulting in a higher proportion of active GTP-bound KRAS in tumor cells. GFH375 is a KRAS G12D inhibitor that targets both the “on” GTP-bound and “off” GDP-bound states of KRAS proteins, allowing it to effectively inhibit KRAS protein function. Consequently, GFH375 blocks the GDP-GTP exchange, preventing the activation of KRAS G12D in tumor cells and subsequently disrupting its interaction with downstream proteins, such as RAF kinases.

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Advantages of GFH375

We believe that GFH375 has the following advantages:

Highly potent dual (“off” and “on”) KRAS G12D inhibitor

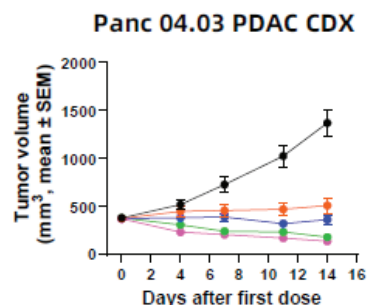
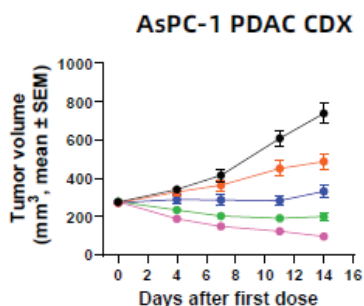
In preclinical studies, GFH375 demonstrated its potential as a specific KRAS G12D inhibitor targeting both active and inactive KRAS. Results from the nucleotide exchange assay showed that GFH375 inhibited SOS1-mediated transition of GDP-bound KRAS G12D mutant to GTP-bound state, with IC_{50} value of 6 nM. In KRAS-RAF1 binding assay, GFH375 prevented GTP-analog (GMPPNP)-preloaded KRAS G12D from interacting with their effector protein RAF1 in the reconstituted setting with IC_{50} value of 2 nM.

Favorable tolerability in preclinical studies

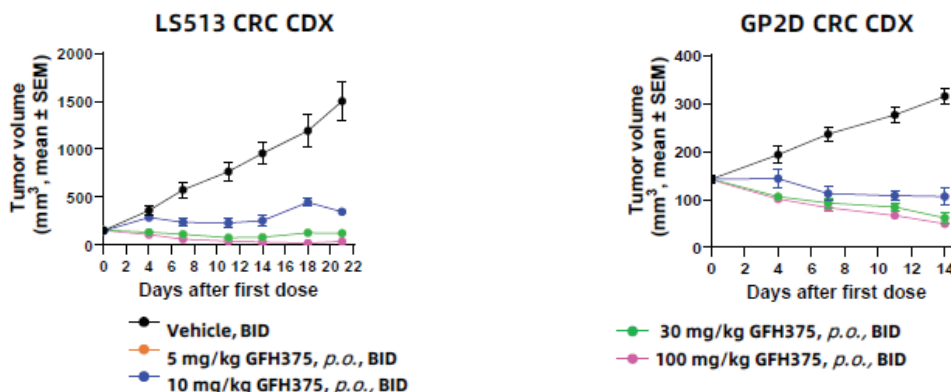
GFH375 has demonstrated favorable tolerability in preclinical studies. For instance, GFH375 had no effect on the central nervous and respiratory systems of Sprague Dawley rats, nor on the cardiovascular system of beagle dogs following a single dose administration. In addition, no death occurred in a 28-day repeated dose toxicity study with beagle dogs. Repeated dosing of GFH375 also showed no impact on the electrocardiograms of the beagle dogs.

Favorable activity in preclinical studies

GFH375 has demonstrated preclinical antitumor activity in controlling tumor growth in different pancreatic cancer and CRC models. The following diagrams depict the dose-dependent antitumor activity of GFH375 in multiple tumor models via oral administration.



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Source: Company information

Notes: AsPC-1 and Panc04.03 are cell lines originally derived from different pancreatic cancer patients. LS513 and GP2D are cell lines originally derived from different patients with colorectal cancer. The above graphs show results of CDX experiments, which involve implanting human cancer cell lines into immunodeficient mice to study tumor growth and test activities of potential treatments in reducing tumor growth.

The significant antitumor activity of GFH375 was also observed in intracranial tumor models, demonstrating GFH375's potential to inhibit brain metastasis.

Differentiated route of administration

GFH375 differentiates itself from other product candidates currently under development for KRAS G12D in terms of route of administration. In the preclinical study, GFH375 demonstrated moderate to high absolute bioavailability across various species, suggesting that GFH375 can be orally available in human. Clinical research indicates that the exposure to GFH375 increases in a dose-dependent manner following once-daily oral dosing. Notably, antitumor activities have been observed at starting doses. Formulated as a once-daily, orally available treatment, we believe GFH375 could potentially ease repeated drug administration, improve patient compliance, and therefore potentially increase the overall efficacy of the treatment regimen.

Summary of Clinical Trials

We retain all rights of GFH375 in Greater China, and we are conducting a Phase I/II clinical trial of GFH375 in China (i.e., GFH375X1101). We received IND approval from the NMPA in June 2024 to initiate the clinical trial. We completed the Phase I part of the clinical trial in January 2025 and initiated the Phase II part in February 2025. The following sets forth an overview of the clinical trial of GFH375.

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GFH375X1101: A Phase I/II clinical trial to evaluate safety, tolerability, and preliminary efficacy of GFH375 in patients with advanced solid tumors harboring the KRAS G12D mutation in China sponsored by us

Overview. This is a multicenter, non-randomized, open-label, single-arm Phase I/II clinical trial to evaluate safety, tolerability, PK, and efficacy of GFH375 in patients with advanced solid tumors harboring the KRAS G12D mutation.

The primary objective of the Phase I trial is to evaluate safety and tolerability of GFH375 in patients with advanced G12D-mutant solid tumors and determine the MTD and RP2D of GFH375. The primary objective of Phase II trial is to evaluate efficacy of GFH375 in patients with advanced solid tumors, including pancreatic ductal adenocarcinoma, CRC, NSCLC and other solid tumors.

The Phase I trial

Trial design. In the Phase I trial, approximately 30 patients will be enrolled and treated with GFH375 administered orally QD for 21-day treatment cycles. Patients will be assigned to sequentially escalating dose groups at doses of 100 mg, 200 mg, 400 mg, 600 mg, 750mg and 900 mg, with three to six patients enrolled at each dose level. During such dose escalation, patients may be administered GFH375 BID for dose finding. If no DLT event occurs during the first treatment cycle, patients will continue to receive treatment and may receive dose adjustments until disease progression, intolerable toxicity, or termination for other reasons. The primary endpoints of the Phase I clinical trial are to evaluate (i) the incidence and severity of AEs and SAEs, (ii) changes in laboratory tests, vital signs, and electrocardiogram; and (iii) the incidence of DLT. The secondary endpoints of the Phase I study include evaluating (i) plasma concentrations and PK profile, and (ii) ORR, DoR, DCR, TTR, PFS and OS. The above trial design is in line with a conventional Phase I clinical trial.

The key inclusion criteria for the trial include but not limited to: (i) male or female patients aged between 18 and 75 years; (ii) patients with a life expectancy of 12 weeks or more; (iii) patients with histologically or cytologically confirmed advanced or metastatic solid tumors harboring the KRAS G12D mutation; and (iv) patients with at least one measurable lesion. The key exclusion criteria for the trial include but not limited to: (i) patients with active brain metastases; (ii) patients with poorly controlled or severe cardiovascular disease; (iii) patients with active hepatitis B or active hepatitis C viruses; (iv) patients with combined major acute or chronic infectious diseases; or (v) patients who have completed palliative radiotherapy within 14 days prior to the first dose.

Scope of IND Approval. An “umbrella” approval of the Phase I and Phase II clinical trials of GFH375 in patients with advanced solid tumors harboring the KRAS G12D mutation in China were granted by the NMPA in June 2024. As of the Latest Practicable Date, all the ongoing and planned clinical trials of GFH375 in China are under this “umbrella” IND approval. The IND approval and the approved trial protocol did not specify the intended line of treatment. No head-to-head comparison is required or planned prior to the pivotal trial.

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Status. The Phase I clinical trial was initiated in July 2024 and the safety evaluation was completed in January 2025. Based on the trial results, we determined the RP2D to be 600mg.

Safety Data of the Phase I Trial. As of the data cut-off date of January 17, 2025, no death or DLT occurred in the trial. The incidences of Grade 3 or higher TEAEs/TRAEs, SAEs, treatment related SAEs, and the termination/dosage reduction/suspension of clinical trial caused by these AEs, for different dosage cohorts, are summarized below.

	100 mg QD (n=1)	200 mg QD (n=1)	400 mg QD (n=7)	600 mg QD (n=10)	750 mg QD (n=8)	900 mg QD (n=3)	300 mg BID (n=3)	Total (n=33)
Grade 3 or higher								
TEAEs	1(100.0%)	0	5(71.4%)	4(40.0%)	2(25.0%)	0	2(66.7%)	14(42.4%)
Grade 3 or higher								
TRAEs	1(100.0%)	0	3(42.9%)	3(30.0%)	1(12.5%)	0	2(66.7%)	10(30.3%)
SAEs	1(100.0%)	0	1(14.3%)	2(20.0%)	1(12.5%)	0	1(33.3%)	6(18.2%)
Treatment Related								
SAEs	1(100.0%)	0	0	1(10.0%)	0	0	1(33.3%)	3(9.1%)
Trial termination								
caused by AE . . .	0	0	0	2(20.0%)	0	1(33.3%)	0	3(9.1%)
Trial termination								
caused by TRAE . .	0	0	0	1(10.0%)	0	1(33.3%)	0	2(6.1%)
Dosage reduction								
caused by AE . . .	0	0	0	0	1(12.5%)	0	0	1(3.0%)
Dosage reduction								
caused TRAE . . .	0	0	0	0	1(12.5%)	0	0	1(3.0%)
Trial suspension								
caused by AE . . .	1(100.0%)	0	5(71.4%)	1(10.0%)	1(12.5%)	0	2(66.7%)	10(30.3%)
Trial suspension								
caused by TRAE . .	1(100.0%)	0	4(57.1%)	1(10.0%)	0	0	2(66.7%)	8(24.2%)

A total of 10 patients experienced Grade 3 or higher TRAEs, which included diarrhea, increased aspartate aminotransferase, increased gamma-glutamyl transferase, fatigue, decreased white blood cell count, decreased neutrophil count, liver dysfunction, anemia, hypokalemia and syncope.

Under the study protocol, one or more dose groups may be selected to enroll additional subjects as backfilling cohorts to receive a dose of GFH375 monotherapy that has been confirmed to be safe and well-tolerated and that has been assessed by the investigator and sponsor as potentially clinically beneficial, in order to better estimate the RP2D of GFH375 monotherapy and characterize its safety, tolerability, PK and efficacy. Accordingly, after the reach of Phase I primary end points and confirm of RP2D dose at 600 mg, we voluntarily chose to continue to enroll backfilling cohort at 400 and 600 mg QD dose groups to further characterize the pharmacokinetics, efficacy as well as safety of GFH375 as a monotherapy. Accordingly, the Phase I clinical trial enrolled a total of 62 patients, including 33 patients for

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the primary safety evaluation to determine whether the primary endpoints were met, and an additional 29 patients as part of the backfilling cohort. As of the data cutoff date of March 31, 2025, among the 62 patients enrolled, there were no DLTs observed across all dose levels (100-900 mg QD and 300 mg BID), and the TRAEs were mostly Grade 1/2. The most common TRAEs occurring in at least 20% of patients were diarrhea, nausea, vomiting, and anemia. TRAEs $\geq$ Grade 3 consisted mainly of decreased neutrophil count (8%) and diarrhea (5%). No TRAE-related deaths were reported. The following tables summarizes TRAEs observed as of the data cutoff date of March 31, 2025:

	All Patients (N=62)		400mg QD + 600mg QD + 300mg BID (N=49)	
	Any Grade	$\geq$ Grade 3	Any Grade	$\geq$ Grade 3
Any TRAE	62 (100%)	18 (29%)	49 (100%)	15 (31%)
TRAEs occurring in $\geq$ 20% of patients, n (%)				
Diarrhea	43 (69%)	3 (5%)	34 (69%)	2 (4%)
Nausea	42 (68%)	0 (0%)	34 (69%)	0 (0%)
Vomiting	38 (61%)	1 (2%)	29 (59%)	1 (2%)
Anemia	32 (52%)	0 (0%)	26 (53%)	0 (0%)
Decreased appetite	24 (39%)	0 (0%)	20 (41%)	0 (0%)
Neutrophil count decreased . .	21 (34%)	5 (8%)	17 (35%)	4 (8%)
White blood cell count decreased	20 (32%)	1 (2%)	15 (31%)	1 (2%)
AST increased	20 (32%)	1 (2%)	16 (33%)	0 (0%)
Hypoalbuminaemia	17 (27%)	0 (0%)	12 (24%)	0 (0%)
Asthenia	17 (27%)	1 (2%)	15 (31%)	1 (2%)
ALT increase	15 (24%)	0 (0%)	13 (27%)	0 (0%)
TRAEs leading to dose reduction, n (%)	7 (11%)	3 (5%)	5 (10%)	1 (2%)
TRAEs leading to dose interruption, n (%)	13 (21%)	7 (11%)	9 (18%)	6 (12%)
TRAEs leading to treatment discontinuation, n (%)	2 (3%) [#]	2 (3%)	2 (4%)	2 (4%)
Treatment Related SAEs, n (%)	6 (10%)	5 (8%)	5 (10%)	4 (8%)

Notes:

Percentage (%) is rounded to the nearest whole number.

Time from first dosing to safety data cutoff is at least 26 days. Median time on treatment was 6.4 weeks (range: 0.1-38.0)

[#] The two patients discontinued treatment due to G3/4 hepatic function abnormality, both were treated at 600 mg QD.

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As of the data cutoff date of May 16, 2025, among the 52 patients across all dose levels and indications who received at least one post-treatment tumor assessment (efficacy evaluable): the overall ORR was 38% and DCR was 90%; 38 patients exhibited reduction in target lesion, and 20 patients achieved partial response.

As of the data cutoff date of May 16, 2025, among 49 patients orally administered at daily dosages of 400 or 600 mg: 43 patients who received at least one post-treatment tumor assessment achieved an ORR of 42% and a DCR of 91%; the ORR was 52% and DCR was 100% among 23 efficacy-evaluable PDAC patients, and the ORR was 42% and DCR was 83% among 12 efficacy-evaluable NSCLC patients. Pharmacokinetic analysis revealed the dose levels of 400 mg and 600 mg QD were able to achieve average trough concentrations that were three times above the IC₉₀ value for p-ERK inhibition in AsPC-1 cells. Moreover, 600 mg QD has been recommended as the phase II dose (RP2D) for the phase II portion which started in February 2025.

Phase II trial

Trial design. The Phase II trial plans to enroll approximately 317 subjects with advanced solid tumors with KRAS G12D mutations to receive continuous monotherapy with GFH375 at RP2D for 21 days. Patients will receive GFH375 monotherapy until disease progression, intolerable toxicity, or termination for other reasons. The primary endpoint of the Phase II clinical trial is to evaluate ORR. The secondary endpoints of the Phase II trial are to evaluate (i) DoR, DCR, TTR, PFS, best overall response and OS; (ii) the incidence and severity of AEs and SAEs; (iii) changes in laboratory tests, vital signs, and electrocardiogram; and (iv) plasma concentrations.

The key inclusion criteria for the trial include but not limited to: (i) male or female patients aged between 18 and 75 years; (ii) patients with a life expectancy of 12 weeks or more; (iii) patients with histologically or cytologically confirmed advanced or metastatic solid tumors harboring the KRAS G12D mutation; and (iv) patients with at least one measurable lesion. The key exclusion criteria for the trial include but not limited to: (i) patients with active brain metastases; (ii) patients with poorly controlled or severe cardiovascular disease; (iii) patients with active hepatitis B or active hepatitis C viruses; (iv) patients with combined major acute or chronic infectious diseases; or (v) patients who have completed palliative radiotherapy within 14 days prior to the first dose.

Status. On February 25, 2025, the ethics committee approved our plan for a Phase II clinical trial, which marked the initiation of the trial. The Phase II clinical trial has started patient enrollment. We expect to complete the trial in the fourth quarter of 2028.

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Safety data of the Phase I/II trial:

As of the data cutoff date of July 17, 2025, 142 patients were enrolled, including 28 patients with NSCLC, 85 patients with PDAC and 29 patients with other solid tumors, whose median exposure time of GFH375 was 2.2 (range: 0.2-11.3) months. The most common TRAEs (reported in $\geq 20\%$ patients) were diarrhea, vomiting, nausea, anemia, decreased appetite, neutrophil count decrease, white blood cell count decrease, aspartate aminotransferase increase, asthenia, hypoalbuminemia and alanine aminotransferase increase. The TRAEs were primarily Grade 1 or 2. TRAEs of Grade 3/4 and SAEs occurred in 27.5% (39/142) and 7.7% (11/142) of the patients. 11 patients (7.7%) had dose reduction, and 6 patients (4.2%) discontinued treatment due to TRAEs. No treatment-related death was recorded.

Efficacy data of the Phase I/II trial:

As of the data cutoff date of July 15, 2025, among the 16 patients treated with GFH375 at 600 mg QD, ORR was 68.8% and DCR was 93.8%.

Tumor response was observed at all dose levels. Among the 28 NSCLC patients recruited in the study, the median follow-up time was 4.5 (range: 1.8-12.2) months, and tumor response was observed at all dose levels. Among the 26 evaluable patients, ORR was 57.7% and DCR was 88.5%.

GFH375X1201: A Phase II study to evaluate GFH375 in patients with KRAS G12D mutant metastatic pancreatic cancer

Overview. This is a multicenter, open-label, Phase II study to explore the efficacy, safety/tolerability and PK of GFH375 in patients with previously treated KRAS G12D mutant metastatic pancreatic cancer. The primary objective is to evaluate the efficacy of GFH375 in treating KRAS G12D mutant metastatic pancreatic cancer. The secondary objectives are to evaluate the safety, tolerability and PK profile of GFH375 in treating KRAS G12D mutant metastatic pancreatic cancer.

Trial Design. About 83 patients will be enrolled and treated with GFH375 administered orally 600 mg QD for 21-day treatment cycles until disease progression, intolerable toxicity, or termination of study treatment due to other reasons. The patients will return to the study center about 30 days after the last treatment to complete a safety follow-up, and survival follow-up will be conducted about every 90 days thereafter. The primary endpoint is to evaluate ORR per RECIST 1.1 by blinded independent central review. The secondary endpoints are to evaluate (i) ORR per RECIST 1.1 by the investigator; (ii) DoR, DCR, TTR, PFS, and OS; (iii) the incidence and severity of AEs and SAEs; and (iv) plasma concentration of GFH375.

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The key inclusion criteria for the trial include: (i) male or female aged between 18 and 75 years; (ii) histologically or cytologically confirmed metastatic pancreatic cancer harboring KRAS G12D mutation; (iii) able to provide tumor tissue samples that meet the requirements; (iv) having at least one measurable lesion according to RECIST1.1; and (v) life expectancy above 12 weeks. The key exclusion criteria for the trial include: (i) active brain metastases; (ii) prior treatment with a KRAS G12D inhibitor or a pan-RAS/KRAS inhibitor; (iii) with poorly controlled or severe cardiovascular disease; (iv) with active hepatitis B or active hepatitis C; and (v) known allergy to the study drug or its components.

Status. We plan to initiate the clinical trial in the fourth quarter of 2025.

Clinical Development Plan

GFH375X1101

We have initiated the Phase II part of the Phase I/II clinical trial in patients with advanced solid tumors harboring the KRAS G12D mutation in China in February 2025. We expect to submit to the NMPA a pre-pivotal study communication request in the third quarter of 2025 and initiate a pivotal clinical study of GFH375 as a treatment of pancreatic ductal adenocarcinoma (“PDAC”) in the fourth quarter of 2025. We expect to submit to the NMPA an NDA for GFH375 as a treatment of PDAC in the third quarter of 2027. In addition, we expect to submit to the NMPA a pre-pivotal study communication request in the fourth quarter of 2025 and initiate a pivotal clinical study of GFH375 as a treatment of NSCLC in the first quarter of 2026. We expect to submit to the NMPA an NDA for GFH375 as a treatment of NSCLC in the third quarter of 2027. We also expect to initiate clinical studies of GFH375 in combination with other drugs in the fourth quarter of 2025 for previously treated CRC, and treatment-naïve PDAC and NSCLC.

GFH375X1201

We plan to initiate the clinical trial in the fourth quarter of 2025.

U.S. Phase 1/2a Study of VS-7375

Verastem has initiated a Phase I/IIa clinical trial of GFH375 in patients with advanced solid tumors harboring the KRAS G12D mutation in the U.S. In June 2025, the first patient was dosed in the trial.

Licenses, Rights and Obligations

We collaborated with Verastem to facilitate the swift development and approval of GFH375 for commercialization outside Greater China, while we retain development and commercialization rights within Greater China. Verastem is a U.S. based Nasdaq-listed biopharmaceutical company committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with RAS/MAPK pathway-driven cancers. Our collaboration with Verastem leverages the latter’s expertise in conducting clinical trials of RAS inhibitor drug candidates in the U.S. and other countries, as well as Verastem’s successful experience in obtaining FDA approval for RAS inhibitor drugs.

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On August 24, 2023, we entered into a collaboration and option agreement with Verastem, pursuant to which, on a program-by-program basis, we granted Verastem options to acquire an exclusive license to develop and commercialize three product candidates, including GFH375, in territories outside of Greater China within the specified option exercise period. Verastem agreed to pay an upfront payment in two installments, certain development costs, as well as stipulated milestone payments, option exercise fees and royalties on future annual net sales. GFH375 was independently discovered and developed by the Company, and Verastem was not involved in its initial discovery or in any clinical research and development activities related to the GFH375X1101 trial. For additional information, see “— Major Collaboration and Licensing Arrangements — Collaboration and Option Agreement with Verastem.” In January 2025, Verastem exercised the option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China.

Material Communications with Competent Authorities

We submitted the IND application for the GFH375X1101 trial to the NMPA in March 2024. In June 2024, the NMPA issued the IND approval without material inquiries or objections. The clinical trial protocol of GFH375X1101 communicated with the CDE of the NMPA covers both Phase Ia/Ib and Phase II clinical trials of GFH375, and Phase Ia/Ib and Phase II clinical trials are two separate trials with different objectives and endpoints. The approved clinical trial protocol does not require us to communicate with the NMPA prior to the commencement of the Phase II trial and only requires obtaining approval from the ethics committee for the clinical trial protocol before commencing Phase II trial. In September 2024, we amended the clinical trial protocol design to specify the BID regime that may be applied to patients in dose exploration in Phase Ia. The starting dose of BID will be selected from one of the five dose groups (100mg, 150mg, 200mg, 300mg, and 400mg), and the total daily dose will be consistent with the QD dose already explored. In November 2024, we amended the clinical trial protocol regarding Phase I, by removing the Phase Ib trial, and amending the QD dose levels to be administered and the size of potential backfilling cohorts. On January 22, 2025, the sponsor and principal investigators of the GFH375X1101 trial had a discussion on the Phase I clinical trial to confirm that the primary endpoints of the Phase I clinical trial had been reached and RP2D had been decided, and therefore the Phase II clinical trial was allowed to be initiated according to the study protocol. We thereafter amended the clinical trial protocol in late January 2025 to provide clinical basis of the determination of the RP2D and amended inclusion and exclusion criteria for PDAC and NSCLC patients.

Each clinical trial protocol amendment mentioned above have been submitted to clinical trial management system, and we have not received any objection or concerns from CDE as of the Latest Practicable Date. Our PRC Legal Advisor has consulted with the CDE, during which (i) the CDE confirmed that all amendments to the initial clinical trial protocol (including removing a previously planned Phase Ib clinical trial), so long as the safety of the subjects remains unaffected, are allowed without requiring additional approvals or review from the CDE, (ii) the CDE did not raise any concerns or questions on our submissions regarding amendments to clinical trial protocol via the CDE’s clinical trial management system; and (iii) the CDE did not object that we can proceed with a Phase II clinical trial after reaching primary

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endpoints in the Phase I clinical trial. According to the “umbrella” approval of the Phase I and Phase II clinical trials of GFH375 from the NMPA and the aforementioned consultation with the CDE, Phase I trial of the Phase I/II clinical trial of GFH375 is a standalone complete trial equivalent to a typical Phase I clinical trial regulated by the Competent Authority.

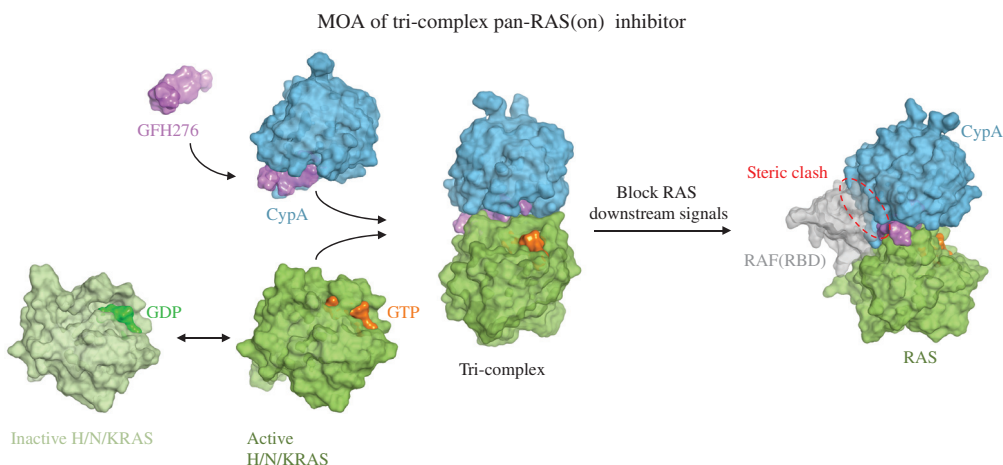
In April 2025, the FDA granted Verastem’s IND application to conduct a Phase I/IIa clinical trial of GFH375 in patients with advanced solid tumors harboring the KRAS G12D mutation in the U.S.

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Preclinical RAS-targeting Candidates

GFH276: A Pan-RAS Molecular Glue

GFH276 is our flagship product candidate exploring pan-RAS approaches. Pan-RAS approaches, which inhibit all mutant and wild-type RAS isoforms, have theoretical advantages over their mutant-specific counterparts. GFH276 acts as a molecular glue by forming a binary complex with the chaperone protein CypA, which in turn associates with RAS in the “on” state, regardless of the particular RAS variants. Formation of the tricomplex of GFH276, CypA and RAS leads to steric occlusion and prevents the binding of downstream effector proteins to RAS, therefore disrupting signaling pathways that drive cell growth. The following diagram depicts the mechanism of action of GFH276.

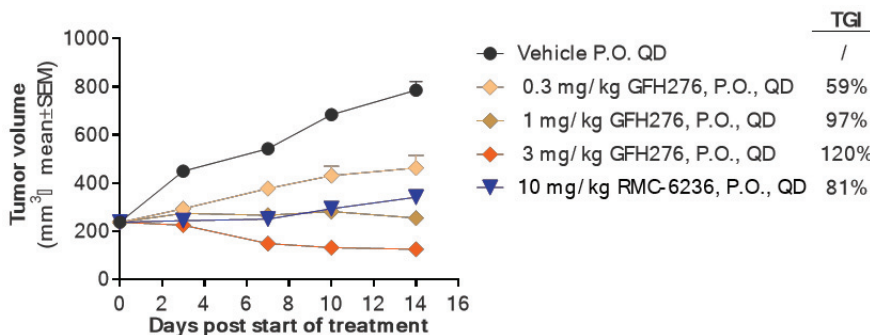


Source: Company information

Notes: CypA: Cyclophilin A; RAF: a family of protein kinase downstream of RAS in the RAS pathway and can be activated by binding to GTP-bound RAS; PI3K: Phosphoinositide 3-kinase, which plays a crucial role in various cellular functions, including cell growth, proliferation and survival, and can be activated by interacting with RAS through its RAS-binding domain.

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RMC-6236, the only pan-RAS candidate with similar mechanism of action as GFH276 under Phase III clinical trial being developed worldwide, has demonstrated potentially favorable clinical efficacy in early trials. Notably, preclinical data of GFH276 showed that its efficacy in animals is better than that of RMC-6236, requiring only one-tenth of the dose to achieve comparable tumor growth inhibition. The diagram below illustrates that in the AsPC-1 CDX pancreatic ductal adenocarcinoma model, GFH276 at a dose of 1 mg/kg was more effective than RMC-6236 at a dose of 10 mg/kg.



Source: Company information

GFH276 also demonstrated potential anti-proliferative activity in cells that harbor a single G12C mutation in KRAS or an additional KRAS mutation that can render the cells resistant to adagrasib, suggesting the potential of GFH276 to control tumor cells growth when acquired resistance renders approved KRAS G12C inhibitors less effective. Furthermore, GFH276 demonstrated potential anti-proliferative activity in cells that are induced to be resistant by sotorasib.

Effect of 2nd KRAS mutation on AP IC₅₀ in Ba/F3 cells lines (nM)

Cell Line	GFH276	RMC-6236	Adagrasib
Ba/F3-KRAS-G12C	0.38	0.25	7.0
Ba/F3-KRAS-G12C-R68S	4.06	1.67	306
Ba/F3-KRAS-G12C-H95Q	0.27	0.21	549
Ba/F3-KRAS-G12C-Y96C	0.33	0.24	757

AP IC₅₀ sotorasib-resistant NCI-H358 cell line

No.	Compound	Compound type	IC ₅₀ (nM)
1	GFH276	panRAS (on) inhibitor	42
2	RMC-6236	panRAS (on) inhibitor	46
3	Sotorasib	SIIP-based KRAS G12C inhibitor	4,396
4	Adagrasib	SIIP-based KRAS G12C inhibitor	2,177
5	Divarasib	SIIP-based KRAS G12C inhibitor	>10,000
6	Cyclosporin A	Inhibitor by CypA	>10,000

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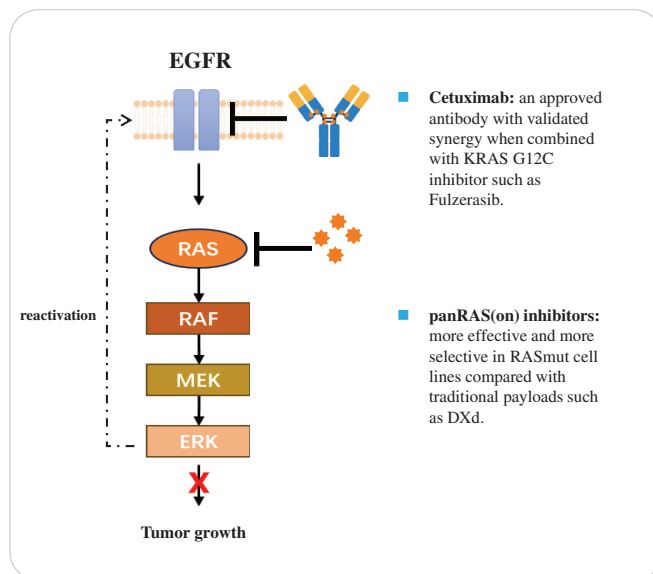
Source: Company information

Note: FGFR2-TACC2: a fusion protein of fibroblast growth factor receptor 2 and transforming acidic coiled-coil protein-2, which appears in multiple tumor types; PBS: phosphate-buffered saline; IC₅₀: half maximal inhibitory concentration, a lower concentration indicates a stronger inhibitory effect.

We believe the encouraging preclinical activities of GFH276 underscore its potential to overcome limitations of mutant specific KRAS inhibitors and benefit a broad patient population in need. We submitted an IND application to the NMPA for conducting a Phase I/II clinical trial of GFH276 in June 2025.

GFS784: EGFR-Pan-RAS Functional Antibody Synergetic Conjugate

GFS784 is our leading functional antibody synergistic conjugate (“**FAScon**”) candidate. FAScon is a class of bioconjugates featuring a combination of antibody and small molecule drug targeting separate components of the same signaling pathway. The design of FAScon also incorporates a highly hydrophilic linker, which is sufficiently stable to prevent premature release of payload in the blood and enables conjugation of hydrophobic small molecules at a high drug-to-antibody ratio. The following diagram depicts the mechanism of action of GFS784.

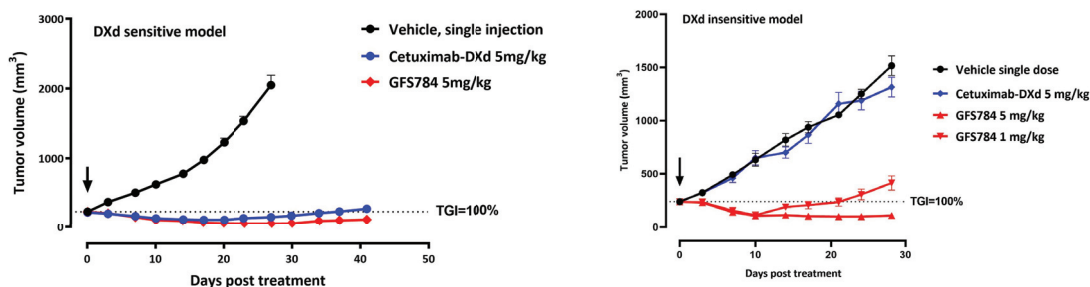


Source: Company information

GFS784 consists of an antibody that blocks EGFR, an upstream cell surface receptor of RAS, and a small molecule pan-RAS inhibitor. We believe this design has the potential to deliver clinical benefits, given the encouraging results of our clinical development of the GFH925/cetuximab combination, which also targets EGFR and a RAS variant. In our preclinical studies, GFS784 demonstrated durable antitumor activity measured by tumor volume in mice models, as showed in the following diagram. Such antitumor activity of

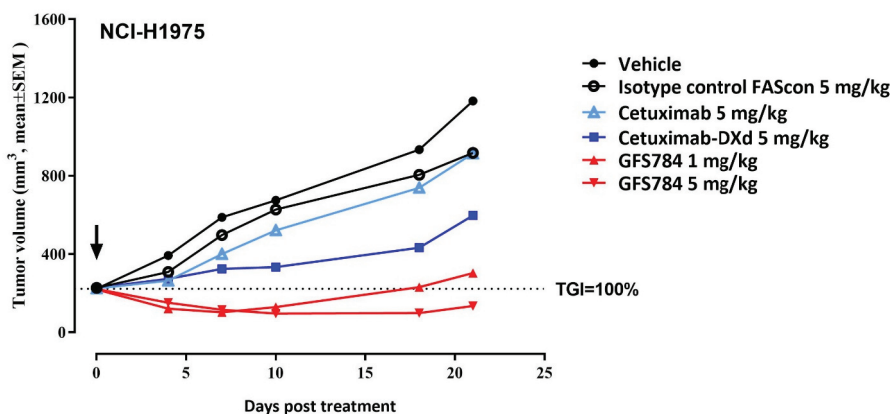
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GFS784 was comparable to that of an EGFR-exatecan derivatives (“**DXd**”) ADC in DXd sensitive mouse model. Dxd is a commonly deployed cytotoxic payload in ADCs. In DXd insensitive model, while the EGFR-DXd ADC demonstrated significantly reduced antitumor activity, GFS784 still inhibited the growth of tumor in a durable manner, underscoring that GFS784 functions through a different mechanism from that of a typical ADC compound.



Source: Company information

In the EGFRm KRAS wildtype H1975 NSCLC xenograft model, single dose administration of GFS784 had demonstrated enhanced efficacy compared to EGFR-DXd ADC, as illustrated in the following diagram, demonstrating potential in treating EGFRm NSCLC patients.



Source: Company information

We plan to complete the preclinical study for GFS784 and file an IND application with the NMPA in the first quarter of 2026.

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OTHER PIPELINE PRODUCTS

GFH312: A Small Molecule Inhibitor of RIPK1

GFH312 is an in-house developed, potent small molecule that targets RIPK1 and inhibits its kinase activity. Activation of RIPK1 plays significant roles in autoimmune disorders, inflammatory conditions and neurodegeneration. We completed one Phase I clinical trial in Australia (GFH312X3101) and one Phase I clinical trial in China (GFH312X1102), both in healthy participants. Both clinical trials demonstrated favorable safety profiles. We have received the IND approval from the FDA for a Phase II clinical trial to evaluate the safety and efficacy of GFH312 for the treatment of PAD with IC. We have also received IND approval from the NMPA for a Phase II clinical trial of GFH312 for the treatment of PBC. The results of the Phase I clinical trial in Australia supported the Phase II IND approval in the United States.

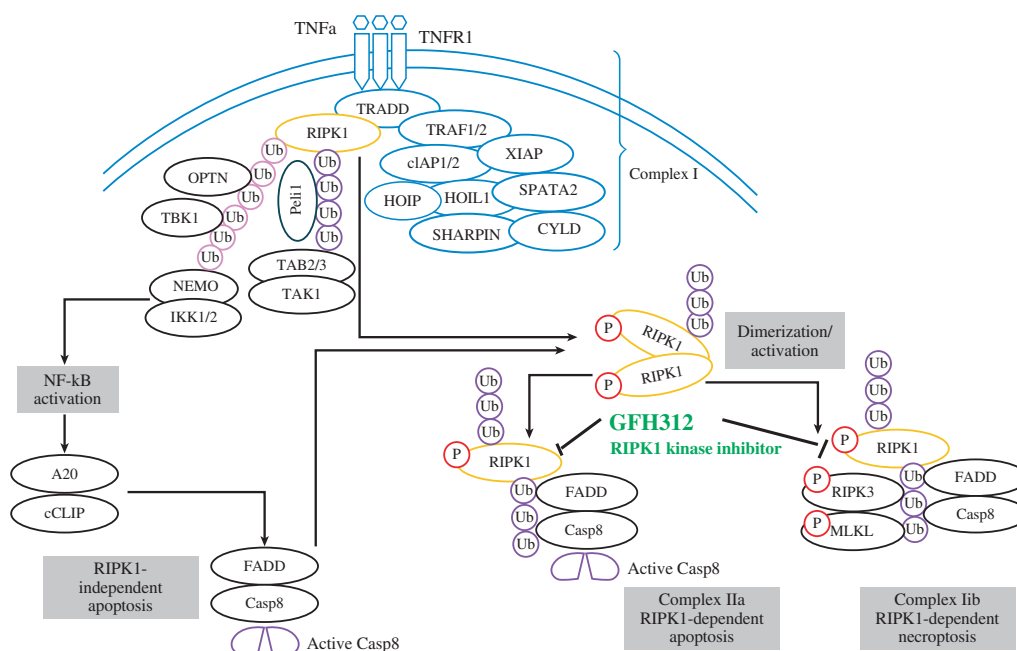
Mechanism of Action

RIPK1 is a master regulator of cellular fate, balancing pro-survival nuclear factor kappa B (“**NF- κ B**”) signaling and cell death in response to a wide range of inflammatory processes, apoptosis, and necroptosis in human diseases. Activation of RIPK1 kinase has been observed in pathological samples from autoimmune, inflammatory, and neurodegenerative conditions. Additionally, both monogenic and polygenic variants of known RIPK1 regulators contribute to inflammatory and neurodegenerative diseases. Furthermore, RIPK1 kinase activation plays a central role in mediating cell necroptosis following the activation of tumor necrosis factor receptor 1 (“**TNFR1**”) by TNF- α , particularly in apoptosis-deficient conditions.

RIPK1 inhibitors downregulate RIPK1 kinase activity and effectively suppress cell death induced by TNF- α and caspase inhibitors. Inhibition of RIPK1 has demonstrated efficacy across a wide range of human diseases, including multiple types of neurodegenerative conditions and autoimmune diseases. GFH312 inhibits RIPK1 kinase activity, blocking cell death and associated inflammation, making it a potent treatment for autoimmune and inflammatory diseases.

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The diagram below illustrates the mechanism of action of GFH312:



Source: Company information

Abbreviations: Casp: Caspase; cCLIP: canonical caspase-dependent lipid-interacting protein; CLAP: caspase-like apoptosis protein; CYLD: Cylindromatosis; FDAA: fluoromethyl ketone-modified dipeptide amino acid; HOIL: HOIP interacting protein; HOIP: HECT domain and Ankyrin repeat containing E3 ubiquitin protein ligase; IKK: IκB kinase; NEMO: NF-κB essential modulator; OPTN: optineurin; SHARPIN: SHANK-associated Romain-binding protein; SPATA: spermatogenesis associated protein; TAB: TAK1-binding protein; TAK: transforming growth factor beta-activated kinase; TBK1: TANK-binding kinase 1; TNF: tumor necrosis factor; TNFR: tumor necrosis factor receptor; TRADD: TNF receptor-associated death domain protein; TRAF: TNF receptor-associated factor; Ub: ubiquitin XIAP: X-linked inhibitor of apoptosis protein

Market Opportunity and Competition¹

As of the Latest Practicable Date, there was no approved RIPK1 inhibitor drug globally. There were seven RIPK1 inhibitor candidates under clinical development globally as of Latest Practicable Date, and GFH312 was the only one developed for the treatment of PAD and PBC.

PAD is a common condition in which atherosclerosis causes narrowed arteries that reduce blood flow to the arms or legs. Atherosclerosis, the gradual buildup of plaque inside the arteries, is closely linked to inflammation. PAD is estimated to affect over 300 million people worldwide, according to Frost & Sullivan. The classic symptom of PAD, IC, is characterized by exertional leg pain that resolves with rest and is estimated to affect approximately 5.5% of the newly diagnosed patients with PAD and 12.6% of the patients with a prior diagnosis of PAD. Patients with PAD with IC have impaired walking ability, poor functional outcomes, and

Note

1. Market information and statistics set out in this subsection have been extracted from an report prepared by Frost & Sullivan.

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a reduced quality of life. However, few pharmacological therapy options are available to address the inflammatory mechanisms of PAD. According to Frost & Sullivan, global PAD drug market grew from US\$8.1 billion in 2019 to US\$10.4 billion in 2024, and is expected to further grow to US\$14.0 billion in 2033. Given the observed elevation of RIPK1 expression in human atherosclerotic lesions, RIPK1 has been viewed as a potential therapeutic target for reducing residual inflammation in patients at high risk of developing coronary artery disease.

PBC is a chronic, slowly progressive autoimmune, cholestatic liver disease. It is characterized by progressive inflammation and destruction of small bile ducts, resulting in fibrosis, cirrhosis, and eventually leading to complications of end-stage liver disease and death. The prevalence of PBC reached 1.2 million globally and 287.3 thousand in China in 2023, according to Frost & Sullivan. As of the Latest Practicable Date, there were four drugs approved by the FDA for the treatment of PBC. Current recommended treatments include first-line treatment of UDCA and second-line treatment of OCA. Similarly in China, UDCA is generally the first-line treatment option to PBC. However, approximately 40% of patients with PBC exhibit incomplete response to UDCA, leaving considerable medical need for novel treatments of PBC. We believe that GFH312 possesses the therapeutic potential to alleviate the root cause of PBC.

Competitive Advantages

We believe that GFH312 has the following competitive advantages:

Demonstrated tolerability in clinical and preclinical studies

GFH312 has demonstrated potentially favorable safety profile in clinical trials. We have completed two Phase I clinical trials in healthy participants in Australia and China. All TEAEs reported were classified as Grade 1 or 2. There were no Grade 3 or above AEs, no SAEs or deaths. The overall safety and tolerability of GFH312 were favorable for repeated doses of up to 200 mg QD.

GFH312 also demonstrated a favorable safety profile in *in vivo* preclinical studies involving rat and monkey models. In particular, GFH312 had no effects on either the central nervous system or respiratory system at any dose tested in rats. Preclinical studies in monkeys also indicated that GFH312 had no effects on cardiovascular function at tested doses.

Favorable activity in preclinical studies

The preclinical activity of GFH312 was evaluated in TNF- α -induced systemic inflammatory response syndrome and myelin oligodendrocyte glycoprotein-induced experimental autoimmune encephalomyelitis mouse models. In the systemic inflammatory response model, a single oral dose of GFH312 increased the survival rate in a dose-dependent manner. In the experimental autoimmune encephalomyelitis mouse model, orally administered GFH312 at doses of 1 mg/kg and 3 mg/kg, twice daily, attenuated the development of experimental autoimmune encephalomyelitis, resulting in significant reductions in clinical scores, protection against body weight loss, and reductions in inflammatory infiltration and demyelination, in a dose-dependent manner.

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Potentially promising PK/PD profile

The Phase I clinical trial of GFH312 (GFH312X3101) conducted on healthy participants in Australia revealed a potentially promising PK/PD profile. In participants receiving a single ascending dose (“**SAD**”) of GFH312, the mean plasma concentration of GFH312 increased with the dose level, and exposures (AUC_{0-t} and C_{max}) increased with increasing dose over the 5 mg to 360 mg range. In participants receiving multiple ascending dose (“**MAD**”) treatment, plasma concentration approached steady-state approximately seven days after administration. The GFH312 CSF concentration following a 100 mg single dose was approximately fourfold higher than the half maximal inhibitory concentration of human monocyte-derived macrophages necroptosis with expected central nervous system penetration. All dose levels of GFH312 in both SAD and MAD treatments resulted in a rapid decrease of phospho-RIPK1 levels from baseline. This decrease was sustained for 24 hours post-dose for SAD and from day 1 to day 14 for MAD. The PD results indicate that GFH312 at a dose level as low as 5 mg is sufficient to produce an effective and sustained inhibition of phospho-RIPK1.

Summary of Clinical Trials

As of the Latest Practicable Date, we had completed one Phase I clinical trial in Australia (GFH312X3101) and one Phase I clinical trial in China (GFH312X1102). We have also received the IND approval from the FDA for a Phase II clinical trial to evaluate the safety and efficacy of GFH312 for the treatment of PAD with IC. The results of the Phase I clinical trial in Australia supported the Phase II IND approval in the United States and were the only clinical results that we submitted for the consideration by the FDA. The following table sets forth an overview of the completed clinical trials of GFH312:

Study Number	Phase	Study Design	Sites	Subjects	Status	Planned/ Actual Patient Enrollment
GFH312X3101 . . . I		Evaluate safety, tolerability and PK of single- and multiple-ascending doses and food effect of GFH312	Australia	Healthy participants	Completed	Planned: 88; Actual: 76
GFH312X1102 . . . I		Evaluate PK profile and safety of GFH312 after single and multiple administrations	Mainland China	Healthy participants	Completed	Planned: 26; Actual: 26

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Scope of the IND Approval/Registration. The Phase I clinical trial of GFH312 in healthy participants in Australia was registered with the TGA in February 2021. The Phase II clinical trial of GFH312 in patients with PAD and IC in the United States was approved by the FDA in August 2022. The Phase I clinical trial of GFH312 for potential treatment of rheumatoid arthritis in healthy subjects in China was approved by the NMPA in September 2022. The Phase II clinical trial of GFH312 in PBC was approved by the NMPA in May 2025. The IND approval and the approved trial protocol did not specify the intended line of treatment. No head-to-head comparison is required or planned prior to the pivotal trial.

The following sets forth an overview of the key clinical trial of GFH312:

GFH312X3101: A Phase I first-in-human, randomized, double blinded, placebo-controlled, two-part study to assess safety/tolerability and PK of single- and multiple-ascending doses and food effect of GFH312 in healthy participants in Australia sponsored by us

Overview. This trial is a first-in-human, randomized, double-blinded, placebo-controlled Phase I clinical trial to evaluate safety, tolerability and PK of SAD and MAD and food effect of GFH312 in healthy participants. The primary objective is to evaluate the safety, tolerability of single (administered under fed and fasted conditions) and repeat doses of GFH312 in healthy participants. The secondary objective is to characterize the PK profile of single and repeat doses of GFH312 in healthy participants.

Trial design. The trial was divided into two parts: an SAD (Part Ia) with an additional food effect cohort (Part Ib), and an MAD (Part II). In Part I, 52 participants were randomized and dosed, with 38 receiving GFH312 treatment and 14 receiving placebo treatment. Each dose level of GFH312 included six participants at 5 mg, 15 mg, 45 mg, and 200 mg; five participants at the 100 mg fasting and 360 mg dose levels; and four participants at the 500 mg dose level. For the fed treatment, six participants received the 100 mg dose of GFH312. In Part II, 24 participants were dosed, with 19 receiving GFH312 treatment and five receiving placebo treatment. This part included six participants at the 60 mg QD and 200 mg QD dose levels, and seven participants at the 120 mg QD dose level.

Subjects in Part Ia had a duration of treatment of up to 62 days and a follow-up visit at Day 31 (± 3 days). Subjects in Part Ib had a duration of treatment of up to 96 days across 2 periods, with an intervening washout period of ≥ 7 days. Part Ib subjects completed all of the study periods for Part Ia (up to 62 days), followed by a washout period of ≥ 7 days, and then up to an additional 34 days composed of a baseline visit at Day -1, 4 days of assessment during the treatment period, a study completion visit at Day 8 (± 1 days), and a follow-up visit at Day 31 (± 3 days). Subjects in Part II had a duration of treatment of up to 75 days, a study completion visit at Day 21 (± 1 days), and a follow-up visit at 30 days after the last treatment (± 3 days).

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The primary endpoints were to evaluate incidence of AEs and SAEs, and change in laboratory values, electrocardiogram, vital signs, and physical examinations. For the single doses of GFH312, the secondary endpoints were to evaluate (i) plasma concentration of GFH312 and derived PK parameters, and (ii) cerebrospinal fluid concentration and cerebrospinal fluid/plasma ratio of GFH312 in one cohort. For the repeat doses of GFH312, the secondary endpoints were to evaluate (i) plasma concentration of GFH312 and derived PK parameters, and (ii) cerebrospinal fluid concentration and cerebrospinal fluid/plasma ratio of GFH312 following repeat doses in one cohort.

The key inclusion criteria for the trial include but not limited to: (i) healthy male and female participants aged between 18 and 55 years; (ii) participants with sitting vital signs within the normal ranges; and (iii) participants weighing at least 50 kg, with a body mass index within the range of 18-32kg/m² inclusive. The key exclusion criteria for the trial include but not limited to: (i) participants with clinically significant electrocardiograph abnormalities; (ii) participants with immunodeficiency diseases; (iii) participants with chronic infection with hepatitis B or hepatitis C viruses; (iv) participants with significant cardiovascular, respiratory, renal or neurological diseases; or (v) participants with recent (within the last three years) and/or recurrent autonomic dysfunction.

Status. The trial was initiated in April 2021, and completed in October 2022 in Australia. The trial enrolled 76 participants.

Safety Data. In the SAD cohorts, the incidence of TEAEs was 42.1% (16 out of 38) among participants receiving GFH312 (0 in the 100mg GFH312 treatment (fed) cohorts; 33.3% in the 5mg, 45mg, 200mg GFH312 treatment (fasting) cohorts; 40.0 % in the 360mg GFH312 treatment (fasting) cohort, 50% in the 15mg and 500mg GFH312 treatment (fasting) cohorts, and 60% in the 100mg GFH312 treatment (fasting) cohort), and 42.9% (6 out of 14) in the participants receiving placebo. TRAEs were reported in two participants receiving GFH312 (5.3%) and two participants receiving placebo (14.3%). The TEAEs reported in at least 5% of the overall participants included headache (7.9% of GFH312 vs. 7.1% of placebo), procedural pain (7.9% of GFH312 vs. 7.1% of placebo), and muscle twitching (5.3% of GFH312 vs. 7.1% of placebo). The TRAEs reported were one headache and one muscle twitching in the GFH312 treatment cohorts, and one muscle twitching and one diarrhea in the placebo treatment cohorts. All TEAEs and TRAEs were Grade 1 according to CTCAE v5.0.

In the MAD cohorts, the incidence of TEAEs was 63.2% (12 out of 19) among participants receiving GFH312 (66.7% in the 60mg GFH312 treatment cohort, 71.4% in 120mg treatment cohort and 50.0% in the 200mg GFH312 treatment cohort), and 40.0% (2 out of 5) of participants receiving placebo. TRAEs were reported in 21.1% (4 out of 19) of participants receiving GFH312 (14.3% and 50.0% in the 120mg and 200mg GFH312 treatment cohorts, respectively), and 20.0% (1 out of 5) of participants receiving placebo. The TEAEs reported in at least 10% of the overall participants included headache, post-procedural complication, procedural pain, back pain and nausea. Most TEAEs were Grade 1 according to CTCAE v5.0, except for three Grade 2 events (positional vertigo in the 60mg GFH312 treatment cohort, back pain in the 120mg GFH312 treatment cohort, and increased blood creatinine in the 200mg

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GFH312 treatment cohort). The TRAEs reported among participants receiving GFH312 included three patients with headache (Grade 1) and one patient with increased blood creatinine (Grade 2, recovered to normal condition at the end of treatment visit). No Grade 3 or above AEs were reported, and there were no SAEs or deaths. Three participants discontinued the treatment early due to TEAEs in MAD cohorts: two participants (10.5%) in the GFH312 treatment cohorts and one participant (20.0%) in the placebo treatment cohort. One participant in the 200mg GFH312 MAD treatment cohort discontinued the treatment early due to increased blood creatinine (Grade 2), which was related to GFH312. All TEAEs were not significantly associated with any specific system organ classes or dose levels.

The results demonstrated that GFH312 was safe and well tolerated in healthy participants. A favorable safety profile was observed with the 120 mg once-daily dose of GFH312 treatment.

GFH312X1102: A Phase I clinical trial to evaluate safety and PK profile of GFH312 after single and multiple administrations in healthy participants in Mainland China sponsored by us

Overview. This trial is a randomized, double-blind, placebo-controlled, parallel-group, single-dose and multiple-dose Phase I clinical trial to evaluate safety and PK profile of GFH312 in healthy participants. The primary objective is to evaluate PK profile of GFH312 after single and multiple administrations in healthy participants. The secondary objectives are to evaluate safety of GFH312 after single and multiple administrations in healthy participants.

Trial design. A total of 26 participants are randomized and treated orally with GFH312 or placebo once daily for 14 days in three cohorts: 100 mg GFH312 in the single-dose cohort, 200 mg GFH312 in the single-dose cohort, and 120 mg GFH312 in the multiple-dose cohort. In each single-dose cohort, eight healthy participants are randomly assigned to receive either GFH312 or placebo in a 3:1 (GFH312: placebo) ratio. The multiple-dose group includes 10 healthy participants who are randomly assigned to receive either GFH312 or placebo in a 4:1 (GFH312: placebo) ratio. The primary endpoints are to evaluate blood concentration and PK profile of GFH312. The secondary endpoints are to evaluate incidence and percentage of AE and SAEs, and change from baseline in physical examination, vital signs, 12-lead electrocardiograph, and laboratory tests.

The key inclusion criteria for the trial include but not limited to: (i) healthy male or female participants aged between 18 and 55 years; (ii) participants with a body mass index between 18-28 kg/m² (inclusive), and weight of at least 50kg; and (iii) participants with normal examination results or with abnormal examination results that are not clinically significant during the screening period and on Day-1. The key exclusion criteria for the trial include but not limited to: (i) participants with abnormal electrocardiogram with clinical significance; (ii) participants with immunodeficiency diseases, including a positive human immunodeficiency virus antibody test; (iii) participants with significant cardiovascular, respiratory or neurological diseases; (iv) participants with any type of malignant tumor within the last five years; or (v) participants with major diseases that have not been recovered within two weeks prior to initiation of dosing.

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Status. The trial was initiated in December 2022 and completed in February 2023 in Mainland China.

Safety Data. A total of 10 subjects (38.5%) experienced 16 TRAEs. In the single-dose cohort, TRAEs were reported in three (25%) participants receiving GFH312 and two (50%) participants receiving placebo. In the multiple-dose cohort, TRAEs occurred in five (62.5%) participants receiving GFH312, with no participants receiving placebo reported. The most common TRAE was an elevation in blood triglyceride, occurred in one (8.3%) participant receiving GFH312 and one (25%) participant receiving placebo in the single-dose group, as well as in only one (12.5%) participant receiving GFH312 in the multiple-dose group. All TRAEs were Grade 1 in severity. No dose-related trends were observed in laboratory findings, vital signs, weight, physical examinations, and electrocardiography, or differences in changes associated with GFH312 or placebo administration. In summary, the overall safety and tolerability of GFH312 were favorable for single doses of 100 mg or 200 mg and multiple repeated doses of 120 mg.

GFH312X1102: A Phase II clinical trial to evaluate the safety and efficacy of GFH312 in patients with PBC who have an inadequate response to UDCA in Mainland China sponsored by us

Overview. This is a randomized, double-blind, placebo-controlled, dose-finding Phase II clinical study to evaluate the safety and efficacy of GFH312 in patients with PBC who have an inadequate response to UDCA. The primary objective is to evaluate the efficacy, safety and tolerability of GFH312 in the PBC patients. The second objectives are to evaluate the PK profile of GFH312 and the changes of the following parameters in the PBC patients including liver function, metabolism, itching, total bile acid, inflammation, and metabolic bone disease.

Trial Design. About 100 patients will be randomized and treated orally with GFH312 or placebo once daily for 12 weeks in four cohorts: placebo cohort; 40 mg GFH312; 80 mg GFH312; 120 mg GFH312. The primary endpoints are to evaluate the percentage change of alkaline phosphatase (“ALP”) from baseline, the AEs, and the change from baseline in physical examination, vital signs, 12-lead electrocardiograph, and laboratory tests. The secondary endpoints include plasma concentration and PK profile of GFH312, change from baseline in total bile acid and inflammatory factors.

The key inclusion criteria for the trial include: (i) male or female aged between 18 and 75 years; (ii) meeting the diagnostic criteria for PBC, which means meeting at least two of the following three items: (1) indicators reflecting cholestasis such as elevated ALP, (2) positive in anti-mitochondrial antibodies (“AMA”) or AMA-M2, or if AMA is negative, positive in PBC-specific antibodies such anti-gp210 antibody or anti-Sp100 antibody, (3) liver biopsy being consistent with PBC; and (iii) patients who had taken UDCA for at least 6 months before enrollment (stable dose of UDCA at no less than 13-15 mg/kg/d for at least 3 months) but had poor treatment outcome. The key exclusion criteria for the trial include: (i) having the following diseases: Active hepatitis B virus or active hepatitis C virus infection, primary sclerosing cholangitis, complete biliary obstruction, acute cholecystitis or gallstones with

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obvious symptoms (such as biliary colic), alcoholic hepatitis, non-alcoholic steatohepatitis, suspected or confirmed primary liver cancer, bile duct cancer; (ii) ALB lower than 3.5g/dL; (iii) platelet level lower than $100 \times 10^9/L$; and (iv) poor blood sugar control, *i.e.*, glycosylated hemoglobin higher than 9.0% at screening.

Status. We plan to initiate the clinical trial in the first half of 2026.

Clinical Development Plan

Other than the GFH312X3101 study, we have no plans for subsequent clinical trials in Australia. The decision to conduct the Phase I trial in Australia was driven by cost-efficiency considerations and the opportunity to collect data from patients of diverse populations. Conducting Phase I trials in Australia is a common practice, as Australia is recognized for its high-quality clinical trial infrastructure, particularly for non-cancer treatments. We choose to conduct clinical trials of GFH312 in China as a treatment of PBC and in the U.S. as a treatment of PAD with IC for the following reasons. The recruitment of PAD patients is more feasible in the U.S., where patients are more likely to seek treatment earlier in the disease progression. In contrast, patients in China often delay in seeking treatment until the late stages of the condition. According to Frost & Sullivan, PAD with IC is more widely recognized in the U.S. We are currently evaluating the competitive landscape across various markets, recognizing that different regions have distinct patient profiles and prevalence rates for specific indications. Additionally, we are collecting clinical data from diverse patient populations.

We have received the IND approval from the FDA for a Phase II clinical trial of GFH312 (GFH312X2201). The Phase II clinical trial is designed as a multicenter, double-blinded, randomized, placebo-controlled Phase II clinical trial to evaluate safety and efficacy of GFH312 after multiple oral doses in patients with PAD with IC. We anticipate enrolling approximately 100 patients, who will be randomized in a 1:1:1:1 ratio into four groups to receive oral doses of 40mg, 80mg, 120mg of GFH312, along with a placebo once daily for 12 weeks, on top of standard treatment of PAD. The proposed dose levels of GFH312 were determined based on the results from the first-in-human trial GFH312X3101 completed in Australia. The primary endpoints will include evaluating (i) absolute change from baseline in maximum walking distance at Week 12, assessed by a 6-minute walking test; (ii) incidence and severity of AEs and SAEs; and (iii) changes in laboratory parameters, vital signs, and electrocardiogram. As of the Latest Practicable Date, we have not commenced the Phase II clinical trial in the U.S., in light of ongoing internal assessments regarding the commercial viability of advancing GFH312 in the U.S. market and overall budgeting considerations.

In addition, we have submitted an IND application for a Phase II clinical trial of GFH312 for the treatment of PBC to the NMPA in March 2025 and obtained NMPA’s approval in May 2025. We plan to initiate the clinical trial in the first half of 2026. In light of the potential of GFH312 in targeting inflammation, we believe GFH312 may be a promising therapeutic option for PBC, which is a chronic, slowly progressive autoimmune, cholestatic liver disease characterized by progressive inflammation and destruction of small bile ducts.

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Material Communications with Competent Authorities

In February 2021, we registered the study protocol for GFH312X3101 with the Therapeutic Goods Administration (the “TGA”) of Australia. In July 2022, we submitted an IND application including results of the Phase I clinical trial in Australia to the FDA for a Phase II clinical trial of GFH312 in patients with PAD with IC.

The results of the Phase I clinical trial in Australia were the only clinical results that we submitted to the FDA in the Phase II IND application dossier. Other than the clinical results, the FDA did not request additional information from the Company for the IND approval. The FDA (1) reviewed and took into account our IND application dossier, which included the design and results of the Phase I clinical trial primarily concerning the safety of GFH312 administration in human conducted in Australia, (2) specifically stated that they completed their safety review of our application dossier (as explained in (1) above), and (3) concluded that we may proceed with our proposed Phase II clinical trial. In a “study may proceed” letter issued in August 2022, the FDA did not raise any inquiries or objections to the safety data derived from our Phase I clinical trial in Australia, which by that time were the first-in-human and only-in-human clinical data on GFH312, or require us to conduct any additional Phase I clinical trial or safety assessment before commencing the proposed Phase II clinical trial in the United States.

The “study may proceed” letter is equivalent to a conventional IND application approval obtained from the FDA, as the letter allowed the applicant to conduct a Phase II clinical trial of a study drug based on the results obtained from the Phase I clinical trial of the same study drug. Here, the letter was based on our IND application, which incorporated primary clinical results obtained in the Phase I clinical trial of GFH312 in Australia. By August 2022, we had obtained the primary clinical results of the Phase I clinical trial in Australia. Since then and until October 2022, the trial was in the close-out process. In October 2022, we obtained the final clinical study report for the Phase I clinical trial in Australia, which we considered as marking the final completion of the trial. The clinical results in the final clinical study report had no substantial changes from those submitted to the FDA previously for the IND application. Because we had obtained all the primary clinical results of the Phase I clinical trial, the FDA granted our application for a Phase II clinical trial. The fact that the FDA completed the safety review of the Phase II IND application materials, including the only in-human safety results from the Australian Phase I clinical trial, did not raise any objections, and allowed us to proceed directly to the Phase II clinical trial in the United States, indicates that the FDA acknowledged and accepted the results of the Australian Phase I clinical trial. The IND approval from the FDA demonstrates that the Phase I clinical trial data in Australia has been reviewed, accepted and regarded as comparable to the completion of a Phase I clinical trial by the FDA.

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In July 2022, the NMPA accepted our IND application for GFH312 in China. The NMPA subsequently issued IND approval in September 2022. We have completed a Phase I clinical trial in healthy participants in China to evaluate the safety and PK profile of GFH312. In November 2024, we had a pre-IND communication with the CDE to propose selecting PBC as the targeted indication for the clinical trial of GFH312, which the CDE agreed. At the request of NMPA, in March 2025, we submitted an IND application for a Phase II clinical trial of GFH312 as a potential treatment of PBC, leveraging the results of the two Phase I clinical trials in China and Australia for GFH312 on healthy participants. In May 2025, NMPA approved the IND application.

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 GFH312 SUCCESSFULLY.

GFS202A: A Novel Bispecific Antibody Targeting GDF15 and IL-6 as a Potential Treatment of Cachexia

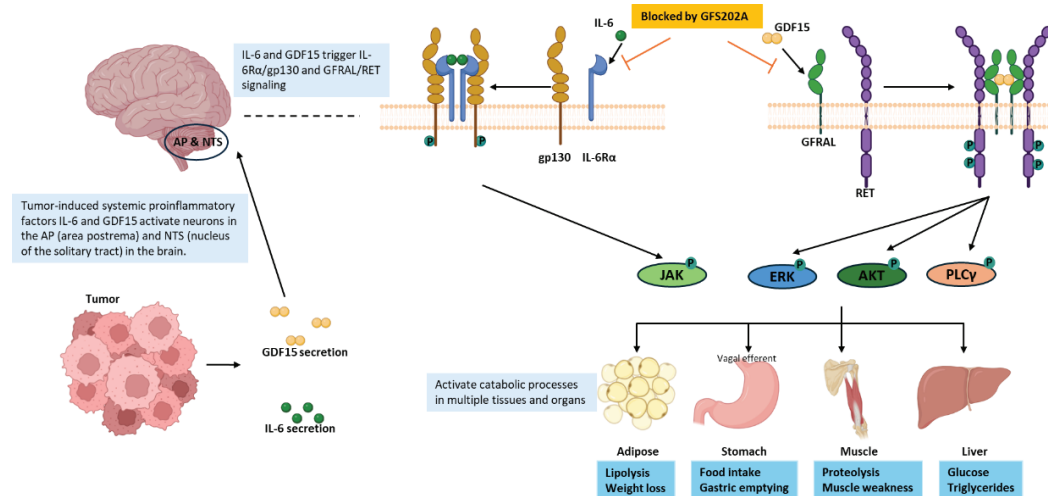
GFS202A is a novel bispecific antibody targeting both GDF15 and IL-6. Both GDF15 and IL-6 are important cytokines that play crucial roles in inflammatory processes, metabolic regulation, cancer progression and cachexia.

Cachexia is a common, life-threatening wasting condition that can significantly impact quality of life in affected patients with cancer or other types of chronic diseases. More than 50% of patients with malignant tumors experience cancer cachexia, characterized by decreased appetite and accelerated catabolism of muscle and adipose tissue during tumor progression, resulting in significant weight loss. These debilitating symptoms not only impact patient tolerability to treatment but also significantly deteriorate their quality of life, with approximately 30% of cancer related death linked to cancer cachexia. As of the Latest Practicable Date, there had been no FDA- or NMPA-approved drug specifically for the treatment of cachexia, according to Frost & Sullivan. Progesterone and glucocorticoids are the main drugs used to alleviate the symptoms of cachexia in clinical practice; however, they demonstrate moderate efficacy accompanied by many adverse drug reactions.

GDF15, a member of the TGF- β superfamily, is associated with many diseases including cancer, inflammation and cardiovascular diseases. Targeting GDF15 for the treatment of cancer cachexia has been demonstrated as a promising approach, as reflected in the recently announced Phase II results of ponesimomab, a GDF15 antibody under development by Pfizer, in improving body weight, appetite, physical activity and muscle mass in cancer patients. As of the Latest Practicable Date, the FDA has granted Pfizer approval to initiate a Phase IIb/III clinical trial targeting cachexia in patients with pancreatic cancer. Combined with the RAS pathway products, our pipeline reflects broader therapeutic coverage of oncology, especially in GI indications such as pancreatic cancer and colorectal cancers that are highly associated with cachexia.

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The diagram below illustrates the mechanism of action of GFS202A:



Source: Company information

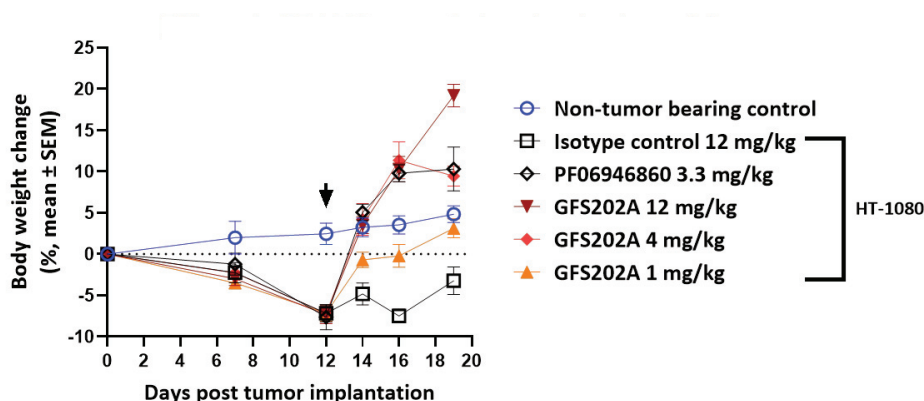
Abbreviations: GFRAL: glial cell line-derived neurotrophic factor family receptor alpha-like; gp130: glycoprotein 130; JAK: Janus kinase; PLC: phospholipase C; RET: rearranged during transfection

A synergistic effect exists between the GDF15 signaling pathway and the IL-6 signaling pathway. The GDF15-GFRAL pathway is associated with the cachexia development, and high levels of GDF-15 are negatively correlated with body weight, adiposity, physical performance, appetite, and survival of patients. Similarly, IL-6 also acts on IL-6R on neurons to induce cachexia. Additionally, the expression of IL-6R on these neurons overlaps with GFRAL expression, and inhibition of IL-6R expression affects the proportion of GFRAL-positive neurons. In light of the interactions between GDF15 and IL-6, we believe a dual neutralization of GDF15 and IL-6 may potentially achieve a better activity compared to targeting GDF15 alone. GFS202A potentially neutralizes GDF15-induced and IL-6-induced receptor activation in cell lines.

In multiple preclinical pharmacologic models, once-weekly administration of GFS202A at doses as low as 1.5-4 mg/kg has shown significant improvement in cachexia with weight loss. In a repeated-dose toxicology study in cynomolgus monkeys, GFS202A was well tolerated at doses ranging from 20 to 300 mg/kg. Additionally, in the HT-1080 human fibrosarcoma induced cachectic mice model, mice were treated 1 mg/kg to 12 mg/kg GFS202A, 12 mg/kg isotype control and 3.3 mg/kg PF0694860 as a positive control, which was equimolar to 4 mg/kg of GFS202A. The following figure shows that mice treated with isotype control experienced remarkable weight loss due to fibrosarcoma induced cachexia, but the administration of GFS202A reversed body weight loss in a dose-dependent manner.

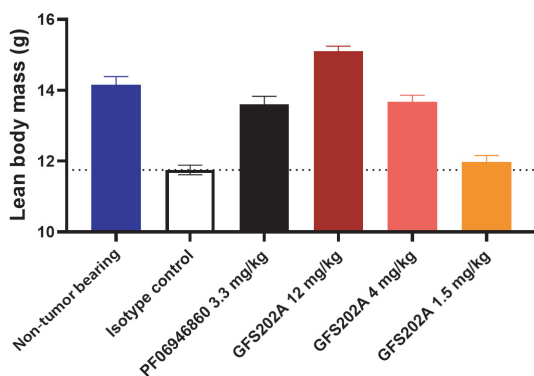
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Efficacy in HT-1080 tumor induced cachexia model

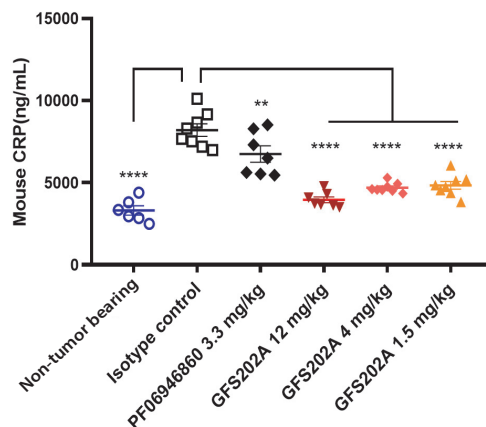


Similar results were observed in preclinical TOV21G human ovarian cancer induced cachectic mice. The following chart shows that mice treated with weekly GFS202A experienced a dose-dependent reversal of lean body mass loss compared to isotype control group. The average lean body mass in the 12 mg/kg GFS202A treatment group was even higher than that of non-tumor bearing healthy individuals. Additionally, C-reactive protein levels, which indicate inflammation, significantly decreased after GFS202A treatment, but remained high in the isotype control treated mice.

Efficacy in TOV21G tumor induced cachexia model



C-reactive protein concentration in TOV21G induced cachexia model



Scope of IND Approval. Phase I clinical trial of GFS202A cancer patients with pre-cachexia and cachexia in China was filed with the NMPA in Decemebr 2024 and granted by the NMPA in March 2025. The IND approval and the approved trial protocol did not specify the intended line of treatment. No head-to-head comparison is required or planned prior to the pivotal trial.

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As of the Latest Practicable Date, our Phase I clinical trial for GFS202A monotherapy for the treatment of pre-cachexia and cachexia was ongoing. We believe that GFS202A represents a potent treatment of cachexia and has the potential to capture a substantial market share.

GFS202AX1101: A Phase I study to evaluate GFS202A in advanced solid tumor patients with pre-cachexia or cachexia in Mainland China sponsored by us

Overview. This is an open-label, multi-center, Phase I study to evaluate the safety/tolerability and pharmacokinetics of GFS202A in advanced solid tumor patients with pre-cachexia or cachexia. The primary objective is to assess the safety/tolerability of GFS202A, determine its MTD and/or RP2D. Additionally, the study will assess GFS202A’s pharmacokinetic profile, and its impact on improving body weight and appetite.

Trial Design. Up to 36 participants will receive GFS202A intravenously every 3 weeks (“Q3W”) in a 21-day cycle. The treatment duration will be 12 weeks. Participants will be enrolled in different dose groups with increasing order, starting at 5 mg Q3W. Six dose levels are planned for evaluation, including 5 mg Q3W, 25 mg Q3W, 100 mg Q3W, 200 mg Q3W, 400 mg Q3W, and 600 mg Q3W. The primary endpoints will be the incidence and severity of AEs/SAEs and the incidence DLTs. The secondary endpoints will include but not limited to the plasma concentration and PK profile of GFS202A, the incidence and percentage of participants with anti-drug antibodies, change of the concentration of GDF-15 and IL-6, and change from baseline in body weight.

The key inclusion criteria for the trial will include: (1) men or women between the ages of 18 and 80 years; (2) patients with histologically or cytologically confirmed solid tumors; (3) pre-cachectic and cachectic patients with weight loss or baseline body mass index below 21 kg/m² within 6 months before the first study dose; (4) persistent concomitant appetite/eating problems related to cancer; (5) adequate organ function; and (6) the expected survival time judged by the investigator to be over three months. The key exclusion criteria for the trial will include: (1) with active brain metastases; (2) with other active diseases that lead to reduced food intake or seriously affect digestion and absorption baseline body mass index above 28 kg/m²; (3) with infectious diseases; (4) with clinically significant cardiovascular disease; (5) with uncontrolled metabolic diseases; (6) with known clinically significant allergic reactions to antibodies and excipients; and (7) with history of drug or alcohol abuse.

Status. The trial was initiated in April 2025. We expect to complete the trial in the second half of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GFS202A SUCCESSFULLY.

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GFH009: A Small Molecule Inhibitor of CDK9 as a Potential Treatment of Cancer

Overview

GFH009 is a selective small molecule compound that targets CDK9 and inhibits the activity of the CDK9/cyclin T1 complex. CDK9, a serine/threonine kinase, plays crucial roles in tumor growth. GFH009 is designed as a potential treatment for multiple types of hematological malignancies. It received from the FDA the orphan drug designation (“**ODD**”) and the fast track designation (“**FTD**”) in October 2023 and January 2024, respectively, for the treatment of acute myeloid leukemia (“**AML**”).

Mechanism of Action

CDKs are serine/threonine kinases that regulate cell proliferation, differentiation, and apoptosis. As a transcriptional regulator, CDK9 plays crucial roles in tumor growth. CDK9, when associated with cyclin T, forms the positive transcription elongation factor b (“**P-TEFb**”) complex. This complex regulates gene transcription elongation and mRNA maturation of super enhancer-regulated genes, including the myelocytomatosis oncogene (“**MYC**”) (a proto-oncogene involved in cell growth and cell-cycle progression) and myeloid cell leukemia 1 (“**MCL1**”) (an anti-apoptosis gene). Together, these genes modulate proliferation and survival of cancer cells. Notably, deregulation in the CDK9-related pathway has been reported in several human malignancies, such as lymphomas, leukemia, neuroblastoma, primary neuroectodermal tumors, rhabdomyosarcoma, and prostate cancer. These findings suggest that CDK9 could be a promising therapeutic target for cancer therapy.

GFH009 is a small molecule compound that targets CDK9 and inhibits the activity of the CDK9/cyclin T1 complex with a nanomolar-level biochemical half maximal inhibitory concentration. Therefore, treatment with GFH009 can lead to decreased protein levels of MCL1 and c-Myc and induction of apoptosis in tumor cells and reduced tumor growth.

GFH009X2101: A Phase I clinical trial to evaluate safety and efficacy of GFH009 monotherapy in Mainland China and the United States

Overview. This is a multi-regional, non-randomized, open-label, single-arm Phase I trial.

This is an open-label trial of GFH009 monotherapy for the treatment of relapsed/refractory hematologic tumors. The primary objectives are to evaluate safety and tolerability of GFH009 in patients with relapsed/refractory hematologic tumors, including AML, CLL/SLL, and lymphoma; and to determine the MTD and RP2D of GFH009. The primary endpoints of this trial are to (i) evaluate incidence of DLT, incidence and severity of all AEs and SAEs, and changes in laboratory indices, vital signs, physical examination, and electrocardiogram; and (ii) dose interruptions and reductions due to toxicity.

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We sponsored and were initially solely responsible for the Phase I clinical trial. The Phase I clinical trial of GFH009 in patients with recurrent or refractory hematologic tumors was approved by the NMPA in China in December 2020 and by the FDA in the United States in June 2020. The IND approval and the approved trial protocol did not specify the intended line of treatment. No head-to-head comparison is required or planned prior to the pivotal trial. The Phase I clinical trial was initiated in November 2020 in the United States and April 2021 in China. Following our entry into a license agreement (the “**SELLAS License Agreement**”) with SELLAS in March 2022, SELLAS became responsible for clinical development of GFH009 in territories outside of Greater China. We completed the Phase I trial in China in April 2024.

The key inclusion criteria for the trial include but not limited to: (i) male or female patients aged 18 or older; (ii) patients with cytologically or histologically confirmed recurrent or refractory hematologic neoplasms (AML, CLL/SLL, and lymphomas); (iii) patients with serum creatinine clearance higher than 60 mL/min; and (iv) patients whose electrolyte and uric acid levels have stabilized for at least 3 days (allowing for interventional therapy) prior to the first treatment with GFH009. The key exclusion criteria for the trial include but not limited to: (i) patients with bulky disease (≥ 10 cm) who require cytoreductive therapy; (ii) patients who received a large radiotherapy within 28 days prior to the first dose of study drug or palliative localized radiotherapy within the previous 7 days; (iii) patients with symptomatic central nervous system metastases or primary lymphoma, molluscum contagiosum, or spinal cord compression; (iv) patient with serious cardiovascular disease within 6 months prior to study entry; or (v) patient with active hepatitis B virus or hepatitis C virus infection or history of human immunodeficiency virus infection or human immunodeficiency virus-positive at screening.

A total of 86 patients, among which 34 had AML and 52 had lymphoma were enrolled in the Phase I clinical trial. The enrolled patients were heavily pretreated and resistant to multiple prior therapies.

Safety Data. The trial includes two disease cohorts: Cohort 1 enrolls 34 AML patients, and Cohort 2 enrolls 52 lymphoma patients. In the AML cohort, 34 patients received at least one dose of GFH009, at dosages of 9 mg BIW, 15 mg BIW, 22.5 mg BIW, 30 mg BIW, 40 mg BIW, as well as 30 mg QW, 45 mg QW, and 60 mg QW. No DLT was observed in the dose groups, and MTD was not achieved. All AML patients experienced at least one TEAE, with 76.5% of patients (26/34) experiencing at least one Grade 3 or higher TEAE. 64.7% (22/34) of patients had at least one TRAE, of which 41.2% (14/34) had at least one Grade 3 or higher TRAE. 35.3% (12/34) of patients had an SAE, with 14.7% (5/34) having a drug-related SAE. The most common TRAEs included decreased platelet count (32.4%, 11/34), decreased white blood cell count (26.5%, 9/34), anemia (26.5%, 9/34), decreased neutrophil count (23.5%, 8/34), nausea (17.6%, 6/34), vomiting (17.6%, 6/34), pyrexia (17.6%, 6/34), hypoproteinemia (17.6%, 6/34) and hyperchloremia (14.7, 5/34). Additionally, in the lymphoma cohort, 52 patients received at least one dose of GFH009, at dosages of 2.5 mg BIW, 4.5 mg BIW, 9 mg BIW, 15 mg BIW, 22.5 mg BIW, 30 mg BIW, 30 mg QW, 45 mg QW, 60 mg QW, 75 mg QW, and 100 mg QW. 98.1% (51/52) of lymphoma patients had at least one TEAE, of which 51.9% (27/52) experienced a Grade 3 or higher TEAE. 84.6% (44/52) patients experienced at least one

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TRAE, with 38.5% (20/52) having Grade 3 or higher TRAE. 28.8% (15/52) patients had an SAE, of which 19.2% (10/52) were drug-related SAE. The most common TRAEs included decreased white blood cell count (48.1%, 25/52), decreased neutrophil count (42.3%, 22/52), anemia (40.4%, 21/52), decreased platelet count (34.6%, 18/52), hyperuricemia (17.3%, 9/52), hypokalemia (17.3%, 9/52), aspartate aminotransferase increased (13.5%, 7/52) and bilirubin increased (11.5%, 7/52). For both AML and lymphoma patients, GFH009 did not significantly affect other tests in terms of laboratory tests, except for the decrease in various types of cells in routine blood tests. No significant effect on ECG was observed after GFH009 administration. The RP2D of GFH009 monotherapy was 60 mg QW for the treatment of AML and 100 mg QW for the treatment of lymphoma.

Efficacy Data. Response was observed across dose levels in both AML cohort and the lymphoma cohort. In the AML cohort, one patient achieved complete remission, with a complete remission rate of 2.9% (90% CI: 0.15% to 13.21%). The duration of sustained remission for this patient was 36.3 weeks. The median PFS was 4.3 weeks (80% CI: 4.29 to 4.57 weeks). In the lymphoma cohort, the best overall response was PR in five patients, and nine patients had stable disease, resulting in an ORR of 9.8% based on 51 patients with target lesion at baseline (90% CI: 3.94% to 19.52%). The median DoR was 12.2 weeks (80% CI: 5.29 weeks to NA). The median PFS was 8.3 weeks (80% CI: 8.14 to 8.43 weeks).

A study of GFH009 in combination with other drugs for the treatment of AML in the U.S. is ongoing. The FDA granted ODD and FTD to GFH009 for the treatment of AML.

Clinical Development Plan

We completed the GFH009 Phase I China Trial in April 2024. We had also previously conducted clinical trials to explore the potential application of GFH009 in the treatment of relapsed or refractory PTCL as a monotherapy and for DLBCL as a combination therapy with zanubrutinib (such trials, the “GFH009 Non-AML China Trials”). As of the Latest Practicable Date, we had strategically decided to focus on AML for GFH009 and therefore not push forward the GFH009 Non-AML China Trials at the moment. With respect to the GFH009 development for treatment of AML in China however, we intend to conscientiously monitor the treatment paradigms of hematological malignancies and the industry landscape revolving around CDK9 inhibitors and formulate appropriate future clinical development plans and/or assess business development opportunities that may potentially maximize the value of GFH009 in the future. Accordingly, we are not currently advancing the GFH009 development for the treatment of AML in China as of the Latest Practicable Date. As of the Latest Practicable Date, we have not formulated a detailed clinical development plan for GFH009 in Greater China.

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

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Licenses, Rights and Obligations

Jiongshuo Agreement

On May 23, 2018, we entered into a technology transfer agreement with Shanghai Jiongshuo Pharmaceutical Technology Co., Ltd (上海炯燦醫藥科技有限公司, “**Jiongshuo**”) in relation to GFH009. In October 2018, we entered into a supplementary agreement with Jiongshuo to clarify that we shall be the sole owner of all the patents and patent applications covering GFH009, and Jiongshuo shall transfer the ownership of a specified patent application (the “**Project Patent**”) to us. Jiongshuo is a company incorporated under the laws of the People’s Republic of China and an Independent Third Party to us.

In 2018, when GFH009 was still in the preclinical stage of development, we bought GFH009 because GFH009 exhibited high selectivity for the CDK family proteins, strong activities and good solubility, making it suitable for development into an injectable solution for the treatment of AML and other hematologic malignancies with clear clinical need and significant market potential.

Pursuant to the aforementioned agreements with Jiongshuo (“**Jiongshuo Agreements**”), Jiongshuo transferred to us the designated pharmacological research reports or original records as well as all patent application materials related to GFH009. The Jiongshuo Agreements established a “scientific enforcement and monitoring committee” which is composed of representatives designated by each party and should hold quarterly meetings to assess the project progress. The committee may, on a consensus basis, vote to terminate the project. Pursuant to the Jiongshuo Agreements, we paid Jiongshuo a one-time technology transfer fee of RMB6 million. The Jiongshuo Agreements allowed us to seek collaboration with third-party pharmaceutical companies to transfer rights under the Project Patent to other third parties after obtaining regulatory approval for clinical development. If such activities occur prior to the expiration of the term of the Project Patent, we agreed to share a portion of the fees that we receive from such activities, with the percentage amounts specified in accordance with the development stages when such activities occur, ranging from mid-single digit to mid-teens. In accordance with this obligation, we made an aggregate payment of RMB9.9 million in 2022 and 2024 to Jiongshuo after entry into the SELLAS License Agreement (as defined below).

Jiongshuo is also entitled to a less than 1% royalty on the net annual sales if GFH009 is advanced to commercialization after we transfer GFH009 to third parties, or a single-digit percentage royalty on the net annual sales if GFH009 is advanced to market by our Company alone.

Jiongshuo agreed to indemnify us for any liabilities imposed on us due to infringement of a third party’s legal rights by practicing the patents or technologies transferred under the Jiongshuo Agreements. Jiongshuo’s obligation of such indemnification has not been triggered as of the Latest Practicable Date.

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Jiongshuo and we agreed to attempt to settle all disputes arising out of the Jiongshuo Agreements in an amicable manner. If such disputes cannot be so resolved, the parties should resort to the China International Economic and Trade Arbitration Commission to resolve the disputes by arbitration in Shanghai.

The term of the Jiongshuo Agreements shall continue until completion of all of the obligations of the parties. However, either party may terminate the Jiongshuo Agreements (i) when the other party commits a material breach and fails to remedy within 30 days of receipt of notice from the non-breaching party, (ii) by executing another written agreement with the other party to terminate the Jiongshuo Agreements, or (iii) by a written notice to the other party when performance of the Jiongshuo Agreements is rendered impractical or impossible by *force majeure*.

SELLAS License Agreement

We collaborated with SELLAS to facilitate the swift development and approval of GFH009 for commercialization outside Greater China, while we retain development and commercialization rights within Greater China. SELLAS is a U.S. based, NASDAQ-listed company with superior capabilities and resources in clinical development in the fields of AML, other hematological tumors and solid tumors. Our collaboration with SELLAS leverages the latter’s accumulated expertise in conducting clinical trials of drug candidates targeting hematological malignancies and solid tumors in the U.S.

On March 31, 2022 (the “**SELLAS Effective Date**”), we entered into a license agreement (the “**SELLAS License Agreement**”) with SELLAS. Pursuant to the SELLAS License Agreement, we granted SELLAS an exclusive (even to ourselves), sublicensable and royalty-bearing right and license to develop, manufacture and commercialize GFH009 across all therapeutic and diagnostic uses worldwide outside of Greater China (Mainland China, Hong Kong, Macau and Taiwan). For details, see “— Major Collaboration and Licensing Arrangements.”

SELLAS is a U.S. based, NASDAQ-listed company with superior capabilities and resources in clinical development in the fields of AML, other hematological tumors and solid tumors. By 2022, we had obtained IND approvals from both the FDA and the NMPA for the Phase I clinical trial of GFH009. To accelerate the overseas clinical development of GFH009, we entered into the licensing agreement with SELLAS.

On October 13, 2022, we entered into a master clinical supply agreement (the “**SELLAS Clinical Supply Agreement**”) with SELLAS concerning the supply of the GFH009 by us to SELLAS for clinical use and development activities outside of Greater China contemplated in the SELLAS License Agreement. Pursuant to the SELLAS Clinical Supply Agreement, we are responsible for manufacturing (either by us or designated CMOs) and supplying GFH009 products in applicable formulation(s) and dosage form(s) as specified by SELLAS. SELLAS shall provide us an order every six months with the product and delivery details. SELLAS will pay us a per unit price for our supply of GFH009 equal to 100% of the fully burdened

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manufacturing cost per unit plus a percentage of mid-twenties of our full-time equivalent (“FTE”) cost for the manufacturing management to the extent not already included in the full burdened manufacturing cost, with a specified capped unit price within three years following the date of execution of the SELLAS Clinical Supply Agreement. Unless earlier terminated, the SELLAS Clinical Supply Agreement will be effective until GFH009 is no longer developed by SELLAS outside of Greater China. Either party may terminate the SELLAS Clinical Supply Agreement in the event of material breach of the other party as detailed in the SELLAS Clinical Supply Agreement. SELLAS may terminate SELLAS Clinical Supply Agreement at any time by providing us a written notice of termination, which includes an effective date of termination at least 60 days after the date of the notice. The SELLAS Clinical Supply Agreement will terminate automatically upon the termination of the SELLAS License Agreement.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GFH009 SUCCESSFULLY.

GFH018: A Small Molecule Inhibitor of TGF- β R1 as a Potential Treatment of Cancer

Overview

GFH018 is a potent small-molecule inhibitor of TGF- β R1. Elevated expression of TGF- β signaling genes is linked to various solid tumors. Results from a Phase I clinical trial in patients with advanced solid tumors in Mainland China demonstrated potentially favorable safety and preliminary efficacy profiles of GFH018.

Scope of IND Approval. In May 2019, the NMPA approved our IND application to conduct a Phase Ib/II clinical trial of GFH018 in patients with advanced solid tumors. In June 2022, the NMPA approved our IND application to conduct a Phase Ib/II clinical trial of GFH018 in combination with toripalimab in patients with advanced solid tumors. The IND approval and the approved trial protocol did not specify the intended line of treatment. No head-to-head comparison is required or planned prior to the pivotal trial.

Mechanism of Action

TGF- β is a multifunctional cytokine that binds to and activates TGF- β receptor II (“TGF- β R2”) on the cell membrane. In turn, TGF- β R2 phosphorylates and activates TGF- β RI, which subsequently phosphorylates downstream Smad2/3, regulating gene expression and facilitating various biological functions. In cancer cells, activation of the TGF- β signaling pathway promotes epithelial-to-mesenchymal transition and metastasis, inhibits antitumor immune responses, and enhances angiogenesis and tissue fibrosis within the tumor microenvironment, thereby driving tumor progression. Furthermore, elevated expression of TGF- β signaling pathway genes in blood and tumors has been observed in patients with various solid tumor, and higher levels of TGF- β expression are also positively correlated with poorer differentiation, advanced tumor stages, and worse prognosis.

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GFH018, a small-molecule inhibitor of TGF- β 1, is designed to inhibit the TGF- β signaling pathway and suppress tumor growth and progression through multiple mechanisms, including the reduction of tumor metastasis, enhancement of antitumor immune responses within the tumor microenvironment, and inhibition of intra-tumor angiogenesis. In addition, the expression level of the TGF β 1 gene is negatively correlated with patient response to PD-1/L1 antibody treatment. Inhibitors of the TGF- β signaling pathway have been shown to enhance efficacy in animal models when combined with immune checkpoint inhibitors. This approach indicates a potential for a synergistic antitumor effect when GFH018 is combined with PD-1/L1 immune checkpoint inhibitors.

GFH018X1101: A Phase I clinical trial to evaluate safety, tolerability, and PK of GFH018 in patients with advanced solid tumors in Mainland China sponsored by us

Overview. This first-in-human, non-randomized, open-label, single-arm Phase I clinical trial aims to evaluate safety, tolerability, and PK of GFH018 in patients with advanced solid tumors following single and multiple administrations. The primary objective is to evaluate safety and tolerability of GFH018 and to determine its MTD and/or RP2D.

Trial design. The clinical trial consists of a dose escalation part to determine MTD and/or recommended extended dose (“**RDE**”); and a dose expansion part to confirm safety of RDE dosing and establish RP2D and to evaluate preliminary efficacy. In the dose escalation phase, 47 patients were enrolled. Of these, 41 patients received doses ranging from 5 mg to 85 mg BID, following a 14-day dosing and 14-day withdrawal schedule of GFH018. Six patients received 85 mg BID with a 7-day dosing and 7-day withdrawal schedule. In the dose expansion phase, three patients were enrolled and received 85 mg BID with a 14-day dosing and 14-day withdrawal schedule of GFH018.

The primary endpoints are to evaluate (i) DLT, (ii) incidence and severity of AEs and SAEs, and (iii) laboratory tests, vital signs, electrocardiogram, and cardiac ultrasound examinations.

The key inclusion criteria for the trial include but are not limited to: (i) male or female patients aged 18 to 75 (inclusive); (ii) patients with a life expectancy of 12 weeks or more; (iii) patients with adequate organ and bone marrow function without severe hematopoietic abnormalities and cardiac, pulmonary, hepatic, renal functional abnormalities or immunodeficiencies; (iv) patients with an evaluable lesion for the first dose escalation part or patients with at least one measurable target lesion for the second dose expansion part; and (v) patients with histologically or cytologically confirmed diagnosis of advanced solid tumors who have no standard therapy or who have failed after standard therapy or for whom standard therapy is not appropriate at this stage. The key exclusion criteria for the trial include but are not limited to: (i) patients with significant underlying disease of the cardiovascular system; (ii) patients with significant gastrointestinal disorders; (iii) patients with clinically uncontrolled pleural and abdominal fluid; (iv) patients with active or previous autoimmune disease with potential for relapse; or (v) patients with major organ surgery within four weeks prior to first dose.

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Status. The trial was initiated in August 2019 and completed in August 2022 in Mainland China. It enrolled 50 patients with various advanced solid tumors for the dose escalation and dose expansion parts.

Safety Data. GFH018 was safe and well-tolerated across the 5 mg to 85 mg BID dosing range, following a 14-day dosing and 14-day withdrawal schedule. No DLT was observed, and MTD was not reached. There were no drug-related deaths or other SAEs. The incidence of TEAEs leading to discontinuation of treatment was 4.0% (2/50), with no TRAEs leading to discontinuation. The incidence of TEAEs and TRAEs leading to discontinuation was 14.0% (7/50) and 6.0% (3/50), respectively. No TEAEs or TRAEs resulted in dose reductions. The majority of TEAEs and TRAEs were Grade 1-2, with similar incidence and severity across all dose groups.

In the GFH018 85 mg BID dosing group following a 7-day dosing and 7-day withdrawal schedule, there were no GFH018-related deaths, other SAEs, or events leading to termination of treatment, treatment suspension, or reduction in TEAEs and TRAEs. Compared to the GFH018 85 mg BID dosing group following a 14-day dosing and 14-day withdrawal schedule, there were no significant differences in TEAEs and TRAEs. Overall, GFH018 demonstrated a good safety and tolerability profile within the dose range. The RP2D of GFH018 was 85 mg BID following a 14-day dosing and 14-day withdrawal schedule. Overall, GFH018 demonstrated a favorable safety profile.

GFH018X0201: A Phase Ib/II clinical trial to evaluate safety, tolerability, PK, and preliminary efficacy of GFH018 in combination with Toripalimab in patients with advanced solid tumors in Mainland China, Taiwan and Australia sponsored by us

Overview. This is a multicenter, non-randomized, open-label, single-arm Phase Ib/II clinical trial to evaluate safety, tolerability, PK, and preliminary efficacy of GFH018 in combination with Toripalimab in patients with advanced solid tumors. The primary objective of Phase Ib trial is to evaluate the safety and tolerability of the combination therapy. The primary objective of Phase II trial is to evaluate efficacy of the combination therapy.

Trial design. The clinical trial consists of a dose escalation Phase Ib part in patient with advanced solid tumors and an indications expansion Phase II part in patients with advanced solid tumors of 14 specific tumor types. The tumor types of Phase II trial include hepatocellular carcinoma, cholangiocarcinoma/cholangiocarcinoma (except pot-bellied carcinoma), pancreatic cancer, colorectal cancer, uroepithelial carcinoma, cervical cancer, squamous cell carcinoma of head and neck, squamous cell carcinoma of esophagus, nasopharyngeal carcinoma, thymic carcinoma, endometrial carcinoma, osteosarcoma, triple-negative breast carcinoma, and extranodal NK/T-cell lymphoma. The primary endpoints of Phase Ib trial are to evaluate (i) incidence of DLT events; (ii) incidence and severity of AEs, SAEs, adverse events of special interest (“**AESIs**”), immune-related adverse events (“**irAEs**”); and (iii) changes in laboratory tests, vital signs, physical examination, electrocardiogram. The secondary endpoints of Phase Ib trial are to assess (i) plasma drug concentration and pk parameters for single dose administration of GFH018; (ii) C_{trough} of Toripalimab and number

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and percentage of patients producing anti-Toripalimab antibodies; and (iii) ORR, DCR, TTR, DoR, PFS, and OS. The primary endpoints of Phase II trial are to evaluate ORR, DCR, TTR, DoR, PFS, and OS. The secondary endpoints of the Phase II trial are to assess incidence and severity of AEs, SAEs, AESIs, irAEs; (ii) C_{trough} of GFH018; and (iii) C_{trough} of Toripalimab and number and percentage of patients producing anti-Toripalimab antibodies.

For the Phase Ib part, 15 patients received doses of 40 mg, and 80 mg BID, following a 14-day dosing and 14-day withdrawal schedule of GFH018 combined with toripalimab 3 mg/kg by intravenous infusion every 2 weeks. For the Phase II part, 133 patients were divided into 14 groups according to specific tumor types and received GFH018 80 mg BID for 14 days on and 14 days off combined with toripalimab 3 mg/kg by intravenous infusion every 2 weeks.

The key inclusion criteria for the trial include but are not limited to: (i) patients aged 18 or older; (ii) patients with a life expectancy of 12 weeks or more; (iii) patients with adequate organ function; (iv) patients whose toxic response to prior antitumor therapy has returned to baseline levels or CTCAE Grade 1 level; and (v) patients with an advanced or metastatic tumor confirmed by histology or cytology that has failed at least one line of standard therapy, is not amenable to standard therapy due to intolerable toxicity, or for which no standard therapy is available. The key inclusion criteria for the Phase II part further include but are not limited to: (i) patients with a specific type of advanced or metastatic tumor diagnosed by histology or cytology; and (ii) patients with at least one measurable lesion. The key exclusion criteria for the trial include but are not limited to: (i) patients with impaired cardiac function or clinically significant heart disease; (ii) patients with an acute or chronic infection; (iii) patients with active central nervous system metastases; (iv) patients with active autoimmune disease or a history of autoimmune disease within one year prior to enrollment; or (v) patients with significant gastrointestinal disorders.

Status. The trial was initiated in June 2022 in Mainland China, November 2021 in Taiwan and October 2021 in Australia, respectively, and was completed in December 2023.

Safety Data. For patients who received 40 mg BID and 80 mg BID following a 14-day on and 14-day off schedule in combination with Toripalimab in the Phase Ib trial, no patients developed DLTs, and the MTD was not reached. The RP2D of GFH018 in combination with Toripalimab is 80 mg BID following the same 14-day on and 14-day off schedule. In this study, 73.6% of patients had at least one TRAE related to the combination regimen, with 19.6% of these patients experienced at least one Grade 3 or higher TRAE. The incidence of treatment related SAEs was 11.5%. The most common TRAEs included rash 26.4% (39/148), fatigue 14.2% (21/148), anemia 11.5% (17/148), nausea 11.5% (17/148), pruritus 11.5% (17/148), and increased aspartate aminotransferase 10.8% (16/148). No other safety signals were observed, and the combination of GFH018 and toripalimab did not increase toxicity. Overall safety and tolerability were good.

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Efficacy Data. The confirmed best overall response was 16.2% (90% CI: 11.44% to 22.04%) and the DCR was 35.8% (90% CI: 29.25% to 42.80%). Specifically, in nasopharyngeal carcinoma patients without any prior treatment with immune checkpoint inhibitors (n = 25), the confirmed ORR was 40% (90% CI: 23.6-58.3%) and DCR was 60% (90% CI: 41.7-76.4%). The median PFS was 9.0 months (90% CI: 1.9-NR), and median DoR was not reached. The results demonstrated that GFH018, in combination with Toripalimab, showed synergistic anticancer activity in solid tumors such as nasopharyngeal carcinoma.

Clinical Development Plan

In addition to the two clinical trials described above, in the past we conducted a Phase II clinical trial to evaluate the efficacy and safety of GFH018 in combination with Toripalimab with concurrent chemoradiotherapy in patients with unresectable, locally advanced stage III NSCLC in China. We decided to focus on other more promising pipeline programs after we initiated the clinical trial to best leverage our limited resources. We will continue to assess our development strategy on GFH018 and formulate appropriate clinical development plan in the future.

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

Licenses, Rights and Obligations

WuXi Agreements

In June 2017, GenFleet HK, a member of the Single Largest Group of Shareholders, entered into a joint development agreement with WuXi AppTec (Shanghai) Co., Ltd. (上海藥明康德新藥開發有限公司) (“**WuXi AppTec SH**”) in relation to the development of an inhibitor against TGF- β receptor (hereafter referred to as GFH018) (as amended and supplemented, the “**GFH018 Joint Development Agreement**”). Between September 2017 and December 2018, members of our Group entered into several supplemental agreements to the GFH018 Joint Development Agreement with WuXi AppTec SH, pursuant to which we were assigned with all rights, privileges and obligations related to GFH018 under the GFH018 Joint Development Agreement. In March 2020, we entered into a confirmatory patent assignment agreement with an affiliate of WuXi AppTec SH, which was then the applicant of certain patent applications regarding GFH018. Pursuant to the confirmatory patent assignment agreement, we were assigned with all patent rights associated with GFH018 listed thereunder.

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Pursuant to the aforementioned agreements (“**WuXi Agreements**”), WuXi AppTec SH was responsible for conducting preclinical studies of GFH018, and our Company is responsible for applying for and obtaining IND approval, as well as conducting subsequent clinical development. The WuXi Agreements set out each parties’ cost contribution to the pre-IND research and development activities. For the clinical development, we shall be solely responsible for the associated costs, and we incurred RMB115.3 million for the clinical development of GFH018 since 2019. We agreed to share a portion of the fees (in the low-to-mid double-digit percentage range) that we receive when we transfer the molecule to other third parties, with the percentage amounts specified in accordance with the development stages when such transfer occurs. WuXi AppTech SH is entitled to a single-digit percentage royalty on net annual sales once GFH018 is commercialized. The WuXi Agreements established a “project committee” composed of six individuals, with three representatives from each party. The “project committee” has decision-making authority with respect to the planning and implementation of the R&D projects provided under the WuXi Agreements.

WuXi AppTec and we agreed to attempt to settle all disputes arising out of the WuXi Agreements in an amicable manner. If such disputes cannot be so resolved, either party may refer the disputes to the China International Economic and Trade Arbitration Commission, which shall finally resolve the disputes by an arbitration award legally binding to both parties.

The WuXi Agreements may be terminated by mutual agreement of both parties but cannot be terminated before March 30, 2018. The R&D activities for GFH018 under the Wuxi Agreements were completed in 2018, and we have fulfilled our payment obligations for such R&D activities under the Wuxi Agreements. As such, WuXi AppTech SH is no longer involved in the decision making of the R&D activities and progression of GFH018 under the Wuxi Agreements.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GFH018 SUCCESSFULLY.

Below is a summary of the clinical results and development status of our drug candidates in clinical development stage.

Compound(s)	Country/ region of clinical development	Development status	Clinical trial participants	Key safety results (with Grade 3 or above AEs, if any)	Key efficacy results	Impact of adverse events ⁽³⁾
GFH925 + cetuximab ⁽¹⁾ .	EU	Phase II trial ongoing for NSCLC	Patients with previously untreated advanced NSCLC harboring KRAS G12C mutation, including 6 patients in Phase I and 40 patients in Phase II	Overall, the combination therapy presented a favorable safety/ tolerability profile. TRAEs occurred in 87.2% of patients and the majority of the TRAEs were graded 1-2; 14.9% of patients experienced at least one grade 3 TRAEs; no grade 4-5 TRAEs.	Interim Phase II results showed that, among the 45 patients who received at least one post-treatment tumor assessment, the ORR was 80% and DCR was 100%.	Suspension/discontinuation of individual participants due to TRAEs include: one patient required dose reductions; four patients, required suspension of GFH925 treatment; three patients discontinued cetuximab treatment.

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Compound(s)	Country/ region of clinical development	Development status	Clinical trial participants	Key safety results (with Grade 3 or above AEs, if any)	Key efficacy results	Impact of adverse events ⁽³⁾
GFH925 . . .	Mainland China	Regulatory approval for NSCLC	No less than 293 patients with advanced NSCLC with KRAS G12C mutations, including 116 patients in Phase II trial	In Phase II, 14.0% of patients had SAE.	In Phase II, ORR was 49.1%, and DCR was 90.5%.	Suspension/discontinuation of individual participants due to AEs include: 2.7% of patients required drug discontinuation; 32.6% required drug suspension; 18.3% required dose reduction.
GFH375 ⁽²⁾ . .	Mainland China	Phase I/II trial ongoing for solid tumors	62 patients with advanced solid tumors harboring the KRAS G12D mutation, including 33 patients with PDAC, 16 patients with NSCLC, 8 patients with CRC and 5 patients with other solid tumors in Phase I/II trial	In Phase I, 29.0% of patients had Grade 3 TRAEs and 8.1% of patients had treatment related SAEs.	among 49 patients at daily dosages of 400 or 600 mg: 43 patients who received tumor assessment achieved an ORR of 42% and a DCR of 91%; the ORR was 52% and DCR was 100% among 23 efficacy-evaluable PDAC patients, and the ORR was 42% and DCR was 83% among 12 efficacy- evaluable NSCLC patients 52 patients across all dose levels and indications who received tumor assessment: the overall ORR was 38% and DCR was 90%.	Suspension/discontinuation of individual participants due to TRAEs include: 11% of patient required does reduction; 21% of patient required dose interruption, 3% of patient required treatment discontinuation.
GFH312 . . .	Mainland China and Australia	Phase I trial ongoing for PAD with IC and PBC	26 healthy individuals in China and 76 healthy individuals in Australia in Phase I trial	The results demonstrate a favorable safety profile, with no Grade 3 or above AEs, SAEs or deaths.	N/A	None

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Compound(s)	Country/ region of clinical development	Development status	Clinical trial participants	Key safety results (with Grade 3 or above AEs, if any)	Key efficacy results	Impact of adverse events ⁽³⁾
GFH009 . . .	Mainland China and U.S.	Phase I trial for AML in China completed; Phase II trial in combination with other drugs for the treatment of AML conducted by SELLAS in the U.S. is ongoing	34 AML patients, and 52 lymphoma patients in Phase I trial	In Phase I, 26 AML patients had Grade 3 or higher TEAEs. 14 AML patients had Grade 3 or higher TRAEs. 12 AML patients had SAEs, with 5 being drug related. In Phase I, 27 lymphoma patients had Grade 3 or higher TEAEs. 20 lymphoma patients had Grade 3 or higher TRAEs. 15 lymphoma patients had SAEs, with 10 being drug related.	In Phase I, one AML patient achieved complete remission, with a complete remission rate of 2.9%. In Phase I, five lymphoma patients achieved partial response and nine achieved stable disease.	Suspension/discontinuation of individual participants due to AEs include: for AML patients, 9.1% required drug discontinuation; 29.4% required drug suspension. For lymphoma patients, 9.6% required drug discontinuation; 21.2% required drug suspension; 8% required dose reduction.
GFH018 . . .	Mainland China, Taiwan and Australia	Phase II trial completed	patients with various advanced solid tumors	Overall safety and tolerability were good. 19.6% patients had Grade 3 or higher TRAEs, and 11.5% had SAEs.	ORR was 16.2%, and DCR was 35.8%.	None

Notes:

- (1) The clinical trial statistics are as of January 14, 2025.
- (2) The clinical trial statistics of key safety results are as of March 31, 2025, and those of key efficacy are as of May 16, 2025.
- (3) The competent authorities did not raise any safety concerns or impose any conditions due to the adverse events that occurred in the clinical trials indicated in the table. Most of these adverse events occurred in the Phase I clinical trials, whose primary objective is to select the appropriate drug dosage and target patient group based in part on the occurrence of adverse events. As such, the frequency of adverse events that occurs with certain drug dosage or target patient group may be higher than others. The adverse events caused temporary suspension or discontinuation of clinical trial for certain individual patients, but not an entire clinical trial.

MAJOR COLLABORATION AND LICENSING ARRANGEMENTS

We have successfully entered into multiple collaboration and licensing agreements with domestic and international partners to expand our coverage in the global market, and maximize the commercial value of our product portfolio. We select our partners with rigorous criteria and strategic synergy for the benefits of the research and development of drug products, and we had not had material disputes with our partners since entering of such agreements.

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Innovent Agreement

On September 1, 2021, we entered into a license and option agreement (the “**GFH925 License Agreement**”) with Innovent. On January 11, 2024, we further entered into a supplementary agreement (the “**GFH925 Supplementary Agreement**,” together with the GFH925 License Agreement, the “**Innovent Agreement**”) with Innovent.

License Agreement with Innovent

On September 1, 2021, we entered into a license and option agreement (the “**GFH925 License Agreement**”) with Innovent, a biopharmaceutical company incorporated in the Cayman Islands and listed on the Hong Kong Stock Exchange (stock code: 1801). Innovent specializes in developing and commercializing monoclonal antibodies and other drug assets in the fields of oncology, ophthalmology, autoimmune diseases, and cardiovascular and metabolic diseases. In September 2021, Innovent assigned all of its rights, privileges and obligations for the territory of Greater China under the GFH925 License Agreement to Innovent Biologics (Suzhou) Co., Ltd. (“**Innovent Suzhou**”), a company incorporated under the laws of the People’s Republic of China and a wholly owned subsidiary of Innovent. Each of Innovent and Innovent Suzhou is an Independent Third Party to us.

Obligations and Responsibilities

According to the GFH925 License Agreement, we grant to Innovent (i) an exclusive, royalty-bearing and sublicensable license under all GenFleet Intellectual Property² to research, import, develop, make (have made), manufacture (have manufactured),³ use, commercialize, sell, offer to sell, distribute, market and promote pharmaceutical products (the “**Licensed Product**”) consisting of or containing compounds targeting KRAS G12C mutation (the

2 The “GenFleet Intellectual Property” means any and all the know-how, trademarks, patents and patent applications that we have obtained an interest in, in a way independent from licensing under the GFH925 License Agreement, such that we may license that interest to Innovent or its affiliates, and (1) such know-how is necessary or reasonably useful in connection with the development, commercialization or other use of the Licensed Product as a treatment for human diseases within Greater China, (2) such trademarks are used in connection with, intended for use, or adopted for use in connection with the Licensed Product, and (3) such patents and patent applications are registered within Greater China and cover the composition of, or methods to manufacture or use the Licensed Product.

3 The word “import” means the act of bringing objects into a country/region from other countries/regions. The GFH925 License Agreement, by using this word, allows Innovent to bring Licensed Products into Greater China from other regions of the world. The phrase “make (have made)” means the act of creating or forming something, regardless of whether the act is completed before or after the execution of the GFH925 License Agreement. The GFH925 License Agreement, by using this phrase, allows Innovent to create or form Licensed Products within Greater China, whether before or after the execution of the GFH925 License Agreement. The word “manufacture (have manufactured),” means all operations involved in the manufacturing, quality control testing (including in-process, release and stability testing, if applicable), storage, releasing and packaging of the Licensed Product, regardless of whether the operations are completed before or after the execution of the GFH925 License Agreement. The GFH925 License Agreement, by using this phrase, allows Innovent to conduct any operations involved in the manufacturing, quality control testing (including in-process, release and stability testing, if applicable), storage, releasing and packaging of the Licensed Product within Greater China, whether the operations are completed before or after the execution of the License Agreement.

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“**Licensed Compounds**”) as specified in the GFH925 License Agreement, including GFH925, for the treatment, prevention or diagnosis of any disease or condition in humans in Mainland China, Hong Kong, Macau and Taiwan (the “**Greater China**”); and (ii) an exclusive option (the “**Ex-China Option**”) to develop and commercialize Licensed Product in the all countries and regions in the world other than Greater China (the “**Ex-China Territory**”). The Ex-China Option was never exercised by Innovent and was terminated on January 11, 2024. For additional information, see “— Supplementary Agreement with Innovent.” There was no transfer of rights of GFH925 in the Ex-China Territory before the termination of the Ex-China Option from us to Innovent, and we conducted overseas clinical development of GFH925 during the same period.

The GFH925 License Agreement established a JSC, which is a forum for the communication and decision-making regarding the parties’ activities under the agreement. We and Innovent shall each appoint three representatives to the JSC and select one representative as each side’s co-chairperson for the JSC. The JSC may change its size from time to time by mutual consent of the parties, provided that the JSC will consist at all times of an equal number of representatives of each party. When voting on any matter properly before the JSC, each party shall have one vote cast by its respective co-chairperson. The JSC holds meetings at least once a quarter and at other times as the co-chairpersons may reasonably determine. All decisions within the JSC must be made on a consensus basis. If the JSC encounters a deadlock on a matter and cannot make a decision, the matter may be referred to the parties’ Senior Representatives (i.e., our Chief Medical Officer and Innovent’s President and Head of R&D) to negotiate and decide. If the parties’ Senior Representatives still cannot resolve the matter, then Innovent shall have the final decision-making authority for matters within Greater China, and we shall have the final decision-making authority for matters outside Greater China.

We conducted all preclinical development of GFH925 and submitted an IND application for the first-in-human GFH925X1101 trial to the NMPA in May 2021. We were responsible for the trial design that resulted in the NMPA’s approval in July 2021 and the approval was addressed to us without any material inquiries or objections. In preparation for the clinical trial and prior to entering into the GFH925 License Agreement, we proactively identified and finalized the arrangement details with the lead principal investigator. We also arranged eight clinical sites in multiple provinces in China, submitted materials for ethics committee approvals for a number of these clinical sites, and activated one clinical trial site in August 2021. Innovent later supported the clinical collaboration by expanding the trial from the eight sites we initially arranged to a total of 55 clinical sites.

After signing of the GFH925 License Agreement, Innovent became the sponsor of the GFH925X1101 trial in China and is thereafter solely responsible for the development and commercialization of GFH925 in the Greater China region. However, we retain a critical role in managing the CMC-related processes, including overseeing process development, finalizing agreements with key stakeholders, and selecting suitable vendors to ensure smooth trial execution. We retain this critical role for several reasons. First, we still retain the ex-China rights of GFH925, which is currently under clinical development overseas, such as in the U.S. and Europe. As the sponsor of such overseas clinical trials, we are responsible for supplying

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GFH925 for these trials. Thus, we need to manage the CMC-related process of GFH925 in the overseas markets. Second, though the Greater China rights of GFH925 have been granted to Innovent, it serves our interest to maintain consistency of GFH925 in formulation and quality in its different target markets. Especially, any quality related issues of GFH925, a Core Product of us, may affect our commercial reputation. Third, equipped with in-depth expertise in CMC (see “— Chemistry, Manufacturing and Controls (“CMC”)”), we are well positioned to take responsibility in managing the CMC-related process. Fourth, managing the CMC-related process of GFH925 and other drug candidates fits with our plan to establish an in-house manufacturing facility to support the formulation production of our pipeline products. The GFH925 License Agreement does not require Innovent to procure GFH925 exclusively from us. However, we have the priority to be appointed by Innovent as the manufacturer and supplier of GFH925 provided that the terms and conditions of our manufacturing and supply are the same or more favorable as provided by other third party to Innovent. Innovent will pay our Company for the drug supply on an ongoing basis, with payments determined by the quantity required to support the trial’s development needs. After the regulatory approval of GFH925 in China in August 2024, we became the supplier of GFH925 to Innovent. In 2024, we generated RMB14.7 million of sales revenue from the supply of GFH925 to Innovent.

Furthermore, Innovent grants to us an exclusive and sublicensable license under all Innovent Intellectual Property⁴, solely for the purpose of developing and commercializing the Licensed Product in the Ex-China Territory.

Intellectual Property

According to the GFH925 License Agreement, we shall remain the exclusive owner of GenFleet Intellectual Property. Innovent shall remain the exclusive owner of Innovent Intellectual Property.

In addition, both parties shall jointly own the intellectual property rights generated from any joint efforts of both parties, including any inventions generated, developed, conceived or reduced to practice (constructively or actually) jointly by or on behalf of Innovent and us, their affiliates and respective sublicensees, in the course of the development, manufacture or commercialization of the Licensed Compounds or the Licensed Product according to the GFH925 License Agreement. Each party may freely exploit such joint inventions without any duty to account to or obtain consent from the other party, provided that each party shall disclose in writing to the other party all joint inventions promptly following the generation, development, conception or reduction to practice thereof. However, Innovent was granted the first right (but not the obligation) to file and maintain the patents that cover inventions jointed developed by both parties. After the termination of the Ex-China Option under the GFH925

⁴ The “Innovent Intellectual Property” means any and all the know-how, patents and patent applications that Innovent has an obtained interest in, in a way independent from licensing under the GFH925 License Agreement, such that Innovent may license that interest to us, and (1) such know-how is necessary or reasonably useful in connection with the development, commercialization or other use of the Licensed Product as a treatment for human diseases within Greater China and (2) such patents and patent applications cover the composition of, or methods to manufacture or use, the Licensed Product or the Licensed Compounds.

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License Agreement in January 2024, we and Innovent separately conducted R&D activities with respect to GFH925 in each one’s respective regions (i.e., Innovent in Greater China and we in Ex-China Territory). As of the Last Practicable Date, the parties conducted, and expected to continue to conduct, R&D activities with respect to GFH925 at different geographical locations in accordance with the GFH925 License Agreement and, as such, no such joint inventions could have occurred. As of the same date, neither party has obtained any patent or filed any patent application for the joint inventions under the Innovent Agreement. As of the same date, to our best knowledge, we are not aware of patents, patent applications or know-how of Innovent that relate to GFH925.

In addition, we have an obligation to indemnify Innovent the potential penalties arising from patent infringement of IP claims asserted by a third party in Greater China.

Payments

Under the GFH925 License Agreement, Innovent has agreed to make various payments to us, including but not limited to, an upfront fee, development and regulatory milestone payments, commercial milestone payments, royalty payments. Innovent will pay us a one-time, non-refundable and non-creditable upfront fee of US\$22.0 million, comprising US\$8.5 million for the license and US\$13.5 million for the Ex-China Option for Ex-China Territory.

Upon achieving (i) pre-specified development and regulatory milestones triggered by certain clinical development progress and regulatory filing regarding GFH925 in Greater China, we are eligible to receive up to US\$27 million milestone payments from Innovent, (ii) pre-determined commercialization milestones triggered by reaching annual sales of GFH925 in Greater China of at least hundreds of millions of U.S. dollars per year, we are eligible to receive up to US\$105 million milestone payments from Innovent. Innovent is also obligated to pay tiered royalties ranging from a single-digit percentage to a low teen percentage of annual net sales of GFH925 upon the achievement of specific thresholds for GFH925 annual net sales achieved by Innovent, its affiliates and sublicensees (although we are not aware of any such sublicensees as of the Latest Practicable Date) on a region-by-region basis. Net sales refers to the gross amount invoiced, less applicable discounts, shipping charges, and taxes as well as customary adjustments. Net sales shall be determined in accordance with US GAAP, IRFS or other accounting standard.

As of the Latest Practicable Date, we had received US\$37.6 million under the GFH925 License Agreement, consisting of US\$22.0 million upfront payments, US\$15.0 million development milestones and US\$0.6 million royalties, and the milestones in commercialization of GFH925 in Greater China have not been triggered.

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Dispute Resolution

The GFH925 License Agreement shall be governed by the laws of the PRC, without regard to its conflicts of law provisions and shall be finally resolved by arbitration administered by the Shanghai International Arbitration Centre.

Termination Clauses

Unless terminated earlier, the GFH925 License Agreement shall continue in full force and effect until the expiration of the Royalty Term under the GFH925 License Agreement, which is determined on a region-by-region basis, defined as: since the first commercial sale of a Licensed Product in a region, until the last to occur of: (a) expiration of the last-to-expire valid claim of our patent(s) covering such Licensed Product in that region; (b) ten years from the first commercial sale of such Licensed Product in that region; and (c) the expiration of marketing or manufacturing exclusivity on such Licensed Product conferred by the applicable regulatory authority in that region. Innovent and we may terminate the GFH925 License Agreement by mutual written agreement. Each party may also terminate the GFH925 License Agreement with advance written notice upon occurrence of one of the following events: (1) the other party’s material breach of the GFH925 License Agreement, (2) bankruptcy of the other party, (3) withdrawal of a Licensed Product required by the competent regulatory authority in a jurisdiction, and (4) an event of force majeure. Also, Innovent may terminate the GFH925 License Agreement in its entirety or with respect to a Licensed Product with advance written notice (1) during the period from the initiation of the first pivotal clinical trial for the Licensed Product and the issuance of the marketing authorization by the competent regulatory authority, or (2) after the issuance of the marketing authorization by the competent Regulatory Authority for the Licensed Product.

Supplementary Agreement with Innovent

On January 11, 2024, we further entered into a supplementary agreement (the “**GFH925 Supplementary Agreement**”) with Innovent. The decision to enter into the GFH925 Supplementary Agreement was based on a range of commercial considerations and aligned with our broader strategy for international expansion. We believe the GFH925 Supplementary Agreement was negotiated at arm’s length basis. As part of our ordinary course of business, we routinely make strategic business development decisions, including the termination of the Ex-China Option, which was one of many such determinations. In making this decision, we considered (i) our own assessment of GFH925’s therapeutic potential and the addressable markets for its intended indications, which also played a role in the decision-making process and (ii) the growing market interest in GFH925 and the favorable reception it has received from potential [REDACTED] and partners, which highlighted its commercial appeal and supported our efforts to secure additional financing.

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Obligations and Responsibilities

According to the GFH925 Supplementary Agreement, all parties agree to terminate the Ex-China Option under the GFH925 License Agreement, including but not limited to Ex-China Option, development milestone payments in the Ex-China Territory and Ex-China Option related payments. We will retain the exclusive rights to develop and commercialize the Licensed Product and the Licensed Compounds for any indication in the Ex-China Territory.

We may license the commercialization rights in Ex-China and/or sublicense the license granted by Innovent under the GFH925 License Agreement through multiple tiers to any third party, without the written consent of Innovent; provided that such sublicense will not relieve us of any obligations under the GFH925 License Agreement and GFH925 Supplementary Agreement, and each sublicense agreement shall not conflict with the GFH925 License Agreement and GFH925 Supplementary Agreement.

All parties agree that upon the effective date of the GFH925 Supplementary Agreement, we shall have sole discretion regarding the development or commercialization activities of the Licensed Product and the Licensed Compounds in the Ex-China Territory.

The GFH925 Supplementary Agreement provides for allocation of responsibilities between the parties for the costs incurred in our activities relating to the License Product in the Ex-China Territory. If Innovent, at our reasonable request, provides support to our activities in development or obtaining regulatory approval of the License Product in the Ex-China Territory, we should reimburse Innovent for the internal and out-in-pocket costs reasonably incurred by Innovent in providing such support. As of the Latest Practicable Date, such reimbursement has not occurred or been triggered.

Payments

In consideration of the termination, we shall pay non-refundable termination fees to Innovent in an aggregate of US\$20.0 million (the “**Termination Fees**”) in installments by December 1, 2026. The higher amount of the Termination Fees than the original fee paid by Innovent on the Ex-China Option in 2021 had taken into account the appreciation of monetary value of the Ex-China Option during such period, as well as the increasing certainty towards the clinical development of GFH925 through the passage of time. Innovent’s efforts and progress achieved in the clinical development of GFH925 had contributed to the added value of the Ex-China Option. According to Frost & Sullivan, a higher amount of termination fee than the original option fee is in line with industry norm. Especially, with the advancement of clinical-stage development of a drug candidate and the accumulation of positive clinical trial results, the probability of success (“POS”) of the drug candidate’s commercialization would increase. As the evaluation of a drug candidate usually relies on the POS, an increase of POS will lead to an increase of drug evaluation. As of the Latest Practicable Date, we had paid US\$2.0 million to Innovent under the GFH925 Supplementary Agreement. The remaining termination fees payment of US\$18.0 million will be paid in two installments by December 2026. If we receive any payments from the sublicense transaction to a third party to use the

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licensed technology/rights to develop and commercialize the product in the sublicensed territory, we shall pay a low double-digit percentage of such sublicensing income (including any upfront, milestone and royalty payment(s), license maintenance fees and other similar payments) to Innovent Suzhou. We shall also pay to Innovent Suzhou revenue sharing payments ranging from a single-digit percentage to a low double-digit percentage based on the total annual net sales of the Licensed Product sold in the Ex-China Territory. Upon the termination of Ex-China Option, we have the right to assign and/or transfer any of the GenFleet Intellectual Property in the Ex-China Territory to any third party (the “**Assignee**”). If we make and actually receive any payments from such assignment and/or transfer (the “**Assignment Income**”), we shall share with Innovent Suzhou the Assignment Income ranging from a low double-digit percentage to a middle double-digit percentage depending on the stage of the development of the Licensed Product in the Ex-China Territory and whether such Assignee is recommended by us. The sharing of licensing payment and Assignment Income with Innovent represented our further recognition of the progress Innovent achieved in the clinical development of GFH925 in China and a further consideration for Innovent’s agreement to terminate the Ex-China Option. Upon such assignment and/or transfer, if the Licensed Product in the Ex-China Territory is at a later stage of clinical development, the Assignment Income to be shared with Innovent Suzhou will be lower. Also, if such assignment and/or transfer is recommended by us to Innovent Suzhou, the Assignment Income to be shared with Innovent will be higher. In the Ex-China Territory, we have complete discretion with respect to GFH925. In particular, we do not require Innovent’s consent, nor does Innovent have any control (directly or indirectly) for authorizing any sublicense transaction, assignment of rights and/or transfer of any GenFleet Intellectual Property and/or determining any of the fees involved in such transactions. We also have complete discretion to decide whether to accept the sublicensees/assignees/transferees recommended by Innovent.

Dispute Resolution

The GFH925 Supplementary Agreement shall be governed by the laws of the PRC, without regard to its conflicts of laws. The dispute resolution mechanism of the GFH925 License Agreement shall also apply to the GFH925 Supplementary Agreement.

Clinical Supply Agreement with Innovent

In December 2022, we entered into a Clinical Supply Agreement with Innovent regarding the supply of GFH925 to Innovent for use in clinical trials, the consideration of which was determined at arm’s length basis.

Price term: Innovent shall pay us for the supply of GFH925 at a fixed price per pill in installments according to the progress of the delivery of GFH925 as determined in the Clinical Supply Agreement.

Quantity term: We shall supply GFH925 to Innovent in the fixed quantity according to the time scheduled provided in the Clinical Supply Agreement.

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Return policy: If the products we supply to Innovent are defective, we have an obligation to replace the defective products for Innovent.

Duration: The Clinical Supply Agreement shall remain effective until the termination of the GFH925 License Agreement, except that we have a right to terminate the agreement due to Innovent’s failure to make undisputed payment within a specified period of time.

Since GFH925 has advanced into commercialization stage in China, the Clinical Supply Agreement have since ceased to be operative without termination by either party.

Drug Supply Settlement Agreement with Innovent

In May 2025, we entered into a Drug Supply Settlement Agreement with Innovent regarding the commercial supply of GFH925 to Innovent, the consideration of which was determined at arm’s length basis.

Price term: Innovent shall pay us for the supply of GFH925 at a non-adjustable fixed price per kilogram in installments according to the progress of the manufacturing and delivery of GFH925 as determined in the Drug Supply Settlement Agreement.

Quantity term: The Drug Supply Settlement Agreement does not set forth a minimum purchase amount or any purchase or supply obligation on either party.

Return policy: The Drug Supply Settlement Agreement does not set forth a return policy. However, Innovent’s payment obligations are triggered by our delivery of non-defective products.

Duration: The Drug Supply Settlement Agreement shall remain effective until the termination of the GFH925 License Agreement.

Settlement of previously delivered API: The Drug Supply Settlement Agreement also specifies the settlement terms for unpaid APIs delivered prior to the execution of the agreement but after the commencement of the commercialization stage, all of which had been fully settled as of the Latest Practicable Date.

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Innovent’s Development of GFH925

After execution of the License Agreement, Innovent renamed GFH925 as IBI351 and has taken over the clinical development and commercialization of IBI351 in Greater China. We are not aware of any negative clinical results from drug programs of Innovent that may negatively affect the development and commercialisation prospects of GFH925. Based on publicly available information, the major progresses achieved in Innovent’s development of IBI351 are summarized below.

Year	Major events
2021	In September, Innovent entered into an exclusive license agreement with the Company for the development and commercialization of GFH925 (<i>i.e.</i>, the License Agreement) in Greater China. In September, Innovent completed the first patient dosed for Phase I/II clinical trial of IBI351 in Chinese patients with solid tumors.
2022	In June, the Phase I dose-escalation study results of IBI351 as monotherapy were released at the ASCO Annual Meeting 2022. Favorable safety and tolerability and promising antitumor activity of IBI351 monotherapy were observed in previously treated advanced NSCLC and CRC harboring KRAS G12C mutation. In the second half of 2022, Innovent initiated Phase Ib studies for IBI351 combination therapy for KRAS G12C mutated cancers. In the second half of 2022, Innovent initiated the pivotal Phase II study for IBI351 for the treatment of 2L KRAS G12C mutated NSCLC.
2023	In January, IBI351 received NMPA BTM for the treatment of patients with advanced NSCLC harboring KRAS G12C mutation. In April, the updated results of the Phase I study of IBI351 as monotherapy in patients with previously treated advanced NSCLC harboring KRAS G12C mutation were presented at the AACR 2023. In May, IBI351 received NMPA BTM for the treatment of patients with advanced CRC harboring KRAS G12C mutation. In June, the preliminary results from a pooled analysis of two Phase I studies of IBI351 as monotherapy in patients with metastatic CRC harboring KRAS G12C mutation were presented at the ASCO Annual Meeting 2023. In June, Innovent entered into a clinical trial collaboration and supply agreement with Merck KGaA for the combination therapy of IBI351 with cetuximab (ERBITUX®) for KRAS G12C-mutated NSCLC in a Phase Ib study in China.

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Year	Major events

In November, the NMPA accepted the NDA and granted Priority Review Designation for IBI351 monotherapy in patients with previously treated advanced NSCLC harboring KRAS G12C mutation who have received at least one systemic therapy.

In December, updated results from the Phase II pivotal study for IBI351 for previously treated KRAS G12C-mutated NSCLC and CRC were presented at ESMO Asia 2023.

2024 Innovent initiated a Phase Ib/III clinical trial to investigate IBI351/cetuximab combination therapy in patients with previously untreated advanced NSCLC harboring KRAS G12C mutation.

In August, the data from the Phase II pivotal study for IBI351 for previously treated KRAS G12C-mutated NSCLC has been published in full manuscript in the *Journal of Thoracic Oncology*.

In August, the NMPA approved Dupert® (IBI351, fulzerasib) as monotherapy for the treatment of advanced NSCLC patients harboring KRAS G12C mutation who have received at least one systemic therapy. Dupert became Innovent’s eleventh product in its commercial portfolio. Innovent has initiated commercialization of Dupert® in Mainland China.

In our communications with EMA and FDA regarding applying for clinical trials of the GFH925/cetuximab combination therapy, we submitted to the two regulatory authorities certain clinical data generated from the GFH925X1101 study conducted by Innovent in China (including the dosage, safety and efficacy profile of GFH925, and patient selection in the study), as well as publicly available past clinical trial results regarding cetuximab (the safety and efficacy profile). Apart from incorporating the above-mentioned information of GFH925 and cetuximab in our ex-China IND applications — as required under the EMA and FDA regulatory framework for combination studies — we have not relied on any research and development activities conducted by Innovent and other third parties. In addition, in advancing the R&D of GFH925 in ex-Greater China regions, we have not relied on or used — and do not intend to rely on or use — any data generated from Innovent’s or other third parties’ clinical studies of the same combination therapy in China.

Merck Agreement

On June 30, 2022, we entered into a clinical trial collaboration and supply agreement (the “Merck Agreement”) with Merck Healthcare KGaA in relation to the clinical development of the GFH925/cetuximab combination therapy for a Phase Ib/II clinical trial (i.e., GFH925X0201) in the EU.

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Obligations and Responsibilities

According to the Merck Agreement, Merck is obligated to provide cetuximab for the use in the clinical trial to us with a maximum number of 3,500 vials and schedule specified in the Merck Agreement according to the clinical trial status and subject to mutual agreement between Merck and our Company. Our Company shall bear all other costs associated with the subject clinical trial. The Merck Agreement does not affect our status as the sole sponsor of or our sole responsibility to conduct the KROCUS trial. The Merck Agreement does not provide for a joint steering committee. Each party agreed to customary indemnification to the other party in relation to losses attributable to such party’s product and, in case of Company, arising from the trial of GFH925/cetuximab combination therapy.

In addition, the Merck Agreement provides that: (1) we shall be the sponsor of the KROCUS study and shall own and hold the respective clinical trial application for the KROCUS study; (2) we shall ensure that all directions from any regulatory authority and/or ethics committee with jurisdiction over the KROCUS study are followed; (3) we shall lead all discussions with any regulatory authority regarding the KROCUS study; (4) we and Merck are responsible for the supply of GFH925 and cetuximab, respectively, to be used in the KROCUS study; (5) the inventions solely relating to GFH925 or cetuximab shall be solely owned by us or Merck, respectively.

Intellectual Property

The Merck Agreement stipulates that all rights to all inventions that are directed to the GFH925/cetuximab combination therapy and variants thereof, except those inventions solely relating to GFH925 or cetuximab, shall be jointly owned by Merck and our Company (the “Joint Invention”). Those inventions solely relating to GFH925 or cetuximab shall be solely owned by GenFleet or Merck, respectively. The Merck Agreement allows us to freely exploit such joint inventions and does not provide for payment obligations in connection with any licensing arrangement. Where a license is required, Merck grants to us a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license under Merck’s right, title and interest in and to all joint inventions to use such inventions for any use, and vice versa. The Merck Agreement granted us the first right (but not the obligation) to file, maintain and defend the patents that cover the joint inventions. However, if we do not want to file or share expenses for a patent application that covers the joint inventions, Merck may at its own expenses continue to file, maintain and defend such a patent application. Also, under the Merck Agreement, we need Merck’s consent in making disclosures to the patent authority regarding jointly inventions. The Merck Agreement does not otherwise affect our existing ownership of intellectual property rights over GFH925. As of the Last Practicable Date, neither party has obtained any patent or filed any patent application for the joint inventions under the Merck Agreement. We will be the sole marketing authorization holder for the combination therapy of GFH925/cetuximab in all Ex-Greater China jurisdictions.

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The Merck Agreement further provides that, where a license is required, Merck grants to us a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license under Merck’s right, title and interest in and to all the Joint Inventions to use the Joint Inventions for any use, and vice versa.

Dispute Resolution

Merck and we agreed to attempt in good faith to settle all disputes arising out of the Merck Agreement in an amicable manner. If such disputes cannot be so resolved, they shall be finally settled at the competent courts of Geneva, Switzerland. We did not have an unresolvable dispute with Merck during the Track Record Period.

Termination Clauses

The term of the Merck Agreement shall continue until completion of all of the obligations of the parties or termination by either party. Either party may terminate the Merck Agreement (i) when the other party commits a material breach and fail to remedy in a specified period, (ii) when the party reasonably determines in good faith, after a review of relevant information, that the trial may unreasonable affect patient safety, (iii) by providing written notice in specified events, including regulatory action or manufacturing or supply chain disruption, (iv) by providing advance written notice in case the study fails to reach any of its endpoints. Merck may terminate the Merck Agreement if it reasonably and in good faith believes that the supplied cetuximab is being used in the trial in an unsafe manner or there is imminent danger to patients, and we fail to promptly incorporate appropriate changes to address such issues after we receive notification from Merck.

Collaboration and Option Agreement with Verastem

On August 24, 2023 (the “**Verastem Effective Date**” referred to below), we entered into a Collaboration and Option Agreement (the “**Verastem Agreement**”) with Verastem. Verastem specializes in developing treatment for cancers and is a member of Nasdaq Biotechnology Index. Verastem is an Independent Third Party to us.

Obligations and Responsibilities

Under the Verastem Agreement, we granted Verastem exclusive options (the “**Verastem Option(s)**”) to obtain an exclusive (including us), royalty-bearing and sublicensable licenses to develop, manufacture, commercialize and otherwise exploit the certain compounds and products (with details below) in territories other than Mainland China, Hong Kong, Macau and Taiwan (the “**Greater China**”) (such territories, the “**Verastem Territories**”). As the Verastem Agreement implicates three programs, Verastem obtained three Verastem Options from us, and the exercise of such options is on a program-by-program basis. Verastem may exercise the option for a program within 45 days after we provide Verastem a package of documents or information related to the products and compounds in connection with the program. As of the Latest Practicable Date, Genfleet had not yet generated the documents or information related

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to the products and compounds in connection with our collaboration with Verastem under the Verastem Options. In January 2025, Verastem exercised the option to acquire an exclusive license to develop and commercialize GFH375 in territories outside of Greater China. In the same month, Verastem made a payment of US\$6 million of the option exercise fee in connection with Verastem’s exercise of the option regarding GFH375 to us, pursuant to the Verastem Agreement.

In connection with the Verastem Options, we agree to collaborate with Verastem to advance three oncology collaboration programs focused primarily on RAS pathway-driven cancers, including (i) the initial program targeting KRAS G12D, including GFH375, (ii) the first additional program, and (iii) the second additional program (each a “**Collaboration Program**”), provided that both the first and second additional programs target specific molecules other than KRAS G12D (the “**Two (2) Additional Programs**”) to be selected by Verastem. The Two (2) Additional Programs are not related to our Core Products and are not included in our pipeline chart as they are currently in the preclinical stage. As of the Latest Practicable Date, the Two (2) Additional Programs had been selected.

The Verastem Agreement established a JSC, to coordinate and oversee the discovery and development activities under the agreement. We and Verastem shall each appoint an equal number of (at least three for each party) employee representatives to the JSC. A representative of either Verastem or us will serve as the chairperson of the JSC, with such chairperson alternating between Verastem and us on an annual basis. The first chairperson will be a representative of Verastem. The JSC holds meetings at least once a quarter and at other times as the JSC may determine. All decisions within the JSC must be made on a consensus basis. If the JSC encounters a deadlock on a matter and cannot make a decision, the matter may be referred to the parties’ Executive Officers (i.e., our Chairman and Verastem’s Chief Executive Officer) to negotiate and decide. If the parties’ Executive Officers still cannot resolve the matter, then Verastem shall have the final decision-making authority for matters covered by exercised Verastem Options outside Greater China (meaning, in the case of GFH375, the development and commercialization of GFH375 in territories outside of Greater China), and we shall have the final decision-making authority for matters within Greater China or not covered by any exercised Verastem Option. If such matter is covered by an exercised Verastem Option and relates to both Greater China and regions outside Greater China, then such matter can only be resolved by unanimous agreement by the parties.

The Verastem Agreement provides for allocation of responsibilities between the parties for the costs incurred in connection with activities under a Collaboration Program.

Intellectual Property

Each party will retain all of its rights, title, and interests in and to all know-how, patent rights, and other intellectual property rights that are controlled by such party prior to the Verastem Agreement or are otherwise conceived, discovered, developed, invented, created, or otherwise made or acquired by such party or its affiliates outside of the performance of activities under the Verastem Agreement, subject to any rights or licenses expressly granted by

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such party to the other party under the Verastem Agreement. Subject to any rights or licenses expressly granted to Verastem, we are the sole owner of all collaboration knowhow and patent rights first generated, conceived, discovered, created, invented, or otherwise made during the term solely by or on behalf of us during the performance of activities under the Verastem Agreement. Subject to any rights or licenses granted to us, Verastem is the sole owner of all collaboration knowhow and patent rights first generated, conceived, discovered, created, invented, or otherwise made during the term solely by or on behalf of Verastem during the performance of activities under the Verastem Agreement. Subject to any rights or licenses granted by one party to the other party, the parties will jointly own all Joint Collaboration Technology on an equal and undivided basis.

In addition, we have an obligation to indemnify Verastem the potential penalties arising from patent infringement of IP claims asserted by a third party outside Greater China.

Payments

According to the Verastem Agreement, Verastem agreed to make an upfront payment of US\$5.0 million in two installments and will provide US\$1.5 million of research support over the first three years of the Verastem Agreement. In addition, pursuant to the Verastem Agreement, upon achievement of pre-specified development milestones triggered by certain clinical development progress and regulatory filing regarding GFH375 and commercial milestones triggered by reaching annual sales of at least hundreds of millions of U.S. dollars per year, and upon Verastem exercising all three Verastem Options, we will be entitled to receive payments (evenly split among the three Verastem Options) of up to US\$620.0 million inclusive of (i) US\$6.0 million upon exercise of each of the three (3) GenFleet Options, (ii) US\$2.0 million of pre-option development milestone payment for each of the Two (2) Additional Programs, (iii) up to US\$49.0 million upon achievement of pre-specified development and commercialization milestones for each of the three (3) licensed programs, (iv) up to US\$150.0 million upon achievement of pre-specified sales milestones for each of the three (3) licensed programs, and (v) up to US\$1.0 million for the manufacture of licensed compound and licensed products. Verastem has also agreed to pay us royalties on annual net sales (determined in accordance with U.S. GAAP) of licensed products in the Verastem Territories ranging from the mid to high single digits. If Verastem grants a sublicense for either of the Two (2) Additional Programs to a third party in the United States, European Union (including the United Kingdom) or Japan, Verastem will pay us a percentage ranging from a middle single-digit to a low double-digit percentage of any upfront payment.

As of the Latest Practicable Date, we had received the full upfront payment of US\$5.0 million, the first annual R&D fee payment of US\$0.5 million from Verastem and US\$6.0 million revenue related to GFH375 in connection with Verastem’s exercise of its option under the Verastem Agreement in January 2025.

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Dispute Resolution

For any dispute between the parties, other than matters subject to resolution by the joint steering committee established by the parties, the parties will first attempt in good faith to resolve such dispute by negotiation. If the dispute is not resolved informally within 10 days, either party may refer the matter to the executive officers of the parties for resolution. The executive officers will then attempt in good faith to resolve the dispute through negotiation within 10 business days following the referral. If the dispute remains unresolved, a party may submit the dispute to arbitration by providing written notice to the other party. Within 30 days after receipt of such notice, the parties shall designate a single arbitrator in writing. If the parties cannot agree on an arbitrator within that 30-day period, the arbitrator shall be selected by the Singapore office of the American Arbitration Association-International Centre for Dispute Resolution. The arbitration shall be governed by the International Arbitration Rules and Procedures of the International Centre for Dispute Resolution. The Verastem Agreement is governed by, and enforced and construed in accordance with, the laws of the state of Delaware, without regard to its conflicts of law provisions.

Termination Clauses

Verastem may terminate the Verastem Agreement in its entirety or on a program-by-program basis or on a licensed product-by-licensed product and country-by-country basis, by providing 90 days written notice to us⁵. Either party may terminate the Verastem Agreement in its entirety or on a program-by-program and country-by-country basis, with 60 days’ written notice for the other party’s material breach if such party fails to cure the breach. Either party may also terminate the Verastem Agreement in its entirety upon the following insolvency events by the other party: (a) files for bankruptcy; (b) making an assignment for the benefit of, or an arrangement or composition generally with, its creditors; (c) appointing an examiner of or a receiver or trustee over all or substantially all of its property or suffering the appointment of such party that is not discharged within 60 days after such filing or appointment; (d) proposing a written agreement of composition or extension of its debts; (e) proposing or being a party to any dissolution, liquidation or winding up; (f) having a bankruptcy petition filed against it that is not discharged or dismissed within 60 days, or (g) admitting in writing its inability generally to meet its obligations as they fall due in the ordinary course.

License Agreement with SELLAS

On March 31, 2022 (the “**SELLAS Effective Date**” referred to below), we entered into a License Agreement (the “**SELLAS License Agreement**”) with SELLAS. SELLAS specializes in developing novel therapeutics for a broad range of cancer indications including hematological malignancies and solid tumors. SELLAS is an Independent Third Party to us.

⁵ The expression of to “continue/terminate/expire” something on a “product-by-product”, “program-by-program”, “region-by-region” and “country-by-country” basis means: whether something is to continue/terminate/expire is determined separately for each particular product, program, region, or country. Here, the expression indicates that the Verastem Agreement may be terminated only as to a particular product, program, or country, while remaining effective as to a different product, program, or country.

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Obligations and Responsibilities

Under the SELLAS License Agreement, we grant SELLAS an exclusive (even as to us), sublicensable, royalty-bearing right and license under relevant patents and know-how controlled by us to develop, manufacture and commercialize GFH009 and any related back-up molecules or intermediaries, or related compound or forms as specified in the SELLAS License Agreement, across all treatment, diagnosis, or prevention of disease in humans and animals uses in regions outside of Greater China (Mainland China, Hong Kong, Macau and Taiwan). SELLAS shall have sole responsibility for the cost and expense of, and the sole authority over and control of the development, manufacture, regulatory approval, and commercialization of the compounds and products, including GFH009, outside of Greater China.

Under the SELLAS License Agreement, the parties will establish a JSC to review and oversee the development and commercialization of the compounds and products, including GFH009, and to coordinate the parties’ activities under the SELLAS License Agreement. Each party shall appoint two representatives to the JSC and designate a co-chairperson from their representatives. The purpose of the JSC is only for the exchange of information and discussion. The JSC has no decision-making authority. SELLAS has final decision-making authority for all matters relating to the development and commercialization of the compounds and products, including GFH009, outside of Greater China. The JSC will hold meetings on a semi-annual basis determined reasonably by the co-chairpersons.

Intellectual Property

Each party shall retain all rights, title and interests in and to any intellectual property rights that it owned, licensed or sublicensed prior to or independent of the SELLAS License Agreement. Ownership of patent rights created or developed under the SELLAS License Agreement after the SELLAS Effective Date and during the term will be determined based on inventorship, with inventorship being determined according to the principles of United States patent law.

Payments

According to the SELLAS License Agreement, SELLAS is obligated to provide us with the following payments: (i) a non-refundable, and non-creditable initial payment of US\$10.0 million; (ii) development and regulatory milestone payments of an aggregate of up to US\$48.0 million upon the achievement of the following milestones: the first dosing of the first subject in the first Phase III clinical trial, application and subsequent regulatory approval of an NDA with the FDA or EMA for the first indication, the second indication and the third indication; and (iii) the sales milestone payments of an aggregate of up to US\$92.0 million upon the achievement of specific levels of the aggregate annual net sales. In addition, SELLAS shall pay us non-refundable, non-creditable royalties at rates ranging from a low single-digit percentage to a high single-digit percentage based on the aggregate net annual sales, calculated on a product-by-product and country-by-country basis. The royalties will be payable during the

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Royalty Term under the SELLAS License Agreement (as defined below). Net sales shall be calculated by gross amount invoiced, less applicable discounts, shipping charges, and taxes as well as other customary adjustments. Net sales shall be determined in accordance with U.S. GAAP.

As of the Latest Practicable Date, we had received the full initial payment US\$10.0 million from SELLAS.

Dispute Resolution

For any dispute regarding the construction of the SELLAS License Agreement or the rights and liabilities of either party, the parties will first attempt in good faith to resolve the dispute through negotiation. If the dispute is not resolved informally within 10 business days, either party may, by written notice to the other party, refer the dispute to an executive officer of the other party for attempted resolution through good faith negotiation within 30 days after such notice is received. If the dispute remains unresolved, it shall be submitted in writing to the other party for arbitration at the office of the American Arbitration Association in New York County, New York, U.S., in accordance with the then-prevailing commercial arbitration rules of the American Arbitration Association.

Termination Clauses

The term of the SELLAS License Agreement shall commence on the SELLAS Effective Date and shall continue, on a product-by-product and country-by-country basis, until the expiration of the applicable Royalty Term under the SELLAS License Agreement, unless earlier terminated. The Royalty Term under the SELLAS License Agreement is determined on a product-to-product and country-to country basis, defined as: since the first commercial sale the GFH009 product in a country, until the later of: (a) ten years following the date of such first commercial sale, or (b) the date upon which the manufacture, use, sale, offer for sale, or importation of such product in such country would no longer infringe, but for the license granted by the SELLAS License Agreement, a valid claim of our patents. Upon the expiration of the Royalty Term on a product-by-product and country-by-country basis, the license granted to SELLAS shall become non-exclusive, perpetual and fully paid up on a product-by-product and country-by-country basis.

Each party may, without prejudice to any other remedies available to it at law or in equity, terminate the SELLAS License Agreement in its entirety if the other party materially breaches any material obligations and fails to cure such material breach within 90 days of receiving notice. SELLAS may terminate the SELLAS License Agreement for the following conditions: (i) with 180 days' prior written notice if a clinical failure occurs during the period from the first anniversary of the SELLAS Effective Date until the first regulatory approval of the product in any country outside of Greater China; (ii) with one year's prior written notice upon receiving the first regulatory approval of the product and continuing through the end of the Term; (iii) upon 90 days' notice if there is a material risk for harm in humans or if the occurrence of any safety concerned required to be reported that results in a clinical hold issued by the FDA, or

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if there is a material toxicity or material drug safety issues or serious adverse event reasonably related to GFH009 that was not publicly known at the time of the SELLAS Effective Date; or (iv) upon notice if we file a petition under any bankruptcy or insolvency act or makes an assignment for the benefit of creditors or has any other events of insolvency as specified in the SELLAS License Agreement. We may terminate the SELLAS License Agreement by delivery of written notice under the following circumstances: (i) if SELLAS fails to make the required payment within 60 days after the receipt of our written notice; (ii) if SELLAS fails to meet the deadline for a diligence milestone event including but not limited to the first dosing of a first patient in Phase II clinical trial within 12 months following completion of Phase I trial for such product; or (iii) if SELLAS files a petition under any bankruptcy or insolvency act or make an assignment for the benefit of creditors or has any other events of insolvency as specified in the SELLAS License Agreement.

Supplementary Agreement with SELLAS

On October 13, 2022 (the “**SELLAS Supplementary Effective Date**”), we further entered into a clinical supply agreement supplement to the SELLAS License Agreement (the “**SELLAS Supplementary Agreement**”) with SELLAS.

Obligations and Responsibilities

According to the SELLAS Supplementary Agreement, we have appointed two leading CDMO companies for the manufacturing of API and drug product of GFH009, respectively, and we shall supply GFH009 in the applicable formulations as specified in each purchase order to SELLAS as a non-exclusive supplier. We will ensure that we deliver GFH009 in conformation with the specifications, and regulatory standards (the “**Manufacturing Requirements**”). SELLAS will provide a purchase order to us every six months, specifying the quantity, formulations, and requested delivery dates. SELLAS retains a right to inspect the shipment and return or destroy any products that do not conform to the Manufacturing Requirements (the “**Non-conforming Product**”), at our option and our costs and expenses. We will then (a) at SELLAS’s election, either promptly (i) deliver replacement to SELLAS at our cost, or (ii) reimburse SELLAS for all amounts already paid to us for such Non-conforming Product; and (b) reimburse SELLAS for shipping costs for the delivery of Non-conforming Product.

Payments

SELLAS will pay us a per unit price for the clinical supply of GFH009 equal to the fully burdened manufacturing cost per unit, plus a percentage of our FTE cost for manufacturing management (the “**Supply Price**”). However, excluding inflation, the Supply Price will not exceed a specified amount per vial within three years following the effective date of the supplementary agreement with SELLAS.

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Upon receipt of a purchase order, SELLAS will pay us a portion of the Supply Price, along with any applicable taxes as outlined in the purchase order. Upon delivery of the first shipment of GFH009, SELLAS will pay us the remaining balance of the Supply Price and applicable taxes as specified in the purchase order.

As of the Latest Practicable Date, we had received US\$0.2 million under the SELLAS Supplementary Agreement.

Dispute Resolution

The dispute resolution mechanism of the SELLAS License Agreement shall also apply to the SELLAS Supplementary Agreement.

Termination Clauses

The term of the SELLAS Supplementary Agreement will commence on the SELLAS Supplementary Effective Date and continue until SELLAS no longer develops GFH009 in countries outside of Greater China.

The SELLAS Supplementary Agreement will terminate (i) upon termination of the SELLAS License Agreement, or (ii) upon either party filing for bankruptcy proceedings. In the event of a material breach of the SELLAS Supplementary Agreement by SELLAS, we have the right to terminate the agreement by providing 30 days’ written notice to SELLAS. Furthermore, SELLAS may terminate the SELLAS Supplementary Agreement (i) for convenience, by delivering written notice to us at least 60 days prior to the effective termination date, or (ii) in the event of a material breach by us, by providing 30 days’ written notice.

RESEARCH AND DEVELOPMENT

R&D Strategy

We aspire to leverage our industry experience and established R&D capabilities to develop innovative and effective treatment options in the fields of oncology, autoimmune and inflammatory diseases. During our endeavor, we have established and leveraged a proven, integrated research and development platform spanning target discovery, molecular discovery and evaluation, translational science and clinical development. Our technological capabilities include discovery of original molecular structures and new molecular entities, investigation of molecular process routes and quality standards, as well as exploration of clinical drug combination development paths. Combining these internally accumulated capabilities and external resources of our collaborators and service providers, we have rendered our pipeline products among the frontrunners in both China and the global market.

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R&D Team

Our R&D team has strong expertise, deep understanding and broad development experience. As of the Latest Practicable Date, 48 members of our R&D team had obtained advanced degrees, including 13 members with doctorate degrees and 35 members with master’s degrees. Our R&D team is led by a team of world-class scientists with years of drug development experience. Our core R&D personnel consists of six members covering the fields of chemistry, biology, pharmacology and medicine. All of our core R&D personnel have been working in the pharmaceutical industry for over 15 years. The core R&D personnel involved in the development of the Core Product are all remained employed by us. The following table sets forth a breakdown of the number of R&D team by function as of the Latest Practicable Date:

Functions	Number of employees by function
Early Research and Development	37
Clinical Development	16
CMC	15
Total	68

The following table sets forth the identities, positions, expertise of our core R&D personnel as of the Latest Practicable Date and their involvement and contributions to the R&D activities, including with regard to our Core Products, up to the same date. We had not experienced any material difficulties in our R&D activities, including the research and development of our Core Products.

Identity	Position	Expertise	Involvement and contributions to the R&D activities, including with regard to our Core Products	Date of joining our Group
Dr. Qiang LU	Executive Director and Chairman of the Board	Over 20 years’ experience in the biopharmaceutical industry	Provide strategic guidance on and oversee our R&D efforts	Since our inception
Dr. Jiong LAN	Executive Director, Chief Executive Officer and General Manager	Over 20 years’ experience in the biopharmaceutical industry	Provide strategic guidance on and oversee our R&D efforts	Since our inception

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Identity	Position	Expertise	Involvement and contributions to the R&D activities, including with regard to our Core Products	Date of joining our Group
Dr. WANG Yu .	Chief Medical Officer	Over 20 years' experience in clinical development	Strategize and execute our clinical development	November 2020
Dr. LI Jingrong	Chief Technology Officer	Over 20 years' experience in the biopharmaceutical industry	Refine the CMC aspects of our pipeline products to advance drug development, optimize cost and ensure consistent quality	January 2022
Dr. SHEN Haige	SVP, clinical development	Over 15 years' experience in drug and clinical development	Design and oversee our clinical development programs	November 2020
Dr. ZHOU Fusheng	VP, drug discovery	Over 15 years' experience in drug development	Supervise our preclinical research and development activities, in particular early drug discovery efforts	April 2018

Drug Discovery

As of the Latest Practicable Date, there were 37 members in the drug discovery function of our Company, who are divided to sub-functions that focus on biology, chemistry, drug metabolism and pharmacokinetics, pharmacology, toxicology, large molecule R&D, project management, computational chemistry, as well as patent information. Each sub-function is directed by a function lead. Most of the team members hold an advanced degree in the relevant fields. The function head typically have over 10 years of experience, while our laboratory staff generally have 5 years or more of experience.

Our Platforms

We have established and leveraged a proven, integrated research and development drug discovery and development system spanning target discovery, molecular discovery and evaluation, translational science and clinical development. Our technological capabilities include discovery of original molecular structures and new molecular entities, investigation of molecular process routes and quality standards, as well as exploration of clinical drug combination development paths. These research and development capabilities organically constitute our drug development framework, which enables us to efficiently advance pipeline programs through different developmental stages.

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Target Discovery Platform

The target discovery platform is rooted in our endeavor to develop differentiated therapeutic options based on clinical needs. We focus on addressing clinical needs by analyzing disease-related factors such as geographical variations, underlying biological mechanisms, primary or secondary drug resistance, and the specifics of medical treatment modalities. We also consider the mechanisms of drug action and the global clinical strategy landscape. By analyzing literature and ongoing research in the field, we are able to identify and prioritize novel and potentially druggable targets. After integrating insights from the developments and future projections of the industry as a whole, our target discovery platform crafts differentiated clinical development strategies tailored to specific disease contexts and therapeutic areas.

Molecular Discovery and Evaluation Platform

The molecular discovery and evaluation platform is a critical component in our new drug development process, which is designed to enhance the efficiency and success rate of our drug discovery efforts. The platform includes integrated molecular design, synthesis and optimization technology, high-quality molecular discovery, efficient drug metabolism and pharmacokinetics research technology, comprehensive biological and drug mechanisms evaluation technology, which together not only accelerate the molecular investigation phase but also significantly increase the likelihood of successful drug development.

With our molecular discovery and evaluation platform, we have been able to explore versatile technologies and modalities to address challenging targets identified by our target discovery platform. For instance, in addition to traditional small molecule drug and antibodies, we are also developing molecular glue and bioconjugates, which are functional antibody synergistic conjugate (FAScon) that aim to realize both precise targeting and synergistic effects of the large and small molecules. With this platform, we also designed a special linker featuring adequate stability to prevent premature release of payload in the blood and enabling conjugation of hydrophobic small molecules at a high drug-to-antibody ratio.

In parallel to our molecular discovery and evaluation platform, we believe that the in-depth CMC experience over the years forms an integral part of our drug discovery efforts. For additional information about our CMC capabilities, see “— Chemistry, Manufacturing and Controls (“CMC”).”

Translational Science and Clinical Development Platform

We seamlessly integrate our early-stage drug discovery activities with later clinical development capabilities. For instance, our early-stage drug discovery platforms enable generation of solid preclinical candidates with optimized design and promising IND-enabling result to facilitate advancement of clinical development, and our clinical development activities may help us refine parameters that we focus during drug discovery efforts. Our translational science and clinical development platform encompasses our biomarker clinical translation technology, precision medicine technology for the entire project lifecycle, clinical development technology based on data science and quantitative analysis. For additional information about our clinical development capabilities, see “— Clinical Development” below.

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External Collaboration

For our preclinical studies, we have collaborated with global CROs and leading research institutes for preclinical development. These partners and collaborators mainly provide us with services related to protein purification, establishment of enzymatic assay, cocrystallization of compounds with target proteins, preclinical toxicity and safety evaluations of our product candidates in accordance with agreed study design and under our supervision. We select our collaborators to facilitate our innovative strategy.

Clinical Development

Clinical Development Team

As of the Latest Practicable Date, our clinical development team consisted of 16 members, including scientists and physicians with strong drug development experience, who participate in clinical development strategy development, clinical trial design, clinical trial operation organization, drug safety monitoring, and clinical trial quality control. Many of our clinical development team members had extensive relevant work experience. Among our clinical development team members, over 60% have obtained post-graduate degrees. Our clinical development team is generally responsible for the clinical development of our Core Products and other pipeline products.

Clinical Trial Design and Implementation

Our clinical development team manages all stages of clinical trials, from protocol design to overseeing the operations and conduct of clinical trials. Our rapid trial advancements are driven by (i) our strategic decision to initiate clinical phase trials based on preclinical results that are assessed as promising, (ii) optimized trial design, enabled by our rigorous quantitative analysis of integrated data, and whole-process oversight, and (iii) long-term partnership with various hospitals and principal investigators from different regions to achieve smooth execution. For pipeline products that are out-licensed to third parties in certain jurisdictions, our clinical development team also keeps track of their clinical development in those jurisdictions and participates in the analysis of clinical results and provides suggestions as needed.

Our clinical development team is also responsible for the selection of trial sites. Our site selection criteria include the site’s overall experience, understanding of the disease state, access to relevant experts and patients, geographical coverage, regulatory and quality management, range of services, staff proficiency, and technology. We have collaborated with numerous hospitals and PIs located in China and overseas that can support our clinical trials of different indications, at different stages and in different jurisdictions. We believe the size and geographic diversity of these facilities provide us with an advantage in implementing large-scale clinical trials in and out of China 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 trials that would otherwise be difficult to fulfill enrollment.

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For the years ended December 31, 2023 and 2024, we cooperated with 116 and 122 PIs, respectively, to conduct the clinical trials of our product candidates. To the best of our Company’s knowledge, none of them has any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates. The PIs are responsible for conducting site-level clinical research activities according to our trial protocols and in accordance with laws, regulations, and the GCP Guideline, a quality standard for the overall conduct of the clinical trial. Each trial has a leading PI with primary responsibility to ensure compliance with trial protocol and good clinical practice over the entire trial.

Relationship with CROs

We collaborate with CROs to conduct and support our preclinical and clinical trials in line with industry practice. We select our CROs by weighing various factors. Upon business engagement, we assess CROs based on their business focus, capabilities and overall market recognition. Secondly, we also value the R&D capabilities of the CROs and the management skills of their leaders based on their experience and previous track record. Overall, we aim to select CROs that have optimal compatibility with our preclinical and clinical development programs. When collaborating with CROs on a given project, our internal project team takes a comprehensive approach to manage such project and closely monitors the progress, engages in regular communication with the CRO teams to understand project milestones, identify potential risks, and ensure the project deliverables. Simultaneously, the project/trial leader maintains close contact with the financial departments of both our Company and the CRO organization, implementing stringent financial controls at different stages of the project to ensure its timely and quality completion. Upon project completion, we will conduct a thorough review and provides feedback to enhance the efficiency of future collaborations with the CRO organizations.

The clinical CROs provide us with an array of services necessary for complex clinical trials in accordance with agreed trial design and under our supervision, including trial preparation, trial management, clinical safety management, data management, and report preparation. We choose to engage a CRO based on the complexity and workload of a specific trial. Led by Dr. Shen (our SVP for clinical development), we have a designated team to oversee the on-the-ground operations of clinical trials implemented by CROs at different locations. 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 studies of our product candidates on humans are conducted in compliance with the applicable laws, regulations and in line with the industry standards. We believe our ability to conduct and work closely with CROs to conduct preclinical studies and clinical trials helps us to shorten the time required for product development as well as generate the requisite data in a reliable and efficient way.

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We mainly determine the service fees paid to the CROs in accordance with market prices of similar services, the number of enrolled patients, the duration of the clinical trials, the complexity of trial, including the number of clinical sites and jurisdictions, and the quality and contents of the services provided.

Regulatory Affairs

Our regulatory affairs team is responsible for the regulatory process of our product 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 in multiple major jurisdictions, including China, the U.S., Europe, and Australia, for our product candidates, which requires filings to be made to and approved by the relevant authorities before clinical trials and commercialization can be initiated. The regulatory affairs team prepares and manages regulatory filings by coordinating filing dossiers drafting, addressing regulatory questions and conducting CMC and GMP readiness assessments for our product candidates. We possess extensive knowledge and experience with regard to regulatory filings in China and overseas. With our presence and expertise in China and overseas jurisdictions, we can design our clinical trials to maximize operational efficiency.

CHEMISTRY, MANUFACTURING & CONTROLS (“CMC”)

CMC Team

As of the Latest Practicable Date, our CMC team consisted of 15 professionals with extensive experience in process development, production and quality management from well-known biopharmaceutical and pharmaceutical companies. Our CMC team members have on average approximately 11 years’ experience. Our CMC team is specialized in preclinical and clinical support throughout the drug development process. The CMC function in our Company 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 quality meets regulatory requirements.

We have established CMC capabilities that cover key aspects from the design of synthetic routes for preclinical candidates to process development and quality control in clinical development. We have in-depth expertise in areas including small molecule process development, dosage form selection, formulation determination, formulation process development, drug quality control strategies, development and validation of quality control methodologies, non-GMP kilogram-scale pilot production, and NDA-stage process validation.

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In particular, the capabilities of our CMC team are reflected in the following aspects. First, our CMC team designs and develops production processes, including but not limited to process route design, process parameter reaction condition development and production-scale setting. In the process development for GFH925, our CMC team designed the process route and validated the same at the kilogram scale in its Shaoxing research facility. Our CMC team then transferred the technology on production processes of GFH925 to the CDMOs to validate and implement the process route at a commercial scale. Second, our CMC team designs and develops quality control methods and then transfers the technology on quality control to the CDMOs to validate the method and set the quality standard. Third, our CMC team manages the CDMOs it collaborates with. Our CMC team not only monitors the CDMOs’ work progress but also offers solutions to the CDMOs when a technical problem arises. Through collaboration, our CMC team helps the CDMOs improve their technical, compliance, and research capabilities.

Our CMC functions facilitate a smooth drug development and enables cost control. In particular, we develop suitable process and ensure quality control according to applicable drug registration regulations at early stages of product development. This strategy enables us to avoid detours in subsequent development stage resulted from CMC issues that could have been addressed earlier in the process, therefore may improve the overall efficiency of our research and development efforts. In addition, our CMC process development capabilities allow us to device efficient synthetic routes and establish measures to ensure consistent and reliable production, thereby contribute to cost control and efficient use of resources. We are able to significantly lower the manufacturing cost of GFH925 by optimizing the process route, and we believe our strong CMC expertise also facilitated GFH925 to receive marketing approval in China in merely approximately three years after it obtained IND approval. We are also actively developing the second-generation manufacturing process for GFH925, taking full responsibility for the entire process, including vendor selection. We have engaged two vendors to collaborate on this initiative. The vendors are two leading CDMOs in China that have passed multiple rounds of on-site inspections by the NMPA and the FDA. By April 2025, the two vendors have completed process qualification and control, as well as method qualification and control, for the second-generation manufacturing process; and their applications for manufacturing license have been submitted to and pending before the competent authorities in China. We anticipate that the second-generation manufacturing process will significantly enhance the cost-efficiency of drug production. The second-generation manufacturing process adopts low-cost starting materials, applies chiral response surface methodology, and optimizes the sequence of process steps. These enhancements have led to lower production costs and higher recovery yields, thereby laying a strong foundation for future scale-up of manufacturing. Compared with the first-generation manufacturing process, the second-generation manufacturing process is expected to generate products of the same quality while achieving over 50% of cost reduction. We are the sole owner of the knowhow or invention generated from second-generation manufacturing process of GFH925. We believe that possessing core competency in CMC expertise will enable us to ensure the safety and quality of the drug supply while positioning us to independently pursue ex-China regulatory approvals and capitalize on potential commercial opportunities for GFH925 once the necessary regulatory milestones are obtained.

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Collaboration with CDMO Partners

As of the Latest Practicable Date, we did not have in-house manufacturing facility. We currently plan to establish our own manufacturing facilities to support the formulation production of certain of our pipeline products. We plan to establish a finished dose manufacturing facility in Zhejiang Province, the PRC. Although we are advancing the second-generation manufacturing process for GFH925, we plan to continue to engage CDMOs for the manufacturing of the active pharmaceutical ingredient of GFH925 and fulfill our drug supply responsibility of GFH925 in the future, and we will no longer reserve manufacturing capacity for this product. We believe the capacity of the contracted CDMO service providers is sufficient to satisfy our needs.

Over the next three years, we expect our Core Product, GFH375, will enter into commercialization stage and require the use of our in-house manufacturing facility, which has a designed annual capacity of 100 million tablets. As of the date of this document, we do not have plan to use our in-house manufacturing facility for other clinical assets. The area of the manufacturing facility is expected to be around 5000m². The manufacturing facility is expected to include manufacturing lines for oral solid dose, tablet and capsule with a designed capacity of hundred million pieces, and a liquid dose manufacturing line. The planned timeline for the construction of the manufacturing facility is as follows: determination of the location by the end of 2025; completion of construction and equipment purchase by September 2026; completion of plant commissioning and technology transfer, and initiation of trial operation of the facility by the end of 2026; commencement of commercial-scale production by the end of 2028. We collaborate with CDMOs to conduct and support our preclinical and clinical trials in line with industry practice. In terms of the involvement and contributions of each of the major CDMO partners to the development of our product candidates, we collaborate with our CDMO partners to manufacture certain raw materials and drug substances, such as the active pharmaceutical ingredients (“APIs”) of our product candidates to supply for preclinical studies and clinical trials. We believe the capacity of the contracted CDMO service providers is sufficient to satisfy our needs.

For instance, we are the manufacturer and supplier of GFH925 in connection with the collaboration with Innovent. To support this supply arrangement, we independently developed a suitable and scalable manufacturing process for GFH925, including robust quality control protocols. We do not manufacture the active pharmaceutical ingredient (“API”) in-house; rather, we engage a reputable and qualified CDMO to produce the API according to our proprietary process and specifications. We maintain oversight of the production process and ensures the continuous, compliant, and high-quality supply of the API.

Once the API is manufactured and released, Innovent is responsible for engaging its own downstream vendor to formulate and manufacture the finished drug product using the API supplied by us. This division of responsibility ensures efficiency, cost control, and regulatory compliance throughout the production and supply chain for GFH925.

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We did not experience any material product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period. Under our agreement with our CDMO partners, the CDMO partners are required to perform their services according to the prescribed time frame as set out in the agreement. Usually, we pay the CDMO partners in installments, with a specified credit period. Our CDMO partners are responsible for manufacturing our required products in accordance with certain product specifications, in compliance with cGMP requirements (where applicable), our quality standards and other applicable laws and regulations. We retain all the intellectual property rights and grant our CDMO partners the right to use our intellectual property rights for such manufacturing and packaging activities during the contract period. We are entitled to inspect and audit our CDMO partner’s manufacturing process. We mainly determine the service fees paid to the CDMOs in accordance with market prices of similar services, the number of products manufactured, and the quality and contents of the services provided. We do not share our IPs, know-hows and trade secrets with CDMOs.

BUSINESS DEVELOPMENT

To maximize the commercial potential and improve the development efficiency of our pipeline products, we actively pursue diversified global business development opportunities. In the past, we collaborated with Innovent to facilitate the swift development and approval of GFH925 for commercialization in China. This collaboration leveraged Innovent’s strong development expertise in advancing clinical trials, as well as their leadership position in China, which includes an established commercialization team and an extensive marketing network. We also forged collaborations with SELLAS, which has significant expertise in hematological malignancies and solid tumors, on GFH009, a small molecule selective inhibitor of CDK9 designed for the treatment of AML and certain lymphomas, as well as with Verastem, a company focused on RAS pathway-driven cancers, on certain of our RAS-targeting pipeline products. For additional information on our business development efforts, see “— Major Collaboration and Licensing Arrangements.”

Going forward, we plan to continue establishing strategic partnerships with leading international and domestic pharmaceutical companies to expand our geographic coverage, as well as accelerate the development of our product candidates, with the ultimate objective to maximize the value of our product pipeline. We will select potential collaborators based on a number of considerations, including the brand awareness of the potential collaborators, their R&D capabilities and/or commercialization networks, the track records of successfully develop and/or commercialize pharmaceutical products, where applicable. We will also seek such potential collaborators with pipelines, R&D and commercialization capabilities, as well as monetary resources that could bring potential synergies to us and our pipelines.

In August 2024, GFH925 obtained the NDA approval from the NMPA for the treatment of adult patients with advanced NSCLC harboring KRAS G12C mutation who have received at least one systemic therapy. Pursuant to the GFH925 License Agreement, Innovent is responsible for the commercialization of GFH925 in Greater China. As of the Latest Practicable Date, none of our pipeline products for which we retain the commercialization rights had been approved for commercialization in China or overseas. To lay a solid foundation for our future marketing and commercialization efforts, we plan to actively engage in academic promotions and industry seminars to familiarize market participants, such as patients,

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physicians and PIs of clinical trials, regarding the potential advantages of our pipeline products. We believe such efforts would also help us gain a favorable brand image and name recognition, which may contribute to maximizing the commercial value of our product portfolio. We intend to closely monitor the updates in the industry and formulate concrete commercialization plans when we advance our pipeline programs closer to the NDA submission stage. We will assess and select an appropriate commercialization model and may seek external collaborations, including engaging third-party contract sales organizations, if we deem it to serve our best interest.

INTELLECTUAL PROPERTY

Intellectual property rights are pivotal to the success of our business. Our commercial future will depend, in part, on our ability to acquire and protect our intellectual property rights for commercially significant technologies, inventions and know-how. This includes acquisition of new patents, defense of existing patents, and protection of our trade secrets. We will also have to operate without infringing, misappropriating, or otherwise violating third parties’ valid, enforceable intellectual property rights.

As of the Latest Practicable Date, we held 72 issued patents and 117 patent applications (including 8 PCT applications). As of the Latest Practicable Date, we held (i) 2, 1, 1 and 8 issued patents related to GFH925 in China, the U.S., the E.U. and in other overseas jurisdictions respectively, and (ii) 5, 4, 3, 1 and 21 patent applications related to GFH925 in China, the U.S., the E.U., under the PCT and in other overseas jurisdictions, respectively. As of the same date, we had not received issued patents related to GFH375, but held 2, 1, 1, 1 and 22 patent applications related to GFH375 in China, the U.S., the E.U., under the PCT and in other overseas jurisdiction, respectively. We currently plan to file patent application related to GFH375 in Hong Kong in the second half of 2025 and in Macau after the receipt of the issued patent in China. As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that makes us to believe that any of the pending patent applications will be finally rejected. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our clinical and preclinical product candidates as of the Latest Practicable Date:

Products	Name of Patent Family ⁽¹⁾	Jurisdiction	Status	Patent Application	Grant Date	Patent Expiration ⁽²⁾	Type	Owner/Applicant	Inventor ⁽³⁾
GFH925	Substituted Heterocyclic Fused Cyclic Compound, Preparation Method Therefor and Pharmaceutical Use Thereof	China, United States, EPO	Granted	2020-10-28	China: 2022-8-5; United States: 2024-8-6; EPO: 2024-10-9	2040-10-28	Invention	GenFleet, GenFleet Zhejiang	Fusheng Zhou, Tao Jiang, Chonglan Lin, Lijian Cai, Wan He, Jiong Lan
		China, United States, EPO	Pending		–	–	Invention	GenFleet, GenFleet Zhejiang	
	Polymorph of KRAS Inhibitor, Preparation Method Therefor, and Use Thereof	China, United States, EPO	Pending	2022-12-23	–	–	Invention	GenFleet, GenFleet Zhejiang	Fusheng Zhou, Jinzhu Zhao, Yudong Cao, Lun Xiong, Rongzhen Shi, Jiong Lan

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Products	Name of Patent Family ⁽¹⁾	Jurisdiction	Status	Patent Application	Grant Date	Patent Expiration ⁽²⁾	Type	Owner/Applicant	Inventor ⁽³⁾
	Pharmaceutical Composition, Use Thereof, and Method for Treating Cancer	China, United States, EPO	Pending	China: 2023-03-30; United States: 2023-03-31	–	–	Invention	GenFleet, GenFleet Zhejiang	Lili Tang, Xiang Yu, Jingyang Zhang, Huizhong Hu, Fusheng Zhou, Yu Wang, Jiong Lan, Qiang Lu
	Pharmaceutical Composition, and Preparation Method Therefor and Use Thereof	PCT, China, EPO	Pending	2023-9-20	–	–	Invention	GenFleet	Yuanyuan Xie, Lina Qi, Can Huang, Jiong Lan, Qiang Lu
	Method for Preparation of Pyrazine-Naphthyridine Diketones and Intermediates Thereof	PCT	Pending	2024-8-15	–	–	Invention	GenFleet	Jinzhu Zhao, Yudong Cao, Lun Xiong, Xiong Wei, Xiangchao Liu, Mengting Meng, Fusheng Zhou, JingRong Li, Jiong Lan, Qiang Lu
GFH375	Pyrimidine-Fused Ring Compound, and Preparation Method Therefor and Use Thereof	China, United States	Pending	2023-9-25	–	–	Invention	GenFleet, GenFleet Zhejiang	Tao Jiang, Fusheng Zhou, Tao Liang, Chonglan Lin, Lijian Cai, Zubo Liu, Xiaoming Xu, Kai Ma, Leitao Zhang, Zhen Li, Jiong Lan
GFH312	Dihydronaphthyridinone Compound, and Preparation Method Therefor and Medical Use Thereof	China	Granted	2021-2-9	2024-2-9	2041-2-9	Invention	GenFleet, GenFleet Zhejiang	Fusheng Zhou, Xiaoming Xu, Leitao Zhang, Xin Li, Lili Tang, Jiong Lan
	Crystal Form of RIPK1 Inhibitor, Acid Salt Thereof, and Crystal Form of Acid Salt Thereof	United States China, United States	Pending Pending	2022-8-2	–	–	Invention	GenFleet, GenFleet Zhejiang	Fusheng Zhou, Yuanzhi Tao, Jinzhu Zhao, Jiong Lan
GFH276	Macrocyclic Compounds, and Preparation Method Therefor and Use Thereof	PCT	Pending	2024-8-30	–	–	Invention	GenFleet	Jichen Zhao, Fusheng Zhou, Tao Liang, Yandong Lu; Tao Jiang; Chonglan Lin; Ling Peng; Jiong Lan; Qiang Lu

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Products	Name of Patent Family ⁽¹⁾	Jurisdiction	Status	Patent Application	Grant Date	Patent Expiration ⁽²⁾	Type	Owner/ Applicant	Inventor ⁽³⁾
GFH009 ⁽⁴⁾	Inhibitor of Cyclin-Dependent Kinase CDK9	China, United States	Granted	China: 2017-4-19; United States: 2018-1-3	China: 2020-6-19; United States: 2021-3-23	China: 2037-4-19; United States: 2038-1-3	Invention	GenFleet, Zhejiang	Gang Zhou
GFH018 ⁽⁴⁾	Benzotriazole-Derived α And β -Unsaturated Amide Compound Used as TGF- β R1 Inhibitor	China, United States	Granted	2017-6-8	China: 2021-2-26; United States: 2020-2-4	2037-6-8	Invention	GenFleet, Zhejiang	Fei Sun, Lifang Wu, Charles Z. Ding, Guoping Hu, Jian Li, Shuhui Chen, Jianyu Lu

Abbreviations: PCT = Patent Cooperation Treaty; EPO = European Patent Office

Notes:

- (1) Unless otherwise indicated, the name of patents and patent applications within the same family is the same and is therefore disclosed once.
- (2) The patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.
- (3) All the inventors of the patents and patent applications listed in this table were employees of the Group when the related inventions were conceived, except for the patents relating to GFH009 and GFH018, because these patents were transferred from third parties. We have no dispute with these inventors regarding the ownership and disposition rights of the patents and patent applications listed in this table.
- (4) The U.S. patents in connection with GFH009 and GFH018, as listed in the table, are owned by GenFleet only.

The term of an individual patent may vary based on the countries/regions in which it is granted. 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 extension or adjustment, the availability of legal remedies in a particular country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned, or in-licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and the methods of manufacturing the same. Nevertheless, as of the Latest Practicable Date, we have not encountered any challenge to the validity to our issued patents from a third party; nor have we identified any prior art or other circumstances that may lead to invalidation of our issued patents. Our IP counsel as to the PRC and U.S. intellectual property law and EU IP Counsel as to the laws of EPC contracting countries, after independent search and review of the legal status of the material patents listed in the above table, are not aware of any claim, action, suit or proceeding pertaining to the validity, enforceability or scope of those issued patents, nor aware of any fact or legal impediment with respect to those pending patent applications that would preclude the issuance of patents.

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Our IP counsels have conducted patent search in the freedom-to-operate analysis for our Core Products GFH925 and GFH375. The coverage of the patent search was limited to the PCT applications, as well as the patents and patent applications in the key target markets where our Core Products are expected to be marketed, namely: China, the U.S. and the European Union for GFH925; China and the U.S. for GFH312; China and the U.S. for GFH375. Accordingly, our freedom-to-operate analysis did not include Taiwan, Hong Kong and Macau. As of the Latest Practicable Date, save as disclosed below, we are not aware of any unexpired patent that may cover these product candidates in their respective key markets.

We have identified that certain issued patents in China and U.S. belonging to third parties appear to cover the chemical structure of or formed by GFH925 and may not expire before our anticipated commercial launch of GFH925 in China and the U.S. To proactively manage any potential risks from these patents, we have been monitoring the status of such patents and their related patent applications; to the extent that we consider as necessary, we have entered into license agreements with certain third party holders of such patents, to ensure our activities relating to GFH925 in target markets will not be hindered by these patents. Specifically, the third-party patents in China may cover the chemical structure of GFH925. This is due to the first-to-file system and publication delays, where those third parties first filed patent applications that were published after a waiting period, during which we filed our own patent applications related to GFH925. As such, we did not have any knowledge of those third parties’ patent applications until their publication, and those third parties acknowledged that we independently developed our own patent rights covering the chemical structure of GFH925 with potentially overlapping claims. We have entered into license agreements with those third-party patent holders to proactively prevent any potential infringement risks. We are required to make a total of RMB34.5 million to the third party patent holders and mid-teens royalties tied to the achievement of specific regulatory, commercialization milestones and receipt of royalty payments to one of the patent holders. Such mid-teens royalties is contingent on our receipt of regulatory, commercial milestone payments and royalty payments from sublicensees (Innovent is currently the only sublicensee). As of the Latest Practicable Date, we have paid such RMB34.5 million pursuant to the license agreement. We do not expect the “mid-teens royalties” will have any material adverse impact on our business operation and financial conditions, as such royalties is contingent on our receipt of payments from regulatory, commercial milestone and royalty payments from sublicensees (Innovent is currently the only sublicensee), and constitutes only a relatively small part of the regulatory, commercial milestone and royalty payments to be received by us. As a result of such licensing agreements, we have pre-empted potential issues over GFH925 in China with those third-party patent holders, whose patents in China would not affect our freedom to operate GFH925 and its future commercialization in China, as advised by our IP counsel as to the PRC intellectual property laws. The same third-party patent holders have patent applications of the same patent family still pending and under review by the USPTO and the EPO, and there remains uncertainty as to whether the patent applications in the U.S. or the EU can be issued with a scope that covers GFH925. Our IP counsel has advised that these pending patent applications do not present a material impact on the FTO analysis of GFH925. In particular, the pending claims of the currently pending U.S. patent application had been amended, to address novelty and enablement issues after a previous rejection by the USPTO, in a form that no longer covers the

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chemical structure of GFH925. For details of relevant license agreements, please see “Risk Factors — Risks Relating to Our Intellectual Property Rights — If we or our collaborators are unable to obtain and maintain adequate patent and other intellectual property protection for our pipeline products throughout the selected markets in the world, our ability to successfully commercialize our pipeline products may be adversely affected.”

We are also aware of a U.S. patent whose claim scope is excessively broad and appears to cover the chemical structure formed by GFH925 bonded to certain residue of KRAS protein, which is a desired functional characteristic of GFH925. To further assess the potential risk, we have conducted a comprehensive freedom-to-operate analysis with respect to our core products, including GFH925, in the U.S. and sought advice from our legal advisor as to the U.S. intellectual property laws. Based on this analysis, and considering the legal standards in the U.S. regarding claim validity, including enablement and written description requirements, we believe that these broadly defined claims, which are solely based on functional characteristics without specifying their chemical structures, may raise concerns about their validity and enforceability in U.S. courts due to insufficient enablement and written description support. Our legal advisor as to the U.S. intellectual property laws has further advised that the likelihood of these broadly defined claims having a significant impact on the freedom to operate of GFH925 in the U.S. is low, and therefore the risk of this U.S. patent hindering our future commercialization efforts in the U.S. is remote. For details of the U.S. patent, please see “Risk Factors — Risks Relating to Our Intellectual Property Rights — We may become subject to intellectual property infringement claims, which could expose us to substantial liability, harm our reputation, limit our research and development or other business activities and/or impair our ability to commercialize our product candidates.” As such, as of the Latest Practicable Date, we have not attempted to approach the holder of the U.S. patent regarding GFH925; nor has the holder approached us or taken any action regarding GFH925 that we are aware of. As of the Latest Practicable Date, neither we nor our IP counsels are aware of any patent infringement proceedings related to GFH925 in China, the U.S., or the EPC contracting countries.

As a result of foregoing, as reviewed and advised by our IP counsels, as of the Latest Practicable Date, we believe that we have sufficient patent protection for our Core Products in their respective key target markets, and we are not aware of any facts that cause us to believe that the development and commercialization of our Core Products would infringe any issued patents of any third party that, in our IP counsels’ opinion, are valid and enforceable in their respective key target markets. Except for the above-mentioned issues related to certain China and U.S. patents, there are no other issues noted from the freedom to operate analysis that may affect our rights to conduct research and development, commercialisation, and submission of patent claims for GFH925 in China, U.S. and E.U. and for GFH375 in China and U.S.

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We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our product candidates. We seek to protect our proprietary product candidates and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors 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. Please see “Risk Factors — Risks Relating to Our Intellectual Property Rights” in this Document for a description of risks related to our intellectual property.

We conduct our business under the brand name of “GenFleet” and/or “勁方.” As of the Latest Practicable Date, we held five registered trademarks in Mainland China and three registered trademarks in Hong Kong. We are also the owner of eight registered software copyrights and one domain name.

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

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OUR CUSTOMERS

In 2023 and 2024 and first four months of 2025, our revenue was generated from three customers relating to multiple performance obligations including (1) grants of licenses to intellectual property rights and (2) the research and development services. We generally grant a credit term of 30 days to 60 days from the first day of the following month after receipt of value-added tax invoice to our customers. Neither of them is our supplier.

Customer	Background	Product/ Service Sold	Credit Terms	Commencement of Business Relationship (Since)	Sale Amount	% of Total Revenue for the Period
						(RMB in thousand)
<i>For the year ended December 31, 2023</i>						
Customer B	Founded in 2011, a biopharmaceutical company that focuses on fields of oncology, cardiovascular and metabolic diseases, autoimmune diseases and ophthalmology; place of incorporation: Cayman Islands	grants of licenses to intellectual property rights	30 to 45 business days	2021	71,779	97.3%
Customer A	Founded in 2012, a late-stage clinical biopharmaceutical company that focuses on development of cancer treatments; place of incorporation: U.S.	grants of licenses to intellectual property rights and R&D services	30 to 60 days	2022	1,955	2.7%
Total					73,734	100.0%

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Customer	Background	Produce/ Service Sold	Credit Terms	Commencement of Business Relationship (Since)	Sales Amount	% of Total Revenue of the Period
					(RMB in thousand)	

For the year ended December 31, 2024

Customer B	Founded in 2011, a biopharmaceutical company that focuses on fields of oncology, cardiovascular and metabolic diseases, autoimmune diseases and ophthalmology; place of incorporation: Cayman Islands	grants of licenses to intellectual property rights and sales of goods	30 to 45 business days	2021	104,703	100.0%
Total					104,703	100.0%

Customer	Background	Product/ Service Sold	Credit Terms	Commencement of Business Relationship (Since)	Sale Amount	% of Total Revenue for the Period
					(RMB in thousand)	

For the four months ended April 30, 2025

Customer B	Founded in 2011, a biopharmaceutical company that focuses on fields of oncology, cardiovascular and metabolic diseases, autoimmune diseases and ophthalmology; place of incorporation: Cayman Islands	grants of licenses to intellectual property rights	30 to 45 business days	2021	4,310	5.2%

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Customer	Background	Product/ Service Sold	Credit Terms	Commencement of Business Relationship (Since)	Sale Amount (RMB in thousand)	% of Total Revenue for the Period
Customer C	Founded in 2010, a biopharmaceutical company that focuses on development of cancer treatments; place of incorporation: U.S.	grants of licenses to intellectual property rights and R&D services	30 to 60 days	2023	77,618	94.5%
Total					81,928	99.7%

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

OUR SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of CROs and CDMOs and we did not experience any material disputes with our 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 relationships with alternative sources based on supply continuity risk assessment. We generally have credit periods of 30 days.

Below is a summary of the key terms of a typical agreement with our CROs and CDMOs.

- *Services.* The CRO or CDMO provides us with services such as implementing a clinical research project, manufacturing products and/or providing materials as specified in the master agreement and completing ad-hoc work orders.
- *Term.* The CRO or CDMO is required to perform its services according to the prescribed time frame set out in the master agreement or a work order.
- *Payment.* We are required to make payments to the CRO or CDMO according to the payment schedule agreed by the parties.

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- *Confidentiality.* We and the CRO or CDMO agree to keep confidential any information in relation to the performance of the master agreement.
- *Credit terms.* We usually arrange payment within one to three months of receipt of invoice from CRO or CDMOs. Installment payments will be made in accordance with the milestone payment arrangements specified in the 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.
- *Medical liabilities.* The CDMO will be liable for medical events and accidents that occur as a result of non-compliance with the quality of drugs manufactured by the CDMO.
- *Liabilities and termination.* The liability of a CRO or CDMO arises at the failure to provide services in accordance with the agreed upon service schedule, and our liability arises at the failure to make timely arrangements for payment in accordance with credit terms. If either party is prevented from or delayed in the performance of its obligations under the agreement by force majeure for more than 60 consecutive or aggregate days or if either party is in breach of the agreement and fails to remedy its breach for more than 30 days after notice is given by the non-breaching party, the non-breaching party shall have the right to terminate the agreement immediately by written notice to such breaching party.

In 2023, 2024 and the four months ended April 30, 2024 and 2025, our purchases from our five largest suppliers in each year/period in aggregate amounted to RMB94.1 million, RMB108.5 million, RMB26.9 million and RMB34.0 million, representing 44.4%, 44.3%, 47.5% and 41.7% of our total corresponding purchases in such period, respectively, and our purchases from the largest R&D supplier in each period accounted for 11.3%, 12.7%, 17.1% and 11.6% of our total corresponding purchases, respectively. Our material increase in the expenses attributable to the five largest suppliers for each year/period during the Track Record Period is in line with the advancement of clinical trials of our product candidates.

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

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period
					(RMB in thousand)	
<i>For the year ended December 31, 2023</i>						
Supplier F . .	Founded in 2006, a CDMO service provider that specializes in the design and manufacturing of drug molecules; place of incorporation: Jiangsu Province	CDMO services	30 working days	2021	23,943.9	11.3%
Supplier B . .	Founded in 2005, offers CRDMO end-to-end solutions in drug development and manufacturing; place of incorporation: Chongqing	CDMO services	30 days	2020	23,368.0	11.0%
Supplier G . .	Founded in 1982, utilizes data, technology, and advanced analysis to provide clinical research service; place of incorporation: U.S.	CRO services	30 days	2022	23,372.1	11.0%

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Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period
					<i>(RMB in thousand)</i>	
Supplier H . .	Founded in 2015, offers CRDMO end-to-end solutions in drug development and manufacturing; place of incorporation: Shanghai	CDMO services	30 working days	2020	12,998.6	6.1%
Supplier I . .	Founded in 2004, offers integrated biopharmaceutical R&D service platform, providing R&D solutions across the drug development cycle; place of incorporation: Zhejiang Province	CRO services	45 days	2018	10,406.9	4.9%
Total					94,089.5	44.4%

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Suppliers	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases of the Period
					(RMB in thousand)	

For the year ended December 31, 2024

Supplier F . .	Founded in 2006, a CDMO service provider that specializes in the design and manufacturing of drug molecules; place of incorporation: Jiangsu Province	CDMO services	30 working days	2021	31,063.5	12.7%
Supplier B . .	Founded in 2005, offers CRDMO end-to-end solutions in drug development and manufacturing; place of incorporation: Chongqing	CDMO services	30 days	2020	27,349.8	11.2%
Supplier G . .	Founded in 1982, utilizes data, technology, and advanced analysis to provide clinical research service; place of incorporation: U.S.	CRO services	30 days	2022	21,880.0	8.9%

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Suppliers	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount <i>(RMB in thousand)</i>	% of Total Purchases of the Period
Supplier J . .	Founded in 2011, a trading and import/export company specializing in chemical products, medical devices, and technical services; place of incorporation: Hengdian, Zhejiang Province	CDMO services	45 days	2022	14,508.7	5.9%
Supplier K . .	Founded in 2015, a CDMO service provider that specializes in antibody, recombinant protein, and ADC drug development and manufacturing; place of incorporation: Hangzhou, Zhejiang Province	CDMO services	45 days	2020	13,733.8	5.6%
Total					108,535.7	44.3%

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Suppliers	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases of the Period
					(RMB in thousand)	

For the four months ended April 30, 2025

Supplier G . .	Founded in 1982, utilizes data, technology, and advanced analysis to provide clinical research service; place of incorporation: U.S.	CRO services	30 days	2022	9,439.8	11.6%
Supplier H . .	Founded in 2015, offers CRDMO end-to-end solutions in drug development and manufacturing; place of incorporation: Shanghai	CDMO services	30 working days	2020	8,891.4	10.9%
Supplier F . .	Founded in 2006, a CDMO service provider that specializes in the design and manufacturing of drug molecules; place of incorporation: Jiangsu Province	CDMO services	30 working days	2021	7,233.3	8.9%

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Suppliers	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount <i>(RMB in thousand)</i>	% of Total Purchases of the Period
Supplier K . . .	Founded in 2015, a CDMO service provider that specializes in antibody, recombinant protein, and ADC drug development and manufacturing; place of incorporation: Hangzhou, Zhejiang Province	CDMO services	45 days	2020	5,012.6	6.1%
Supplier L . . .	Founded in 2006, a CDMO service provider that specializes in small molecules, biologics and new modalities such as ADCs/ XDCs, peptides and PROTACs drug development and manufacturing; place of incorporation: Shanghai	CDMO services	45 days	2018	3,455.0	4.2%
Total					34,032.1	41.7%

All of our five largest suppliers in each year/period during the Track Record Period are Independent Third Parties. None of our Directors or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED], nor any of their respective associates had any interest in any of our five largest suppliers in each year/period during the Track Record Period.

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The following table sets forth details of the five largest CROs we engaged for each year/period during the Track Record Period.

CRO	Background	Commencement of Business Relationship (Since)	Purchase Amount (RMB in thousand)	Drug Candidate for which the CRO provided service
<i>For the year ended December 31, 2023</i>				
CRO A (i.e., Supplier G)	Founded in 1982, utilizes data, technology, and advanced analysis to provide clinical research service; place of incorporation: U.S.	2022	23,372.1	GFH925
CRO B (i.e., Supplier I)	Founded in 2004, offers integrated biopharmaceutical R&D service platform, providing R&D solutions across the drug development cycle; place of incorporation: Zhejiang Province	2018	10,406.9	GFH018, GFH925, GFH009
CRO C	Founded in 2019, focuses on providing full-service clinical research and development of drugs and devices; place of incorporation: Shanghai	2022	7,950.3	GFH018, GFH009, GFH312
CRO D	Founded in 1997, provides clinical development services across all phases of clinical trials and therapeutic areas; place of incorporation: Australia	2021	7,451.9	GFH018
CRO E	Founded in 2014, one of the world’s largest CROs that provides full range of Phase I to IV clinical development services; place of incorporation: Ireland	2020	3,560.3	GFH009

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CRO	Background	Commencement of Business Relationship (Since)	Purchase Amount (RMB in thousand)	Drug Candidate for which the CRO provided service
<i>For the year ended December 31, 2024</i>				
CRO A (i.e., Supplier G)	Founded in 1982, utilizes data, technology, and advanced analysis to provide clinical research service; place of incorporation: U.S.	2022	21,880.0	GFH925
CRO B (i.e., Supplier I)	Founded in 2004, offers integrated biopharmaceutical R&D service platform, providing R&D solutions across the drug development cycle; place of incorporation: Zhejiang Province	2018	6,804.7	GFH018, GFH925, GFH009, GFH375, GFS202A
CRO C	Founded in 2019, focuses on providing full-service clinical research and development of drugs and devices	2022	4,910.0	GFH018, GFH009, GFH375
CRO D	Founded in 1997, provides clinical development services across all phases of clinical trials and therapeutic areas; place of incorporation: Australia	2021	4,625.2	GFH018
CRO E	Founded in 2014, one of the world’s largest CROs that provides full range of Phase I to IV clinical development services; place of incorporation: Ireland	2020	4,325.0	GFH009

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CRO	Background	Commencement of Business Relationship (Since)	Purchase Amount (RMB in thousand)	Drug Candidate for which the CRO provided service
<i>For the four months ended April 30, 2025</i>				
CRO A (i.e., Supplier G)	Founded in 1982, utilizes data, technology, and advanced analysis to provide clinical research service; place of incorporation: U.S.	2022	9,439.8	GFH925
CRO F	Founded in 2010, offers screening and discovery services, non-clinical pharmacodynamics, non-clinical pharmacokinetics, non-clinical safety evaluation, clinical sample bioanalysis, biomarkers and translational research; place of incorporation: Shanghai	2018	1,609.3	GFH276, GFS784, GFH375, GFS202A
CRO C	Founded in 2019, focuses on providing full-service clinical research and development of drugs and devices	2022	851.1	GFH018, GFH375
CRO B (i.e., Supplier I)	Founded in 2004, offers integrated biopharmaceutical R&D service platform, providing R&D solutions across the drug development cycle; place of incorporation: Zhejiang Province	2018	748.9	GFH009, GFH375, GFH925, GFS202A
CRO D	Founded in 1997, provides clinical development services across all phases of clinical trials and therapeutic areas; place of incorporation: Australia	2021	236.8	GFH018

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The following table sets forth details of the five largest CDMOs we engaged for each year/period during the Track Record Period.

CDMO	Background	Commencement of Business Relationship (Since)	Purchase Amount (RMB in thousand)	Drug Candidate for which the CRO provided service
<i>For the year ended December 31, 2023</i>				
CDMO A (i.e., Supplier F)	Founded in 2006, a CDMO service provider that specializes in the design and manufacturing of drug molecules; place of incorporation: Jiangsu Province	2021	23,943.9	GFH375, GFH925, GFH312
CDMO B (i.e., Supplier H)	Founded in 2015, it provides services in medicinal chemistry SAR development, synthetic route scouting, process optimization, and production to multi-ton scale; place of incorporation: Shanghai	2020	12,998.6	GFH925
CDMO C	Founded in 2004, offers comprehensive research, development, and manufacturing service capabilities throughout the drug discovery, preclinical, clinical development, and commercialization process for small molecules, biologics, and CGT products; place of incorporation: Beijing	2019	7,806.3	GFH018, GFH375, GFH925, GFH009
CDMO D	Founded in 2007, provides one-stop service for new drug R&D as well as commercial production and dedicates to the drug discovery, pharmaceutical processes R&D, and the commercial manufacturing of APIs and intermediates; place of incorporation: Shanghai	2023	3,669.8	GFH375
CDMO E (i.e., Supplier B)	Founded in 2005, offers CRDMO end-to-end solutions in drug development and manufacturing; place of incorporation: Chongqing	2020	3,259.7	GFH925, GFH009

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CDMO	Background	Commencement of Business Relationship (Since)	Purchase Amount (RMB in thousand)	Drug Candidate for which the CRO provided service
<i>For the year ended December 31, 2024</i>				
CDMO A (i.e., Supplier F)	Founded in 2006, a CDMO service provider that specializes in the design and manufacturing of drug molecules; place of incorporation: Jiangsu Province	2021	31,063.5	GFH375, GFH276, GFS784, GFH925
CDMO E (i.e., Supplier B)	Founded in 2005, offers CRDMO end-to-end solutions in drug development and manufacturing; place of incorporation: Chongqing	2020	27,349.8	GFH925
CDMO F (i.e., Supplier J)	Founded in 2011, a trading and import/export company specializing in chemical products, medical devices, and technical services; place of incorporation: Hengdian, Zhejiang Province	2022	14,508.7	GFH925
CDMO G (i.e., Supplier K)	Founded in 2015, provides stable cell line development services, one-stop R&D and production solution for antibodies, fusion proteins, and ADC products from protein engineering, early druggability evaluation, CMC process development to commercial production; place of incorporation: Zhejiang Province	2020	13,733.8	GFS202A
CDMO H	Founded in 2009, it provides CRO/CDMO services of the APIs and pharmaceutical intermediates from lab scale R&D, to process development, to pilot production and commercial production; place of incorporation: Jiangsu Province	2020	1,319.3	GFH925

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CDMO	Background	Commencement of Business Relationship (Since)	Purchase Amount (RMB in thousand)	Drug Candidate for which the CRO provided service
<i>For the four months ended April 30, 2025</i>				
CDMO I (i.e., Supplier H) . . .	Founded in 2015, offers CRDMO end-to-end solutions in drug development and manufacturing; place of incorporation: Shanghai	2020	8,891.4	GFH925
CDMO A (i.e., Supplier F) . . .	Founded in 2006, a CDMO service provider that specializes in the design and manufacturing of drug molecules; place of incorporation: Jiangsu Province	2021	7,233.3	GFH375, GFH276, GFH312
CDMO G (i.e., Supplier K) . . .	Founded in 2015, a CDMO service provider that specializes in antibody, recombinant protein, and ADC drug development and manufacturing; place of incorporation: Hangzhou, Zhejiang Province	2020	5,012.6	GFS202A, GFS784 GFS101A
CDMO J (i.e., Supplier L) . . .	Founded in 2006, a CDMO service provider that specializes in small molecules, biologics and new modalities such as ADCs/XDCs, peptides and PROTACs drug development and manufacturing; place of incorporation: Shanghai	2018	3,455.0	GFH276, GFH375, GFH925, GFH312
CDMO H	Founded in 2009, it provides CRO/CDMO services of the APIs and pharmaceutical intermediates from lab scale R&D, to process development, to pilot production and commercial production; place of incorporation: Jiangsu Province	2020	2,896.9	GFH925

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We plan to continue engaging these major CROs/CDMOs. In 2023, we engaged 5 CROs and 15 CDMOs, for which we incurred expenses of RMB52.7 million and RMB86.1 million, respectively. In 2024, we engaged 5 CROs and 10 CDMOs, for which we incurred expenses of RMB42.5 million and RMB89.4 million, respectively. In the first four months of 2025, we engaged 5 CROs and 10 CDMOs, for which we incurred expenses of RMB12.9 million and RMB29.2 million, respectively. The decrease in the expenses incurred for engaging CROs and the number of engaged CDMOs were primarily due to the changed needs of many of our R&D projects.

COMPETITION

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

We focus on leveraging our industry experience and established R&D capabilities for the in-house discovery and development of differentiated therapeutics in the fields of oncology, autoimmune and inflammatory diseases. We face fierce competition from existing products and product candidates under development in the market. See “Industry Overview” for more details on the competitive landscape of the various markets in which we compete. We face uncertainties in clinical trial development which are subject to a variety of factors, including satisfactory safety and efficacy results from clinical trials, successful enrollment of patients, and performance of CROs and other parties involved in clinical trial development and others.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover adverse events in clinical trials. We maintain social insurance for our employees in accordance with relevant PRC laws and regulations. We also purchase property insurances against property loss. We currently do not maintain insurance for environmental liability. Please refer to “Risk Factors — Risks Relating to Our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.” in this Document.

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

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EMPLOYEES

As of the Latest Practicable Date, we had 90 employees in total (excluding two co-founders). The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Functions	Number of employees by function	Percentage
Research and Development	68	76%
Business Strategy and Corporate Development . . .	3	3%
General and Administrative	19	21%
Total	90	100.0%

We expect to make ordinary-course adjustments to our human capital, including our research and development team from time to time for various reasons, including strategic initiatives to enhance operational efficiency and voluntary departures of our staff. The number of R&D staff responsible for clinical development of our Core Products has generally remained stable during the Track Record Period, and we do not currently anticipate any material changes to our key R&D personnel that would have a significant impact on our operations or the research and development of our Core Products.

We enter into individual employment contracts with our employees covering salaries, bonuses, employee benefits, workplace safety, confidentiality and non-competition, work product assignment clause and grounds for termination.

To maintain our workforce’s quality, knowledge, and skill levels, we provide continuing education and training programs, including internal training, to improve their technical, professional or management skills. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including competitive salaries, bonuses and share-based payment, particularly our key employees.

Our employees’ remuneration comprises salaries, bonuses, provident funds, social security contributions, and other welfare payments. We have made contributions to our employees’ social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations. We have complied with all statutory social security insurance fund and housing fund obligations applicable to us under the laws and regulations in China in all material aspects during the Track Record Period and as of the Latest Practicable Date, except that we did not make full social security insurance contributions for certain employees who are not PRC citizens, which we estimate to be approximately RMB1.1 million during the Track Record Period. We currently plan to make such full contributions in 2026. As of the Latest Practicable Date, (i) the employees had confirmed such arrangement and

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had raised no objections in relation thereto; (ii) there had been no disputes between us, such employees and/or the third-party human resources agency with regard to such arrangement, as the case may be; and (iii) we had not received any notice of rectification from, or been imposed any administrative penalty by, the relevant governmental authorities as a result of such arrangement or nonpayment for employees who are not PRC citizens. As advised by our PRC Legal Advisor, taking into consideration the above, the risk of us being subject to material penalties as a result of not paying social insurance premium for employees who are not PRC citizens, or paying the social insurance premium and housing provident funds for the relevant employee through the third-party agency, which thus have a material adverse effect on our financial condition or results of operations taken as a whole, is relatively low. Please refer to the section headed “Risk Factors — Risks Relating to Doing Business in Jurisdictions Where We Operate — We are subject to risks in relation to our social insurance and housing provident fund contributions.” in this Document.

Workplace Safety

We have adopted and maintained a series of rules, standard operating procedures, and measures to maintain our employees’ healthy and safe environment. We implement safety guidelines to set out information about potential safety hazards and procedures. We require employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. Also, we have policies in place and have adopted relevant measures to ensure the hygiene of our work environment and the health of our employees.

Our PRC Legal Advisor has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to health, work safety, social and environmental protection.

PROPERTIES

As of the Latest Practicable Date, we did not own any real property. We leased several properties in Mainland China with an aggregate GFA of approximately 4,159.4 sq.m. We did not lease any properties overseas. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs.

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

Usage	Location	GFA (sq.m)	Expiry Date
Office, R&D and General Business Operations	Shanghai, China	3,063.4	October 31, 2028
R&D	Shaoxing, China	1,000.0	September 13, 2024 (in the process of renewal)

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We also leased certain properties with an aggregate GFA of approximately 96 sq.m for satellite office in Shanghai and employee dormitory purpose in Shaoxing.

We plan to comply with the lease agreement registration requirement regarding our lease agreements. However, as the filing of the lease agreements requires the coordination of both lessors and lessees, the lessors may not cooperate and complete the registration in a timely manner.

As of the Latest Practicable Date, none of our lease agreements for properties in China had been registered with relevant authorities in China. Our PRC Legal Advisor is of the view that the non-registration of lease agreements will not affect the validity of the lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and if we fail to so rectify, we may be subject to a fine of between RMB1,000 and RMB10,000 for each of these leasing properties. For further details, please see the sections headed “Risk Factors — Risks Relating to Doing Business in Jurisdictions Where We Operate — We are subject to risks associated with our leased properties.”

As of the Latest Practicable Date, no single property interest that formed part of non-property activities had a carrying amount of 15%, and no single property interest that formed part of property activities had a carrying amount of 1%, of our total assets. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong), this Document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which requires a valuation report with respect to our Group’s interests in land or buildings.

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations in the PRC and the United States and such licenses, permits and certifications all remain in full effect. For more details regarding the laws and regulations to which we are subject, see “Regulations” in this Document. We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. There is no material legal impediment in renewing such licenses, permits, approvals and certificates as they expire in the future as long as we are in compliance with applicable laws, regulations and rules. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates.

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The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

<u>License/Permit</u>	<u>Issuing Authority</u>	<u>Holder</u>	<u>Grant Date</u>	<u>Expiration Date</u>
High-tech Enterprise Certificate.	Science and Technology Commission of Shanghai Municipality, Shanghai Municipal Finance Bureau, Shanghai Municipal Tax Service, State Taxation Administration	Our Company	December 14, 2022	December 13, 2025
Quality Management System Certification (ISO9001).	TUVHD Certification Testing Co., Ltd	Our Company	May 18, 2024	May 17, 2027
Shanghai Pathogenic Microorganism Laboratory Certificate.	Pudong Health Commission of Shanghai Municipality	Our Company	December 31, 2019	N/A
Consignee and Consignor of Import and Export Goods . . .	Pudong Customs	Our Company	January 20, 2022	July 31, 2068

AWARDS AND RECOGNITION

We have leveraged our independent R&D capabilities and innovative strategy to achieve over dozens of certifications and accolades since our establishment. Many awards received since 2024, exclusively open to companies with commercialized products, highlight our growth in scale, pipeline strength, and commercialization success.

In 2022, we obtained national “High-Tech Enterprise” certification (國家級高新技術企業認定) on our first application and advanced in 2024 to be recognized as a “National Specialized and New ‘Little Giant’ Enterprise (國家級專精特新“小巨人”企業稱號).” Within three years since our inception, we were also named a “Shanghai Multinational Corporation R&D Center (上海跨國公司研發中心),” reflecting our focus on globally innovative products and international vision.

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Over the past two years, we have been featured on the Hurun Global Gazelle Enterprise Ranking, recognized for our rapid valuation growth from a “Cheetah Enterprise” to a “Gazelle Enterprise.” This year, with the launch of our first commercial product through collaborations with our partner, we were included in Fortune magazine’s IMPACT “China’s Most Socially Influential Startups” list.

The table below sets forth an indicative list of some of the awards and recognitions we have received as of the Latest Practicable Date.

Awards	Year	Grant Authority
Shanghai Science and Technology “Little Giant” Cultivation Enterprise (上海市科技小巨人培育企業)	2024	Science and Technology Commission of Shanghai Municipality, Shanghai Municipal Finance Bureau and Shanghai Municipal Commission of Economy and Informatization
Hurun Future Unicorns – Global Gazelles Index 2024 (2024胡潤全球瞪羚企業榜)	2024	Hurun Report
National Specialized and New “Little Giant” Enterprise (國家級專精特新“小巨人”企業稱號).	2024	Ministry of Industry and Information Technology (MIIT)
National Biopharmaceutical Enterprise Platform Governing Unit (全國生物醫藥企業平台理事單位)	2024	National Biopharmaceutical Enterprise Platform
Key Service Unicorn (Potential) Enterprise in Shanghai (上海市重點服務獨角獸(潛力)企業)	2024	Shanghai MCEI SME Service Center
Shanghai Municipal Enterprise Technology Center Title (上海市企業技術中心稱號)	2024	Shanghai Commission of Economy and Informatization/ Shanghai Tax Bureau/Shanghai Finance Bureau/Shanghai Customs
Fortune China’s Most Socially Impactful Startups Top 60	2024	Fortune Magazine
Forbes China’s Top 100 Most Influential Chinese Elites	2024	Forbes

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Awards	Year	Grant Authority
Shanghai Specialized and New SME	2023	Shanghai Municipal Commission of Economy and Informatization (“Shanghai MCEI SME Service Center”)
2023 Hurun Global Gazelle Enterprise	2023	Hurun Report
National High-Tech Enterprise Certification (國家級高新技術企業認定)	2022	Shanghai Science and Technology Commission/Shanghai Municipal Finance Bureau/National Tax Bureau, Shanghai
Biopharmaceutical Innovation Golden Seed Award (生物醫藥創新金芽獎)	2022	China Pharmaceutical Industry Information Center
2022 Hurun Global Gazelle Enterprise	2022	Hurun Report
2021 VENTURE50 Investment Community Leaderboard	2021	PEDaily.cn
Shanghai Multinational Corporation R&D Center (上海跨國公司研發中心)	2019	Shanghai Municipal Commission of Commerce

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

Corporate Governance

ESG Governance Framework

The Board fully recognizes the importance of Environmental, Social, and Governance (ESG) management in achieving the Company’s green, compliance, and sustainability realization. Therefore, throughout the Company’s management and operation processes, the Board actively promotes the implementation of ESG principles and integrates them into the Company’s governance framework. The Board has authorized the CEO to establish an ESG Management Committee, which is responsible for monitoring and researching laws, regulations, and policies in the company’s ESG domain, identifying, and managing ESG-related risks and opportunities that have a significant impact on the Company’s business, assessing the Company’s overall ESG performance, and providing corresponding recommendations. The ESG Management Committee shall consist of one Chairperson, who will be the CEO, and the CEO may appoint another senior executive as the Executive Chairperson of the ESG Management Committee. The remaining members shall be composed of department heads, directors, and other members deemed necessary for inclusion. The Chairperson and Executive Chairperson are responsible for unified leadership, approving

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various ESG tasks, and overseeing related information disclosures. The other members are responsible for implementing the ESG Management Committee’s directives and overseeing the management and implementation of ESG issues. Under the ESG Committee, an ESG Working Group is established to promote the implementation and execution of ESG issues, monitor the implementation status of ESG issues, and regularly collect, organize, and report the progress, performance, and case studies related to ESG issues managed by each responsible department. Each issue is assigned a responsible person composed of personnel from several functional departments.

The Board and all the employees have already acquired relevant ESG knowledge and are actively applying ESG principles in practice. Looking ahead, we will also consider engaging external experts to provide professional ESG training for the Board and all the employees. This measure is intended to ensure that our Board could continuously update and maintain current ESG knowledge, thereby enabling informed and effective ESG-related decision-making. Upon the [REDACTED], we will further refine and enhance our ESG governance framework as necessary.

Materiality ESG Issues

The Company actively implements the environmental, social, and governance requirements in all aspects, with its basic ESG obligations fulfilled as a [REDACTED] company. We have maintained good relationships with stakeholders of the Company, including government and regulatory authorities, shareholders and [REDACTED], customers, business partners, employees, and the public, adhering to principles of mutual benefit and consistently upholding our social responsibilities.

Drawing on the MSCI ESG Industry Materiality Map, with reference to the healthcare industry materiality list in the Hong Kong Stock Exchange’s Environmental, Social, and Governance Reporting Guide, the SASB Healthcare Materiality Map, and the key material ESG issues identified by industry leading ESG-rated enterprises — together with the Company’s actual situation, we have preliminarily identified the following material ESG issues:

Materiality Issue	Materiality	Quantitative Metrics
Business Ethics & Anti-Corruption	Highly material	Average training hours completed per employee for anti-corruption (hours/person) Number of corruption lawsuits filed and/or adjudicated (case)
R&D and Innovation	Highly material	R&D expenses as a percentage of operating revenue (%)
Intellectual Property Protection . .	Moderately material	Number of intellectual properties held (item)
Development & Training	Highly material	Employee training coverage rate (%)

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Materiality Issue	Materiality	Quantitative Metrics
Occupational Health and Safety	Highly material	Lost Days Due to Work Injury (Days)
Risk Management	Highly material	Number of significant risk incidents (case)
Data Privacy & Security	Highly material	Total number of incidents violating regulations and voluntary guidelines related to customer privacy (case)
Climate Change	Moderately material	Total greenhouse gas (GHG) emissions (tons) Economic losses due to climate change (RMB0'000)
Product Quality & Safety	Moderately material	Percentage of the total number of products sold or shipped that have to be recalled for safety and health reasons (%)
Resource Usage	Moderately material	Water usage (tons) Electricity consumption (MWh)
Waste Management	Moderately material	Hazardous waste emissions (tons)
Supply Chain Management	Moderately material	Number of suppliers (companies)
Equal Employment	Moderately material	Female employee ratio (%)
Customer Relations	Moderately material	Customer complaint resolution rate (%)
Community Contribution	Generally material	Amount invested in social public welfare (RMB0'000)

Upon the [REDACTED], the ESG working team will further refine its diversified communication mechanisms together with proactive connections with stakeholders to gain an understanding of their views and suggestions on sustainable performance and future development strategies. The feedback collected from the continuing review on materiality issues would be integrated and reported to the Board so that it could timely assess the materiality of various issues to stakeholders and enterprise which conduces to the formulation of the materiality matrix more applicable to the Company.

Business Ethics

We place great importance on anti-corruption and strictly complies with relevant laws and regulations, including *the Company Law of the People's Republic of China*, *the Anti-Unfair Competition Law of the People's Republic of China*, and *the Opinions on Certain Issues Concerning the Application of Law in Handling Criminal Cases of Commercial Bribery*. The Company maintains a zero-tolerance policy towards corruption, bribery, extortion, fraud, and money laundering. All the employees are required to comply with local laws and regulations as well as the Company's internal policies, and must not leverage their positions or work-related advantages to seek improper benefits or damage the Company's interests. In addition, the Company actively fosters clean and transparent cooperation with stakeholders, further standardizes its procurement processes, and advances integrity in procurement practices.

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Employee Rights Protection

Training and Development

One of our corporate values is “Collaborative Coexistence”: boosting efficiency with synergy, growing across boundaries. By collaborating across functions and roles, we aim to achieve business growth and ensure every employee’s development. The Company provides internal and external training to ensure employees enhance and refine their skill sets related to their work. To encourage skill enhancement and broaden career paths, each employee would be offered with open, fair, and impartial self-development opportunities and platforms based on his/her qualified performance and potential. The clear rank and promotion channels would be available for current employees while key ones shall attain targeted trainings.

Health and Safety

The health and safety of employees is a top priority for the Company. We strictly comply with relevant laws and regulations, including the *Production Safety Law of the People’s Republic of China (2021 edition)*, the *Occupational Disease Prevention Law of the People’s Republic of China*, the *Regulations on the Safety Management of Hazardous Chemicals*, and the *Work Injury Insurance Regulations*. We have established and continuously improves safety management and occupational health systems, formulating a range of policies including the Safety Production Responsibility System, the Occupational Health (including Work Injury) Management System, the Safety Management System for Hazardous Chemicals (including Controlled Substances), and the Management Measures of Personal Protective Equipment. Considering the functional characteristics of each department, the Company clearly defines departmental responsibilities in safety management, as well as employees’ job duties and health objectives in their operational activities. These measures ensure the safety and health of employees throughout the production process. The safety management department is responsible for the organization of the relevant departments, whose trainings for employees include aspects of production safety and compliance with rules and regulations, three-level education for new employees, and pre-job training and certification for employees with special work types. Through these initiatives, the Company actively fulfills its primary responsibility for occupational health and safety.

Green Operations and Response to Climate Change

We incorporate the principles of green chemistry into the research, testing, and production processes for every product. The Company is committed to ensuring the safety of pharmaceutical raw materials, prioritizing atom economy in reaction design, and focusing on environmentally friendly outcomes. We continuously refine our processes and promote cutting-edge technologies such as enzyme catalysis and crystallization engineering. These efforts reduce the use of hazardous substances and the generation of waste, thereby fulfilling our commitment to environmental safety and public health. Our strict enforcement of the biological and chemical experiment system standards in the pharmaceutical industry, brings protection for the environment and employees’ health, along with our green chemical design

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practices and experimental waste emission guidelines. In collaboration with multiple enterprises, we adopt a high-tech-driven, eco-friendly model to develop the “one center and three strengths” innovation hub in Zhangjiang Headquarters Park. We will continue to develop and optimize our energy management system, establish internal environmental risk assessment protocols, and implement wastewater and exhaust gas treatment systems. In doing so, we fulfill our social responsibility to conserve energy and reduce emissions.

Resource Use

We comply with the Energy Conservation Law of the People’s Republic of China (《中華人民共和國節約能源法》) and the Circular Economy Promotion Law of the People’s Republic of China (《中華人民共和國循環經濟促進法》), along with other relevant laws and regulations. We have issued the “Civilized Office Initiative,” aiming to reduce resource usage through various measures:

- Resource Conservation: When employees need to use vehicles for business travel, they must strictly follow the Company’s procedures for application and approval, effectively saving gasoline and reducing company costs. We advocate for paperless office practices, with black and white double-sided default printing settings, and require print previews to ensure accuracy before printing.
- Energy Conservation: We manage air conditioning usage rationally to avoid resource waste caused by unnecessary usage. We implement detailed management of electrical equipment, ensuring that devices are not left on standby for extended periods.
- Water Conservation: We post water-saving signs and encourage employees to develop the habit of turning off water taps when not in use, fostering water conservation awareness.

Our primary resource consumption involves gasoline, electricity, and water. The summary of the total consumption and intensity for 2023 and 2024 are summarized as follows:

Water consumption

	2023	2024
Tons	1,752	1,255
(Tons per person)	14.24	11.21

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Gasoline consumption

	2023	2024
L	7,082	7,332
Intensity (L per person)	57.58	65.46

Electricity consumption

	2023	2024
MWh	970.41	791.99
Intensity (MWh per person)	7.89	7.07

Pollutant Emissions

We strictly comply with the national and local laws and regulations, including the *Atmosphere Pollution Prevention and Control Law of the People’s Republic of China*, the *Water Pollution Prevention and Control Law of the People’s Republic of China*, and the *Law of the People’s Republic of China on the Prevention and Control of Environmental Pollution by Solid Wastes*. We have established an environmental protection management system that covers emissions of exhaust gases, water, and hazardous waste. We also provide training to relevant personnel to reinforce our environmental management practices. Apart from regular checks on facilities, the Company employs qualified institutions to routinely monitor wastewater and exhaust gas emissions to ensure they have met emission standards when the management and disposal of solid waste have been systematized in daily operations.

Since we are currently still focused on drug research and development, the volume of hazardous waste we generated is limited. This primarily includes experimental waste liquids, experimental waste mother solution, experimental waste residue, experimental waste drugs, used laboratory vessels, waste activated carbon and waste HEPA filter element. We have set up a temporary storage area for storing hazardous waste as a qualified third-party company would remove and dispose of it on a regular basis. General waste, primarily consisting of domestic refuse, is collected and handed over to property or sanitation department for centralized transportation. All solid waste treatment and disposal measures strictly adhere to environmental protection requirements.

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We adopt a strategy of purchasing in smaller quantities more frequently to avoid the accumulation of expired or unusable hazardous chemicals due to excessive inventory, thus reducing hazardous waste generation. We also prioritize using reagents with higher safety profiles to reduce the risk of generating hazardous waste. For the years ended December 31, 2023 and 2024, the amount of hazardous and non-hazardous waste generated by us is as follows:

	<u>2023</u>	<u>2024</u>
Hazardous Waste (tons)	15.55	14.62

In order to effectively mitigate the environmental impact of exhaust gas emissions, we have implemented different treatment measures for various types of emissions. Solid dosage dust is collected by fume hoods and enclosed equipment systems. Laboratory waste gases generated from volatile organic reagents and disinfectants are centrally collected through dedicated ventilation ducts, treated by accompanying activated carbon adsorption devices, and then discharged through exhaust pipes high on the rooftop of the buildings they locate. Biological aerosols are treated by HEPA filters inside biological safety cabinets prior to releasement into the laboratory. We also reduce exhaust emissions by increasing the frequency of replacing activated carbon materials in our adsorption devices. For the years ended December 31, 2023 and 2024, the total amount of pollutants emitted from our laboratory’s exhaust is as follows:

	<u>2023</u>	<u>2024</u>
Volatile Organic Compounds (VOCs) (tons)	0.37	0.43

Our wastewater mainly consists of liquid waste generated from pharmaceutical R&D activities and domestic wastewater. The wastewater generated from R&D is strictly controlled in compliance with applicable laws and regulations by the Company. Our experimental wastewater primarily comes from the cleaning of chemical laboratory equipment and vessels, pure water preparation, ice-making, and evaporative condensate drainage. Among the above, the rinsing method is used in the first two stages of wastewater from chemical experimental cleaning, where wastewater contains higher concentrations of reagents to be disposed as hazardous waste by a third-party contractor. The subsequently collected cleaning wastewater, pure water preparation wastewater, and ice-making wastewater are directed to the municipal sewage pipe network together with domestic wastewater. Furthermore, we implement several measures to minimize wastewater generation, including collection of water from dehumidifiers for flushing toilets, and setting up a centralized dishwashing area to reduce water usage and wastewater discharge, thus lowering the overall volume of sewage produced. For the years ended December 31, 2023 and 2024, the details of our wastewater emission are as follows:

	<u>2023</u>	<u>2024</u>
Chemical Oxygen Demand (kg)	106.47	72.35
Ammoniacal Nitrogen (kg)	5.89	0.68

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Greenhouse Gas Emissions

For the years ended December 31, 2023 and 2024, our carbon dioxide emissions are as follows:

	2023	2024
Scope 1 (tons of CO ₂ equivalent)	18.84	19.5
Scope 2 (tons of CO ₂ equivalent)	533.42	451.67
Total Greenhouse Gas Emissions (tons of CO ₂ equivalent)	572.26	471.17
Intensity (tons of CO ₂ equivalent per person)	4.65	4.21

Goals and Strategies

The majority of our carbon emissions come from Scope 2 emissions associated with purchased electricity. Accordingly, a series of environmental management plans have been developed to continually improve our resource consumption efficiency with guarantee for observance of all our operations with relevant government environmental regulations and requirements to avoid or reduce the negative environmental impacts. We have been constantly reducing electricity usage in daily office operations utilizing approaches including green lighting controls, energy-saving settings for office equipment and air conditioning, and conference room usage management.

To lessen Scope 1 carbon emissions, tightened management and minimized usage of official vehicles have been carried out. The electric vehicles are considered as priority choices when there are needs for replacing official vehicles or purchasing new vehicles.

We have also attached significance to Scope 3 carbon emissions. We plan to initiate an assessment of our Category 3 greenhouse gas emissions and have implemented a series of reduction measures targeting these emissions. We aim to complete data collection for Scope 3 in 2024 by early 2025, which will serve as our baseline for future data comparisons.

To reduce Scope 3 emissions, we have developed, among others, the following measures:

(i) Posting water and electricity conservation signs in prominent office locations to raise employees’ environmental awareness; (ii) Encouraging double-sided printing and the use of electronic reports to promote a paperless office environment; (iii) Encouraging teleconferencing or online meetings to reduce unnecessary business travel for face-to-face meetings; (iv) Urging employees to prioritize public transportation for commuting and business travel to achieve greener mobility; (v) Maximizing recycling, repurposing, and remanufacturing in our production processes to improve solid waste utilization rates and reduce waste generation; (vi) Evaluating suppliers’ environmental performance in areas such as energy use, production processes, and transportation methods, and encouraging them to optimize their carbon emissions.

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We will continue to closely monitor suppliers and upstream/downstream transportation to lower carbon emissions in these segments. Using 2023 as our baseline year, we are committed to achieving a 10% reduction in water intensity in mainland China and ensuring 100% compliant disposal of hazardous waste by 2030. We will also regularly review our progress towards these goals and adjust and refine our strategies in line with the Company’s ongoing development.

The Board is responsible for the evaluation and management of ESG-related risks, opportunities, and goals. Our overall resource consumption and emissions are expected to increase with business expansion. We are committed to improving the environmental performance across our entire value chain, including office operations, supplier selection, raw material inflows, experimental processes, and waste management, to control the intensity of resource consumption and waste levels. Based on our historical energy consumption and average industry level, we have formulated the following specific ESG-related goals:

	<u>2024 (Actual)</u>	<u>Goals for the Next Three Years (2025-2027)</u>
Greenhouse Gas Emissions (Scope 1 + 2) (tons of CO ₂ equivalent per person)	4.21	no more than 5
Electricity Consumption Intensity (MWh per person).	7.07	no more than 8

The Board will regularly review the Group’s performance against ESG goals. If significant deviations are identified, appropriate adjustments will be made to the ESG-related measures. Our directors believe that these measures will not affect the Company’s operations, either financially or non-financially.

Response to Climate Change

Following the unceasing expansion in scope of global climate change, it is becoming an increasingly prominent international issue. The impact of frequent extreme weather events and natural disasters has rapidly changed public perceptions, drawing widespread attention. With a sustained focus on the effects of climate change on the pharmaceutical industry and our business operations, the Company, with reference to TCFD recommendations, assesses and implements a variety of climate change risk management measures. These efforts aim to ensure our long-term resilience to climate risks and maintain vigilance in responding to the potential climate-related impacts and risks.

We will monitor climate-related risks and opportunities at least once a year during Board meetings to safeguard the smooth progress on climate-related issues in compliance. The ESG Committee is responsible for formulating and reviewing climate-related strategies, coordinating climate-related efforts, and communicating the latest issues affecting the Company to the Board. To keep the Board updated on climate-related risks and opportunities, we provide climate-related trainings every two years, inviting external experts to share their insights.

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Given the current nature of our business, climate change is not expected to pose a significant impact on our operations. However, in the future, we may face acute and chronic physical risks such as extreme weather events (e.g. typhoons and floods) and increases in average temperatures, which could damage our property and assets, including buildings, and cause business disruptions due to delays in timely delivery by production/supply chains. By implementing property insurance, emergency preparedness plans, and strengthening supply chain management, we aim to address these risks.

Certain climate-related transition risks may also get close to us, including rising costs of energy and raw materials as well as the disposal of pollutants or hazardous waste under increasingly stringent environmental regulations, the costs associated with low-emission technology transformation (e.g. R&D in green chemistry technologies), and shifts in downstream customer preferences (e.g. order losses and revenue declines due to failure of disclosure on carbon neutrality goals and data to meet downstream customers’ demand). To address these risks, we will enhance compliance operations and information disclosure, improve communication with stakeholders, strengthen the introduction and training of professional talent, and reinforce supply chain management. In addition, we will actively advance green chemistry R&D, intensify energy conservation and consumption reduction efforts, and improve energy efficiency.

LEGAL PROCEEDINGS AND NON-COMPLIANCE

Legal Proceedings

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

Legal Compliance

According to our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operation. Our Directors confirmed that we had complied with all material applicable laws and regulations for our operations in the PRC and the United States and we were not involved in any material or systemic non-compliance incidents in the PRC and the United States.

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RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. For more details, see “Risk Factors — Risks Relating to Our Operations” in this Document. Our Directors oversee and manage the overall risks associated with our operations. We have prepared written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code and Corporate Governance Report as set out in Appendix C1 to the Listing Rules.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an Audit Committee to review and supervise our financial reporting process and internal control system;
- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure;
- provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations; and
- attend training sessions by our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies [REDACTED] in Hong Kong.

Internal Control

We have employed an independent internal control consultant to assess our internal control system in connection with the [REDACTED]. The internal control consultant has conducted a review procedure on our internal control system in certain aspects, including financial reporting and disclosure controls, corporate level controls, information system control management and other procedures for our operations. We had improved our internal control system by adopting and implementing the corresponding enhanced internal control measures. Going forward, we will continue to regularly review and improve these internal control policies, measures and procedures.

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We have also appointed external legal counsel to advise us on compliance matters, such as compliance with the regulatory requirements on clinical R&D. Under our whistle blowing policy, we make our internal reporting channel open and available for our employees to report, on an anonymous basis, any non-compliance incidents and acts, including bribery and corruption. Reported incidents and persons will be investigated and appropriate measures will be taken in response to the findings. We have also established anti-bribery guidelines and compliance requirements. After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations.

We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant laws and regulations regularly to proactively identify any concerns and issues relating to any potential non-compliance.

Anti-bribery

We maintain a strict code of conduct and anti-corruption policies among our employees and third parties. We believe we will be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses should be rejected and promptly reported. Misleading, incomplete or false entries in our books and records are never acceptable. We will also ensure that future commercialization team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

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

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Conflict of Interest and Non-Competition

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

All of the Company’s executives have signed a non-compete agreement upon joining the Company, which prohibits them from engaging in any way in a business that competes with the Company’s business, and, unless agreed to in writing by the Company, working for any third party full-time or part-time. Any of our employees shall not, without prior written approval from our Company, own, manage, operate or control any other entity that competes with our Company.

Data Privacy Protection

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

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

We attach importance to data protection, data transfer and data security, and have taken relevant measures as follows:

1. We have established a clinical trial data security management system to standardize our internal data security management;
2. We hold routine staff training to enhance the compliance and safety awareness of all staff to ensure compliance and safety of data processing;
3. We have continuously upgraded our information security technology and established firewalls to improve data security;
4. We entered into agreements with CROs and other collaboration partners contain data protection clauses setting out their responsibilities for data protection.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any breach of confidential client information or any other client information-related incidents which could cause a material adverse effect on our business, financial condition or results of operations. Our PRC Legal Advisor have confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to data privacy, and had been in compliance with the relevant PRC laws and regulations in all material aspects in this regard. During the Track Record Period, as advised by our PRC Legal Advisor, we had not been subject to administrative penalties relating to data transfer, and we have been in compliance with relevant PRC laws and regulations in all material aspects in this regard.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board comprises eight Directors, including three executive Directors, two non-executive Directors and three independent non-executive Directors. Pursuant to the Articles of Association, our Directors are elected and appointed by our Shareholders at a Shareholders’ meeting for a term of three years, which is renewable upon re-election and re-appointment.

The following table sets out information regarding the Directors.

Name	Age	Position/Title	Date of Appointment as a Director	Date of Joining Our Group	Roles and Responsibilities
Executive Directors					
Dr. Qiang LU . . . [59]		Executive Director and Chairman of the Board	November 2017	August 2017	Overall strategic planning, financial management, and business management of our Group
Dr. Jiong LAN . . [53]		Executive Director, Chief Executive Officer and General Manager	November 2017	August 2017	Overall supervision and management of the business operation of our Group
Ms. ZHANG Wei [46] (張巍)		Executive Director, secretary to the Board and joint company secretary	November 2024	August 2017	Supervision of financing and investment related matters of our Group
Non-executive Directors					
Mr. ZHU Jingyang (朱競陽)	[36]	Non-executive Director	August 2022	August 2022	Providing strategic advice and making recommendation on the operation and management of our Group

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position/Title	Date of Appointment as a Director	Date of Joining Our Group	Roles and Responsibilities
Ms. TAO Sha (陶莎)	[32]	Non-executive Director	November 2024	November 2024	Providing strategic advice and making recommendation on the operation and management of our Group
Independent non-executive Directors					
Ms. Christine Shaohua LU-WONG (盧韶華)	[56]	Independent Non-executive Director	December 2024 ^(Note)	December 2024	Advising our Group on issues relating to corporate governance, audit and providing independent opinion to the Board
Dr. ZHOU Demin (周德敏)	[59]	Independent Non-executive Director	December 2024 ^(Note)	December 2024	Advising our Group on issues relating to corporate governance, audit and providing independent opinion to the Board
Mr. LI Bo (李波)	[54]	Independent Non-executive Director	December 2024 ^(Note)	December 2024	Advising our Group on issues relating to corporate governance, audit and providing independent opinion to the Board

Note: The appointment will become effective upon the [REDACTED].

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Executive Directors

Dr. Qiang LU, aged [59], is our executive Director and Chairman of the Board. Dr. Lu is the co-founder of our Group and is responsible for overall strategic planning, financial management, and business management of our Group. Dr. Lu is also in charge of the Company’s finance related functions. Dr. Lu was appointed as a Director in November 2017.

Dr. Lu has over 20 years of experience in the biotechnology and pharmaceutical industry. Before founding the Group, Dr. Lu served as a senior vice president of CStone Pharmaceuticals (Suzhou) Co., Ltd. (基石藥業(蘇州)有限公司) until August 2017, which later became a wholly-owned subsidiary of CStone Pharmaceuticals (基石藥業), a pharmaceutical company listed on the Hong Kong Stock Exchange (stock code: 2616). Before he joined CStone Pharmaceuticals (Suzhou) Co., Ltd., he successively served as chief scientific officer and a vice president of Harbin Gloria Pharmaceuticals Co., Ltd. (哈爾濱譽衡藥業股份有限公司), a pharmaceutical company listed on the Shenzhen Stock Exchange (stock code: 002437) from February 2015 to May 2016; and chief scientific officer of Yangtze River Pharmaceutical Group Co., Ltd. (揚子江藥業集團有限公司), a pharmaceutical company, from June 2013 to February 2015. From April 2008 to June 2013, he served as a vice president at WuXi AppTec (Shanghai) Co., Ltd. (上海藥明康德新藥開發有限公司), a wholly-owned subsidiary of WuXi AppTec Co., Ltd. (無錫藥明康德新藥開發股份有限公司), a pharmaceutical company listed on the Shanghai Stock Exchange (stock code: 603259) and the Hong Kong Stock Exchange (stock code: 2359). Before he joined WuXi AppTec (Shanghai) Co., Ltd., he served as head of ion channel and cellular toxicology in Novartis Institutes for BioMedical Research, Inc., a pharmaceutical research organization of Novartis AG, a medicines company, until April 2008. From April 2000 to February 2006, he worked at Wyeth, a pharmaceutical company.

Dr. Lu received his bachelor’s degree in biochemistry from Peking University (北京大學) in China in July 1987 and Doctor of Philosophy degree in biochemistry from Brandeis University in the United States in May 1996. After receiving his Doctor of Philosophy degree, he continued his research at the Departments of Physiology and Neuroscience at Tufts University School of Medicine in the United States.

Dr. Jiong LAN, aged [53], is our executive Director, Chief Executive Officer and General Manager. Dr. Lan is the co-founder of our Group and is responsible for overall supervision and management of the business operation of our Group. Dr. Lan was appointed as a Director in November 2017.

Dr. Lan has over 20 years of experience in the biotechnology and pharmaceutical industry. Before founding the Group, he served as general manager of Shanghai Haiyan Pharmaceutical Technology Co., Ltd. (上海海雁醫藥科技有限公司), a wholly-owned subsidiary of Yangtze River Pharmaceutical Group Co., Ltd. (揚子江藥業集團有限公司), a pharmaceutical company, from August 2013 to August 2017. From October 2011 to July 2013, he served as head of the department of medicinal chemistry at Shanghai Hengrui Pharmaceuticals Co., Ltd. (上海恆瑞醫藥有限公司), a wholly-owned subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

蘇恒瑞醫藥股份有限公司), a pharmaceutical company listed on the Shanghai Stock Exchange (stock code: 600276). From March 2005 to October 2011, he served as an investigator at Novartis Institutes of Biomedical Research, a pharmaceutical research organization of Novartis AG, a medicines company.

Dr. Lan received his bachelor’s degree in organic chemistry from Lanzhou University (蘭州大學) in China in 1994 and Doctor of Science degree in organic chemistry from Lanzhou University (蘭州大學) in China in June 1999. After receiving his Doctor of Science degree, he continued his research in organic synthetic chemistry at University of Rochester in the United States.

Ms. ZHANG Wei (張巍), aged [46], is our executive Director, secretary to the Board and a joint company secretary. Ms. Zhang is responsible for supervising financing and investment related matters of our Group. Ms. Zhang joined the Group in August 2017 when the Company was established, and was responsible in leading each round of the [REDACTED] financings conducted by the Company. She was then appointed as a Director in November 2024. Prior to joining our Group, Ms. Zhang has worked in different companies in the biotechnology and pharmaceutical related field, where she had gained knowledge in the industry and experience in working with different companies in the industry. Such experience and knowledge allow her to provide valuable insights and support to the [REDACTED] financing and investment related matters of the Group.

From October 2009 to December 2016, she worked at PerkinElmer Enterprise Management (Shanghai) Co., Ltd. (珀金埃爾默企業管理(上海)有限公司), a company primarily engaged in the provision of analytical and enterprise solutions in various aspects, including but not limited to medical device testing solutions, laboratory services solutions and forensics and toxicology solutions. She was responsible for new products launch and solutions and technology application. Before she joined PerkinElmer Enterprise Management (Shanghai) Co., Ltd. and since August 2009, she worked at WuXi AppTec (Shanghai) Co., Ltd. (上海藥明康德新藥開發有限公司), a wholly-owned subsidiary of Wuxi Apptec Co., Ltd. (無錫藥明康德新藥開發股份有限公司), a pharmaceutical company listed on the Shanghai Stock Exchange (stock code: 603259) and the Hong Kong Stock Exchange (stock code: 2359). From December 2006 to August 2009, she served as a research assistant at Shanghai Genomics Inc. (上海睿星基因技術有限公司), a biopharmaceutical company.

Ms. Zhang received her bachelor’s degree in chemical engineering in July 2000 and a bachelor’s degree in English language in July 2001 from Dalian University of Technology (大連理工大學) in China. She received a master’s degree in biology and biotechnology from Lille 1 University in France in September 2006. She obtained a master’s degree in science, health and applications, with a focus on structure, proteomics, and functional genomics from Université Paris VII in France in March 2007.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Non-executive Directors

Mr. ZHU Jingyang (朱競陽) (formerly named ZHU Daqiang (朱大強)), aged [36], is our non-executive Director. Mr. Zhu is responsible for providing strategic advice and making recommendation on the operation and management of our Group. Mr. Zhu was appointed as a Director in August 2022.

Mr. Zhu has ample experiences in investment management. He is currently an investment director at HuaGai Healthcare Fund (華蓋醫療健康基金) of HuaGai Capital (華蓋資本).

Mr. Zhu obtained a master’s degree in medicine in microbiology and biochemical pharmacy from Peking Union Medical College (北京協和醫學院), Tsinghua University School of Medicine (清華大學醫學部) in China in January 2014.

Ms. TAO Sha (陶莎), aged [32], is our non-executive Director. Ms. Tao is responsible for providing strategic advice and making recommendation on the operation and management of our Group. Ms. Tao was appointed as a Director in November 2024.

Ms. Tao is currently a vice president at Shanghai CDH Futai Venture Capital Management Co., Ltd. (上海鼎暉賦泰創業投資管理有限公司), a fund manager under CDH Investments (鼎暉投資), an asset management group focusing on investment in China.

Ms. Tao received her dual bachelor’s degrees in business and biochemistry from Brandeis University in the United States in February 2017. She received her master’s degree in strategic management from HEC Paris in France in March 2019.

Independent non-executive Directors

Ms. Christine Shaohua LU-WONG (盧韶華), aged [56], is appointed as our independent non-executive Director with effect from the [REDACTED]. Ms. Lu-Wong is responsible for advising our Group on issues relating to corporate governance, audit and providing independent opinion to the Board.

Ms. Lu-Wong brings invaluable senior executive leadership and experiences in corporate financial strategy and governance. She is also qualified as a certified public accountant in the United States. She held various senior management positions at various listed companies, including vice president of finance at WuXi PharmaTech (Cayman) Inc. (NYSE ticker before delisting: WX) from August 2007 to August 2009, executive vice president and chief financial officer at Pactera Technology International Ltd. (NASDAQ ticker before delisting: PACT) from January 2010 to November 2012, chief financial officer at Xueda Education Group (NYSE ticker before delisting: XUE) from November 2012 to December 2015, and chief financial officer at WuXi Biologics (Cayman) Inc., a company listed on the Hong Kong Stock Exchange (stock code: 02269.HK) from January 2016 to November 2021.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

She has been serving the independent non-executive director and chairwoman of the audit committee at WuXi AppTec Co., Ltd. (無錫藥明康德新藥開發股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 603259.SH) and Hong Kong Stock Exchange (stock code: 02359.HK) since May 2023 and June 2023, respectively.

Ms. Lu-Wong obtained a bachelor’s degree in foreign trade and economics from Guangdong University of Foreign Studies (廣東外語外貿大學) in China in July 1990 and an MBA degree in accounting from Golden Gate University in the United States in April 1994.

Dr. ZHOU Demin (周德敏), aged [59], is appointed as our independent non-executive Director with effect from the [REDACTED]. Dr. Zhou is responsible for advising our Group on issues relating to corporate governance, audit and providing independent opinion to the Board.

Dr. Zhou has served as a professor of Peking University School of Pharmaceutical Sciences (北京大學藥學院) since September 2008, where he consecutively served as the deputy dean from December 2009 to January 2016 and the dean from January 2016 to July 2023. He is currently the director of State Key Laboratory of Natural and Biomimetic Drugs (天然藥物及仿生藥物國家重點實驗室).

Dr. Zhou has been serving as an independent non-executive director of Hangzhou Jiuyuan Gene Engineering Co., Ltd. (杭州九源基因工程股份有限公司) (a company listed on the Hong Kong Stock Exchange (stock code: 2566)) since November 2023; an independent director of Chengdu Kanghong Pharmaceutical Group Co., Ltd. (成都康弘藥業集團股份有限公司) (a company listed on the Shenzhen Stock Exchange (stock code: 002773)) since August 2023; an independent non-executive director of Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司) (a company listed on the Hong Kong Stock Exchange (stock code: 2157)) since December 2020. He was an independent director of North China Pharmaceutical Co, Ltd. (華北製藥股份有限公司) (a company listed on the Shanghai Stock Exchange (stock code: 600812)) from May 2019 to May 2025.

Dr. Zhou obtained bachelor’s degree in chemistry from the pharmaceutical college of Beijing Medical University (北京醫科大學) (currently known as Peking University Health Science Center (北京大學醫學部)) in China in July 1990 and a Doctor of Science from the same university in June 1996. Dr. Zhou has been certified by Peking University (北京大學) as a professor since September 2008. Dr. Zhou was also recognized as “973 Chief Scientist” (973 首席科學家) by Ministry of Science and Technology of the PRC (中華人民共和國科學技術部) in 2010, and “Changjiang Scholar Distinguished Professor” (長江學者特聘教授) by Ministry of Education of the PRC (中華人民共和國教育部) in 2013. He is also a vice chairman of the council of Beijing Pharmaceutical Society (北京藥學會) and a member of the professional committee on pharmaceutical chemistry of Chinese Pharmaceutical Association (中國藥學會).

Mr. LI Bo (李波), aged [54], is appointed as our independent non-executive Director with effect from the [REDACTED]. Mr. Li is responsible for advising our Group on issues relating to corporate governance, audit and providing independent opinion to the Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Li has ample experiences in asset management. Mr. Li has been serving as the partner of Shanghai Real Estate Asset Management Co., Ltd. (上置資產管理(上海)有限公司) since April 2023.

Mr. Li served as an independent director of Shanghai Chuangxin Resources Development Co., Ltd. (上海創興資源開發股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600193), from July 2021 to May 2023.

Mr. Li received his bachelor’s degree in hoisting, transporting, and engineering machinery from Hebei Coal Construction Engineering College (河北煤炭建築工程學院) (currently known as Hebei University of Engineering (河北工程大學)) in China in July 1994. He received his master’s degree in engineering science from Shanghai Jiao Tong University (上海交通大學) in China in February 1997.

SUPERVISORY COMMITTEE

Our Supervisory Committee currently consists of three supervisors, one of whom is the chairperson of our Supervisory Committee.

Each of the Supervisors is appointed for a term of three years which is renewable upon re-election and re-appointment. Pursuant to the Articles of Association, the functions and powers of our Supervisory Committee include, but not limited to, reviewing the financial management of our Company, monitoring the performance of duties of our Directors and senior management members, and requesting Directors and senior management members to rectify actions detrimental to our Company’s interests. In addition, our Supervisory Committee is responsible for exercising other powers, functions and duties in accordance with the Articles of Association, and all applicable laws and regulations. The following table sets forth the key information of our Supervisors:

Name	Age	Position/Title	Date of Appointment as a Supervisor	Date of Joining Our Group	Roles and Responsibilities
Mr. XUE Mengjun (薛孟軍).	[53]	Shareholders’ representative Supervisor	August 2022	August 2022	Supervising the performance of our Directors and members of senior management, and performing other supervisory duties

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position/Title	Date of Appointment as a Supervisor	Date of Joining Our Group	Roles and Responsibilities
Mr. LIN Chonglan (林崇懶)	[42]	Employees’ representative Supervisor	September 2024	July 2019	Supervising the performance of our Directors and members of senior management, and performing other supervisory duties
Ms. MA Rui (馬睿)	[33]	Employees’ representative Supervisor	September 2024	March 2019	Supervising the performance of our Directors and members of senior management, and performing other supervisory duties

Supervisors

Mr. XUE Mengjun (薛孟軍), aged [53], is our Supervisor. He is responsible for supervising the performance of our Directors and members of senior management, and performing other supervisory duties. Mr. Xue was appointed as a Supervisor in August 2022.

Mr. Xue has ample experiences in investment management. Since September 2010, he has been serving as the managing partner of Shanghai Panlin Asset Management Co., Ltd. (上海磐霖資產管理有限公司), an asset management and investment firm focusing on investment in Healthcare and Biotechnology field as well as To B and Technology field.

Mr. Xue received his bachelor’s degrees in statistics and economics from Shanghai University of Finance and Economics (上海財經大學) in China in July 1994.

Mr. LIN Chonglan (林崇懶), aged [42], is our Supervisor. He is responsible for supervising the performance of our Directors and members of senior management, and performing other supervisory duties. Mr. Lin was appointed as a Supervisor in September 2024. Mr. Lin joined the Company in July 2019 as a manager and senior researcher of the R&D department.

Mr. Lin has more than 15 years of experiences in chemical and pharmaceutical industry. From August 2017 to July 2019, he worked at Shanghai Haiyan Pharmaceutical Technology Co., Ltd. (上海海雁醫藥科技有限公司), a wholly-owned subsidiary of Yangtze River Pharmaceutical Group Co., Ltd. (揚子江藥業集團有限公司), a pharmaceutical company. From March 2008 to August 2017, he worked successively at Shanghai ChemExplorer Co., Ltd. (上海開拓者化學研究管理有限公司) and Shanghai ChemPartner Co., Ltd. (上海睿智化學研究有限公司).

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Lin received his bachelor’s degree in chemistry from Wenzhou University (溫州大學) in China in June 2005 and his master’s degree in organic chemistry from Sun Yat-sen University (中山大學) in China in June 2007.

Ms. MA Rui (馬睿), aged [33], is our Supervisor. Ms. Ma is responsible for supervising the performance of our Directors and members of senior management, and performing other supervisory duties. Ms. Ma was appointed as a Supervisor in September 2024. Ms. Ma joined the Company in March 2019 and is currently the deputy manager of human resources.

Ms. Ma has ample experiences in human resources management. Prior to joining the Group, she served as a human resources specialist at Shanghai Shoen International Trade Co., Ltd. (上海昭遠國際貿易有限公司), a company focusing on the manufacturing and supply of new energy related products and parts from May 2017 to March 2019. From October 2014 to May 2017, she worked at Shanghai Haiyan Pharmaceutical Technology Co., Ltd. (上海海雁醫藥科技有限公司), a wholly owned subsidiary of Yangtze River Pharmaceutical Group Co., Ltd. (楊子江藥業集團有限公司), a pharmaceutical company.

Ms. Ma received her bachelor’s degree in e-commerce from Anhui University Jianguhuai College (安徽大學江淮學院) in China in July 2013.

SENIOR MANAGEMENT

The following table sets out information regarding the members of senior management of our Company.

Name	Age	Position/Title	Date of Appointment as a Senior Management	Date of Joining Our Group	Roles and Responsibilities
Dr. Qiang LU . . . [59]		Executive Director and Chairman of the Board	August 2017	August 2017	Overall strategic planning, financial management, and business management of our Group
Dr. Jiong LAN . . [53]		Executive Director, Chief Executive Officer and General Manager	August 2017	August 2017	Overall supervision and management of the business operation of our Group
Ms. ZHANG Wei [46] (張巍)		Executive Director, secretary to the Board and joint company secretary	August 2017	August 2017	Supervision of financing and investment related matters of our Group

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position/Title	Date of Appointment as a Senior Management	Date of Joining Our Group	Roles and Responsibilities
Dr. WANG Yu (汪裕)	[53]	Chief Medical Officer	November 2020	November 2020	Supervision of our clinical development strategy and execution, and our whole R&D strategy and project planning

For biographical details of Dr. Lu, Dr. Lan and Ms. Zhang, see “— Executive Directors” in this section. The details of the other senior management member are set out below:

Dr. WANG Yu (汪裕), aged [53], is our Chief Medical Officer. Dr. Wang is responsible for the supervision of our clinical development strategy and execution, and our whole R&D strategy and project planning. Dr. Wang joined the Group as the Chief Medical Officer in November 2020. Dr. Wang was appointed as a Director in December 2020 and has resigned from directorship with effect before [REDACTED] to streamline and adjust the Board and management structure upon [REDACTED].

Dr. Wang has over 20 years of experiences in the antitumor drug development and the pharmaceutical industry. Prior to joining the Group, he served as consulting partner of ZenRhyme Consulting Services Co., Ltd. (詳妍(上海)商務資訊諮詢有限公司) from January 2018 to October 2020, and chief medical officer of Abbisko Therapeutics (上海和譽生物醫藥科技有限公司), a wholly-owned subsidiary of Abbisko Cayman Limited, a company listed on the Hong Kong Stock Exchange (stock code: 2256) from March 2020. From November 2016 to December 2017, he served as chief scientist of Beijing Panacro Pharmaceutical Technology Co., Ltd. (北京博納西亞醫藥科技有限公司), a contract research organization specializing in pharmaceutical R&D and clinical research. From September 2013 to November 2016, he served as clinical program leader, oncology translational medicine of China Novartis Institutes for Biomedical Research Co., Ltd. (諾華(中國)生物醫學研究中心). From April 2012 to September 2013, he served as clinical research director of Sanofi (China) Investment Co., Ltd. Shanghai Branch (賽諾菲(中國)投資有限公司上海分公司). From February 2010 to March 2012, he served as a medical director at GlaxoSmithKline (China) Investment Co., Ltd. (葛蘭素史克(中國)投資有限公司), a subsidiary of GSK PLC, a company listed on the London Stock Exchange (stock code: GSK) and New York Stock Exchange (stock code: GSK). From April 2007 to February 2010, he served as an associate medical director at Eli Lilly Asia, Inc. Shanghai Rep. Office (美國禮來亞洲公司上海代表處). From April 2005 to April 2007, he served as a senior research fellow at Shanghai Sunway Biotech Co., Ltd. (上海三維生物技術有限公司). From July 2000 to January 2001, he worked at the Shanghai Huadong Hospital (上海華東醫院).

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. Wang received his medical degree in clinical medicine from Tongji Medical University (同濟醫科大學), which is now known as Tongji Medical College of Huazhong University of Science and Technology (華中科技大學同濟醫學院) in China in June 1995. He received a doctorate degree in surgery from Shanghai Medical University (上海醫科大學), which is now known as Shanghai Medical College of Fudan University (復旦大學上海醫學院) in China in June 2000 and was a post-doctorate fellow in oncology at the Barbara Ann Karmanos Cancer Institute of the Wayne State University in the United States from July 2001 to August 2004.

CONFIRMATION FROM OUR DIRECTORS

Rule 8.10 of the Listing Rules

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, either directly or indirectly, with our Company’s business which would require disclosure under Rule 8.10 of the Listing Rules.

Rule 3.09D of the Listing Rules

Each of our Directors confirms that he or she (i) has obtained the legal advice referred to under Rule 3.09D of the Listing Rules in December 2024, and (ii) understands his or her obligations as a director of a [REDACTED] under the Listing Rules.

Rule 3.13 of the Listing Rules

Each of the independent non-executive Directors has confirmed (i) his/her independence as regards each of the factors referred to in Rules 3.13(1) to (8) of the Listing Rules, (ii) he/she has no past or present financial or other interest in the business of the Company or its subsidiaries or any connection with any core connected person of the Company under the Listing Rules as of the Latest Practicable Date, and (iii) that there are no other factors that may affect his/her independence at the time of his/her appointments.

GENERAL

Save as disclosed above, none of the Directors, Supervisors or members of senior management of our Company has been a director of any public company the securities of which are listed on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this Document.

None of the Directors, Supervisors or members of the senior management of our Company is related to any other Directors, Supervisors and members of the senior management of our Company.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

None of the Directors, Supervisors or members of the senior management of our Company has completed his/her respective education programs as disclosed in this section by way of attendance of long distance learning or online courses.

Save as disclosed herein, to the best knowledge, information and belief of our Directors and Supervisors having made all reasonable inquiries, there was no other matter with respect to the appointment of our Directors or Supervisors that needs to be brought to the attention of the Shareholders and there was no information relating to our Directors or Supervisors that is required to be disclosed pursuant to Rule 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

JOINT COMPANY SECRETARIES

Ms. Zhang was appointed as our joint company secretary in November 2024. For further details, see “— Executive Directors” above.

Mr. NG Tung Ching Raphael (吳東澄), was appointed as our joint company secretary in November 2024. Mr. Ng is a seasoned professional with over 14 years of extensive experience in the legal and company secretarial domains, specializing in corporate governance and compliance. He currently serves as the assistant vice president of Computershare Hong Kong Investor Services Limited.

Mr. Ng holds a master’s degree in Chinese business law from the Chinese University of Hong Kong and a master’s degree in professional accounting and corporate governance from The City University of Hong Kong. He earned his bachelor’s degree in law from Manchester Metropolitan University. Mr. Ng is an associate member of both The Hong Kong Chartered Governance Institute (the “HKCGI”, formerly known as the Hong Kong Institute of Chartered Secretaries) and The Chartered Governance Institute in the United Kingdom. He also possesses the practitioner’s endorsement from HKCGI.

BOARD COMMITTEES

Our Board delegates certain responsibilities to various committees. In accordance with the relevant PRC laws and regulations and the Corporate Governance Code as set out in the Appendix C1 to the Listing Rules, our Company has formed three Board committees, namely the Audit Committee, the Remuneration Committee and the Nomination Committee.

Audit Committee

We have 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. The Audit Committee consists of three Directors, namely Ms. Christine Shaohua LU-WONG, Mr. ZHU Jingyang and Dr. ZHOU Demin. Ms. Christine Shaohua LU-WONG,

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

who holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules, serves as the chairperson of the Audit Committee. The primary duties of the Audit Committee include, but not limited to, the following:

- proposing the appointment or change of external auditors to our Board, and monitoring the independence of external auditors and evaluating their performance;
- guiding internal audit work;
- examining the financial information of our Company, reviewing financial reports and statements of our Company and giving comments on relevant matters;
- assessing the effectiveness of internal control;
- coordinating the communication among management, internal audit department, related departments and external audit agency; and
- dealing with other matters that are authorized by the Board or involved in relevant laws and regulations.

Remuneration Committee

We have established a Remuneration 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 Committee consists of three Directors, namely Mr. LI Bo, Dr. Lan and Dr. ZHOU Demin. Mr. LI Bo serves as the chairperson of the Remuneration Committee. The primary duties of the Remuneration Committee include, but not limited to, the following:

- formulating individual remuneration plans for Directors and members of the senior management in accordance with the terms of reference of the job responsibilities, the importance of their positions as well as the remuneration benchmarks for the relevant positions in other comparable companies;
- examining the criteria of performance evaluation of Directors and the senior management of our Company, and conducting annual performance evaluation;
- supervising the implementation of the remuneration plan of the Company;
- reviewing and/or approving matters relating to share schemes under Chapter 17 of the Listing Rules; and
- dealing with other matters that are authorized by the Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Nomination Committee

We have 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 three Directors, namely Dr. Lu, Ms. Christine Shaohua LU-WONG and Mr. LI Bo. Dr. Lu serves as the chairperson of the Nomination Committee. The primary duties of the Nomination Committee include, but not limited to, the following:

- making recommendations to our Board with regards to the size and composition of our Board based on our Company’s business operation, asset scale and equity structure;
- researching and developing standards and procedures for the election of our Board members, general managers and members of the senior management, and making recommendations to our Board;
- conducting extensive search and providing to our Board suitable candidates for Directors, general managers and other members of the senior management;
- examining our Board candidates, general manager and members of the senior management and making recommendations to our Board;
- assessing and reviewing the independence of independent non-executive Directors; and
- dealing with other matters that are authorized by our Board.

REMUNERATION OF DIRECTORS AND SUPERVISORS

For more information on the remuneration of the Directors, Supervisors and chief executive during the Track Record Period as well as information on the five highest paid individuals, please see Notes 10 and 11 of the Accountants’ Report set out in Appendix I.

Under the arrangement currently in force, we estimate the remuneration of our Directors and our Supervisors for the year ending December 31, 2025 to be approximately RMB7.2 million.

During the Track Record Period, no remuneration was paid by our Company to, or receivable by, our Directors, Supervisors or the five highest paid individuals as an inducement to join or upon joining our Company or as compensation for loss of office in connection with the management positions of any subsidiary of our Company.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

During the Track Record Period, none of our Directors or Supervisors waived any remuneration. Save as disclosed above, no other payments have been paid, or are payable, by our Company or any of our subsidiary to our Directors, Supervisors or the five highest paid individuals during the Track Record Period.

CORPORATE GOVERNANCE CODE

Our Company is committed to achieving high standards of corporate governance with a view to safeguarding the interests of our Shareholders. To accomplish this, our Company intends to comply with Corporate Governance Code set out in Appendix C1 to the Listing Rules and the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules after the [REDACTED]. Our Directors consider that upon [REDACTED], we will comply with all applicable code provisions of the Corporate Governance Code as set out in Appendix C1 to the Listing Rules.

BOARD DIVERSITY POLICY

We are committed to promoting the culture of diversity in the Company. We have strived to promote diversity to the extent practicable by taking into consideration a number of factors in our corporate governance structure.

We have adopted the board diversity policy (the “**Board Diversity Policy**”) which sets out the objective and approach to achieve and maintain diversity of our Board in order to enhance the effectiveness of our Board. Pursuant to the board diversity policy, we seek to achieve Board diversity through the consideration of a number of factors, including but not limited to gender, age, race, cultural background, educational background, industry experience and professional experience. Our Directors have a balanced mix of knowledge and skills, including knowledge and experience in the areas of biotechnology, pharmaceutical, chemistry, and investment banking. They obtained degrees in various areas including biology, chemistry, economics and business. Our Board Diversity Policy is well implemented as evidenced by the fact that there are Directors ranging from [32] years old to [59] years old and comprises three female Directors and five male Directors. We will use our best efforts to maintain at least one or 10% female representation in the Board and continue to take steps to promote diversity at all levels of the Company including but without limitation to our Board and senior management levels, to enhance the effectiveness of corporate governance of the Company as a whole. Going forward, we will continue to work to enhance gender diversity of our Board when selecting and recommending suitable candidates for Board appointments.

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After the [REDACTED], our Nomination Committee will examine the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy on an annual basis.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

COMPLIANCE ADVISOR

We have appointed Guotai Junan Capital Limited as our Compliance Advisor pursuant to Rules 3A.19 and 3A.23 of the Listing Rules. The Compliance Advisor will provide us with guidance and advice as to compliance with the Listing Rules and other applicable laws, rules, codes and guidelines. Pursuant to Rule 3A.23 of the Listing Rules, the Compliance Advisor will advise our Company in certain circumstances including:

- (a) before the publication of any regulatory announcement, circular or financial report;
- (b) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases;
- (c) where we propose to use the [REDACTED] of 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
- (d) where the Hong Kong Stock Exchange makes an inquiry to our Company regarding unusual movements in the price or [REDACTED] volume of its [REDACTED] securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

Pursuant to Rule 3A.24 of the Listing Rules, the Compliance Advisor will, on a timely basis, inform our Company of any amendment or supplement to the Listing Rules that are announced by the Hong Kong Stock Exchange. The Compliance Advisor will also inform our Company of any new or amended law, regulation or code in Hong Kong applicable to us, and advise us on the continuing requirements under the Listing Rules and applicable laws and regulations.

The term of the appointment will commence on the [REDACTED] and is expected to end on the date on which our Company complies with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

SUBSTANTIAL SHAREHOLDERS

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and the conversion of our Unlisted Shares to H Shares assuming the [REDACTED] is not exercised, the following persons will have an interest and/or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the 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 our share capital carrying rights to vote in all circumstances at general meetings of our Company:

Name of Shareholder	Nature of Interest	As of the Latest Practicable Date without taking into account the [REDACTED]		Immediately following the [REDACTED] (taking into account the [REDACTED] and assuming the [REDACTED] and the [REDACTED] are not exercised)		
		Number of Unlisted Shares	Approximate percentage of shareholding in our total share capital	Number of Shares ⁽¹⁾	Approximate percentage of shareholding in Unlisted Shares/ H Shares ⁽²⁾	Approximate percentage of shareholding in our total share capital ⁽²⁾
Dr. Lu	Interest in controlled corporations	1,383,607 ⁽³⁾ 5,372,465 ⁽⁴⁾	5.17% 20.06%	[REDACTED] [REDACTED]	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Dr. Lan	Interest in controlled corporations	5,372,465 ⁽⁴⁾	20.06%	[REDACTED]	[REDACTED]%	[REDACTED]%
GenFleet HK ⁽⁴⁾	Interest in controlled corporations	1,000,000	3.73%	[REDACTED]	[REDACTED]%	[REDACTED]%
	Beneficial owner	4,372,465	16.33%	[REDACTED]	[REDACTED]%	[REDACTED]%
Ourea Biotech ⁽⁵⁾ . . .	Beneficial owner	2,241,889	8.37%	[REDACTED]	[REDACTED]%	[REDACTED]%
HL Partners II L.P. ⁽⁵⁾ .	Interest in controlled corporations	2,241,889	8.37%	[REDACTED]	[REDACTED]%	[REDACTED]%
HL GP II Company Limited ⁽⁵⁾	Interest in controlled corporations	2,241,889	8.37%	[REDACTED]	[REDACTED]%	[REDACTED]%
Long Star ⁽⁶⁾	Beneficial owner	1,509,115	5.64%	[REDACTED]	[REDACTED]%	[REDACTED]%
CDH Growth Fund III (USD Parallel), L.P. ⁽⁶⁾	Interest in controlled corporations	1,509,115	5.64%	[REDACTED]	[REDACTED]%	[REDACTED]%
CDH R-III Parallel Holdings Company Limited ⁽⁶⁾	Interest in controlled corporations	1,509,115	5.64%	[REDACTED]	[REDACTED]%	[REDACTED]%
Hongyong Bingde ⁽⁷⁾ .	Beneficial owner	1,317,182	4.92%	[REDACTED]	[REDACTED]%	[REDACTED]%
Hongyong Bingde Capital (Cayman) Limited ⁽⁷⁾	Interest in controlled corporations	1,317,182	4.92%	[REDACTED]	[REDACTED]%	[REDACTED]%
Sinopharm ⁽⁸⁾	Beneficial owner	947,615	3.54%	[REDACTED] [REDACTED]	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of Interest	As of the Latest Practicable Date without taking into account the [REDACTED]		Immediately following the [REDACTED] (taking into account the [REDACTED] and assuming the [REDACTED] and the [REDACTED] are not exercised)		
		Number of Unlisted Shares	Approximate percentage of shareholding in our total share capital	Number of Shares ⁽¹⁾	Approximate percentage of shareholding in Unlisted Shares/ H Shares ⁽²⁾	Approximate percentage of shareholding in our total share capital ⁽²⁾
Shanghai Jianyi Private Fund Management Co., Ltd. ⁽⁸⁾	Interest in controlled corporations	947,615	3.54%	[REDACTED] [REDACTED]	[REDACTED] % [REDACTED] %	[REDACTED] % [REDACTED] %
CSPC NBP ⁽⁹⁾	Beneficial owner	441,176	1.65%	[REDACTED]	[REDACTED] %	[REDACTED] %
CSPC Pharmaceutical Group Limited ⁽⁹⁾	Interest in controlled corporations	441,176	1.65%	[REDACTED]	[REDACTED] %	[REDACTED] %
Pu'en Guoxin	Beneficial owner	395,607	1.48%	[REDACTED]	[REDACTED] %	[REDACTED] %
Huajin Lingjian ⁽¹⁰⁾	Beneficial owner	470,271	1.76%	[REDACTED] [REDACTED]	[REDACTED] % [REDACTED] %	[REDACTED] % [REDACTED] %
Zhuhai Huajin Lingchuang Fund Management Co., Ltd. ⁽¹⁰⁾	Interest in controlled corporations	470,271	1.76%	[REDACTED] [REDACTED]	[REDACTED] % [REDACTED] %	[REDACTED] % [REDACTED] %
Zhuhai Huajin Alpha No. 6 Equity Investment Fund Partnership (Limited Partnership) ⁽¹⁰⁾	Interest in controlled corporations	470,271	1.76%	[REDACTED] [REDACTED]	[REDACTED] % [REDACTED] %	[REDACTED] % [REDACTED] %
Zhuhai Huaying Investment Co., Ltd. ⁽¹⁰⁾	Interest in controlled corporations	470,271	1.76%	[REDACTED] [REDACTED]	[REDACTED] % [REDACTED] %	[REDACTED] % [REDACTED] %
Huajin Capital ⁽¹⁰⁾	Interest in controlled corporations	470,271	1.76%	[REDACTED] [REDACTED]	[REDACTED] % [REDACTED] %	[REDACTED] % [REDACTED] %
BOCOM Sci-Tech ⁽¹¹⁾	Beneficial owner	189,048	0.71%	[REDACTED]	[REDACTED] %	[REDACTED] %
Shanghai Boli Investment Co., Ltd. ⁽¹¹⁾	Interest in controlled corporations	189,048	0.71%	[REDACTED]	[REDACTED] %	[REDACTED] %
BOCOM International Holdings Company Limited ⁽¹¹⁾	Interest in controlled corporations	189,048	0.71%	[REDACTED]	[REDACTED] %	[REDACTED] %

Notes:

- The letter “L” denotes the person’s long position in the Shares.

SUBSTANTIAL SHAREHOLDERS

2. The calculation is based on the total number of [REDACTED] Unlisted Shares and [REDACTED] H Shares in issue immediately after completion of the [REDACTED] since [REDACTED] Unlisted Shares will be converted into H Shares and [REDACTED] H Shares will be issued pursuant to the [REDACTED], taking into account the [REDACTED] and assuming that the [REDACTED] and the [REDACTED] are not exercised.
3. Shanghai Kunjin is our ESOP Platform. As of the Latest Practicable Date, Shanghai Kunjin is deemed to be controlled by Dr. Lu as its sole general partner, and none of the limited partners of Shanghai Kunjin held more than one-third of the partnership interest in Shanghai Kunjin. Therefore, by virtue of the SFO, Dr. Lu is deemed to be interested in the Shares held by Shanghai Kunjin.
4. Auspicious Delight is our ESOP Platform. As at the Latest Practicable Date, GenFleet HK was held as to 53.69% by Dr. Lu and 46.31% by Dr. Lan. GenFleet HK held 64.5% of the issued share capital of Auspicious Delight. Therefore, by virtue of the SFO, each of Dr. Lu and Dr. Lan is deemed to be interested in the Shares held by GenFleet HK and Auspicious Delight.
5. Ourea Biotech is controlled by HL Partners II L.P., a limited partnership established under the laws of the Cayman Islands, which is ultimately managed by its general partner, HL GP II Company Limited. Therefore, by virtue of the SFO, each of HL Partners II L.P. and HL GP II Company Limited is deemed to be interested in the Shares held by Ourea Biotech.
6. Long Star is indirectly wholly owned by CDH Growth Fund III (USD Parallel), L.P., a limited partnership incorporated in the Cayman Islands. The general partner of CDH Growth Fund III (USD Parallel), L.P. is CDH R-III Parallel Holdings Company Limited. Therefore, by virtue of the SFO, each of CDH Growth Fund III (USD Parallel), L.P. and CDH R-III Parallel Holdings Company Limited is deemed to be interested in the Shares held by Long Star.
7. Hongyong Bingde is wholly-owned by Hongyong Bingde Capital (Cayman) Limited. Therefore, by virtue of the SFO, Hongyong Bingde Capital (Cayman) Limited is deemed to be interested in the Share held by Hongyong Bingde.
8. Shanghai Jianyi Private Fund Management Co., Ltd. is the executive partner of Sinopharm. Therefore, by virtue of the SFO, Shanghai Jianyi Private Fund Management Co., Ltd. is deemed to be interested in the Shares held by Sinopharm.
9. CSPC NBP is a wholly-owned subsidiary of CSPC Pharmaceutical Group Limited. Therefore, by virtue of the SFO, CSPC Pharmaceutical Group Limited is deemed to be interested in the Shares held by CSPC NBP.
10. Huajin Lingjian is a limited partnership incorporated under the laws of the PRC, with its executive partner being Zhuhai Huajin Lingchuang Fund Management Co., Ltd., which is a wholly-owned subsidiary of Huajin Capital. The single largest limited partner of Huajin Lingjian is Zhuhai Huajin Alpha No. 6 Equity Investment Fund Partnership (Limited Partnership), which holds approximately 99.80% of the partnership interests in Huajin Lingjian. The executive partner of Zhuhai Huajin Alpha No. 6 Equity Investment Fund Partnership (Limited Partnership) is Zhuhai Huaying Investment Co., Ltd. Therefore, by virtue of the SFO, each of Zhuhai Huajin Lingchuang Fund Management Co., Ltd., Huajin Capital, Zhuhai Huajin Alpha No. 6 Equity Investment Fund Partnership (Limited Partnership) and Zhuhai Huaying Investment Co., Ltd. is deemed to be interested in the Shares held by Huajin Lingjian.
11. Shanghai Boli Investment Co., Ltd. is the executive partner of BOCOM Sci-Tech. Shanghai Boli Investment Co., Ltd. is controlled by BOCOM International Holdings Company Limited. Therefore, by virtue of the SFO, each of Shanghai Boli Investment Co., Ltd. and BOCOM International Holdings Company Limited is deemed to be interested in the Shares held by BOCOM Sci-Tech.

Save as disclosed above and the section headed “Statutory and General Information — Further Information about our Directors, Supervisors, Senior Management and Substantial Shareholders” in Appendix IV, our Directors are not aware of any person who will, immediately following completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), have any interest and/or short position in the Shares or underlying Shares of our Company which will be required to be disclosed to our Company and the Stock Exchange pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO, or, who are, 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 meeting of the Company or any other member of our Group.

SHARE CAPITAL

This section presents certain information regarding our share capital before and upon completion of the [REDACTED].

BEFORE THE COMPLETION OF THE [REDACTED]

As of the Latest Practicable Date, the issued share capital of our Company was RMB26,774,063, comprising 26,774,063 Unlisted Shares of nominal value RMB1.00 each.

UPON THE COMPLETION OF THE [REDACTED] AND THE [REDACTED]

Assuming the [REDACTED] and the [REDACTED] are not exercised, the share capital of our Company immediately following completion of the [REDACTED] (taking into account the [REDACTED]) will be as follows:

Description of Shares	Number of Shares	Approximate percentage of the total share capital of our Company
Unlisted Shares in issue	[REDACTED]	[REDACTED]%
H Shares to be converted from Unlisted Shares . . .	[REDACTED]	[REDACTED]%
H Shares to be issued under the [REDACTED] . .	[REDACTED]	[REDACTED]%
Total	<u>[REDACTED]</u>	<u>100.00%</u>

Assuming the [REDACTED] and the [REDACTED] are fully exercised, the share capital of our Company immediately following completion of the [REDACTED] (taking into account the [REDACTED]), will be as follows:

Description of Shares	Number of Shares	Approximate percentage of the total share capital of our Company
Unlisted Shares in issue	[REDACTED]	[REDACTED]%
H Shares to be converted from Unlisted Shares . . .	[REDACTED]	[REDACTED]%
H Shares to be issued under the [REDACTED] . .	[REDACTED]	[REDACTED]%
Total	<u>[REDACTED]</u>	<u>100.00%</u>

SHARE CAPITAL

RANKING

Upon completion of the [REDACTED] and the conversion of the Unlisted Shares into H Shares, the Shares will consist of H Shares and Unlisted Shares. Upon completion of the [REDACTED], we would have only one class of Shares. H Shares and Unlisted Shares are all ordinary Shares in the share capital of our Company. However, apart from certain [REDACTED] in the PRC, the qualified PRC [REDACTED] under the Shanghai — Hong Kong Stock Connect or 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 for by or [REDACTED] between legal or natural persons of the PRC.

Unlisted Shares and H Shares will rank *pari passu* with each other in all 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 the H Shares are to be paid by us in Hong Kong dollars or in the form of H Shares.

CONVERSION OF OUR UNLISTED SHARES INTO H SHARES

According to the regulations issued by the CSRC, the holders of our Unlisted Shares may, at their own option, authorize the Company to apply to the CSRC for conversion of their respective Unlisted Shares to H Shares, and such converted Shares may be [REDACTED] and [REDACTED] on an overseas stock exchange provided that the required filings with the securities regulatory authorities of the State Council for the conversion, [REDACTED] and [REDACTED] of such converted Shares have been completed. Additionally, such conversion, [REDACTED] and [REDACTED] shall meet any requirement of internal approval process and in all respects comply with the regulations prescribed by the securities regulatory authorities of the State Council and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. Save as disclosed in this Document and to the best knowledge of our Directors, we are not aware of the intention of such existing Shareholders to convert their Unlisted Shares.

If any of the Unlisted Shares are to be converted, [REDACTED] and [REDACTED] as H Shares on the Stock Exchange, the filings and approvals with the relevant PRC regulatory authorities, including the CSRC, and the approval of the Stock Exchange are necessary for such conversion. Based on the procedures for the conversion of Unlisted Shares into H Shares as set forth below, we will apply for the [REDACTED] of all or any portion of the Unlisted Shares on the Stock Exchange as H Shares in advance of any proposed conversion after the [REDACTED] to ensure that the conversion process can be completed promptly upon notice to the Stock Exchange and delivery of Shares for entry on the [REDACTED]. As the [REDACTED] of additional Shares after the [REDACTED] on the Stock Exchange is ordinarily considered by the Stock Exchange to be a purely administrative matter, it does not require such prior [REDACTED] for [REDACTED] at the time of our [REDACTED] in Hong Kong. No class Shareholder voting is required for the conversion of such Shares or the [REDACTED] and [REDACTED] of such converted Shares on an overseas stock exchange.

SHARE CAPITAL

Any [REDACTED] for [REDACTED] of the converted shares on the Stock Exchange after our initial [REDACTED] is subject to prior notification by way of announcement to inform our Shareholders and the public of any proposed conversion.

After all the requisite filings have been completed and approvals have been obtained, the relevant Unlisted Shares will be withdrawn from the Unlisted Share register, and our Company will re-register such Shares on the [REDACTED] maintained in Hong Kong and instruct the [REDACTED] to issue [REDACTED]. Registration on the [REDACTED] of our Company will be on the conditions that (i) the [REDACTED] lodges with the Stock Exchange a letter confirming the entry of the relevant H Shares on the [REDACTED] and the due dispatch of [REDACTED]; and (ii) the admission of the H Shares to be [REDACTED] on the Stock Exchange complies with the Listing Rules and the General Rules of HKSCC and the HKSCC Operational Procedures in force from time to time. Until the converted Shares are re-registered on the [REDACTED] of our Company, such Shares would not be [REDACTED] as H Shares.

TRANSFER OF SHARES ISSUED PRIOR TO THE [REDACTED]

Pursuant to the PRC Company Law, our Shares issued prior to the [REDACTED] shall not be transferred within one year from the [REDACTED].

Shares transferred by our Directors, Supervisors and members of the senior management each year during their term of office shall not exceed 25% of their total respective shareholdings in our Company unless otherwise permitted by applicable laws and regulations. The Shares that the aforementioned persons hold in our Company cannot be transferred within half a year after they leave their positions as Directors, Supervisors and members of the senior management in our Company.

[REDACTED] EQUITY INCENTIVE SCHEME

We adopted the [REDACTED] Equity Incentive Scheme in 2020 as amended and restated in July 2023 and established the ESOP Platforms. All awards granted under the [REDACTED] Equity Incentive Scheme had been vested and exercised and no further awards will be granted under the [REDACTED] Equity Incentive Scheme upon [REDACTED].

SHAREHOLDERS' GENERAL MEETING

See “Appendix III — Summary of Articles of Association” for details of circumstances under which our general meeting is required.

FINANCIAL INFORMATION

You should read the following discussion and analysis with our consolidated financial information, including the notes thereto, included in the Accountants’ Report in Appendix I to this Document. Our consolidated financial information has been prepared in accordance with International Financial Reporting Standards issued by the International Accounting Standards Board, which may differ in material aspects from generally accepted accounting principles in other jurisdictions, including the United States. 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 our current views with respect to future events and financial performance. These statements are based on our assumptions and analysis in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, whether actual outcomes and developments will meet our expectations and predictions depends on a number of risks and uncertainties. In evaluating our business, you should carefully consider the information provided in the section headed “Risk Factors” and “Business” in this Document.

For the purpose of this section, unless the context otherwise requires, references to the year of 2023 and 2024 refer to our financial year ended December 31 of such year. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis. Discrepancies between totals and sums of amounts listed in this section in any table or elsewhere in this document may be due to rounding.

OVERVIEW

We are a biopharmaceutical company featuring a global vision, international collaborations and operations. We adhere to an innovative development strategy, with a vision to propel ourselves with the advancement of science and technology to build a globally competitive biopharmaceutical company.

As of the Latest Practicable Date, we had established a product pipeline consisting of eight product candidates, with five under clinical development. A substantial part of our pipeline programs revolves around therapies targeting RAS family members, which are key regulators during cellular signaling transduction to stimulate or silence downstream proteins to effectuate regulation on cell growth, differentiation and survival. In particular, one of our Core Products, GFH925 (fulzerasib, marketed under the brand name Dupert[®]), has been approved for commercialization in China for the treatment of advanced NSCLC. In addition to RAS, we also explore treatment options for autoimmune and inflammatory diseases, including our product candidate GFH312, and other cancer-related therapies. We believe that this diverse range of pipeline products reflects our commitment to innovation and addressing various medical needs through advanced therapeutic approaches.

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During the Track Record Period, we realized revenues from licenses of intellectual property and provision of research and development services. The revenues amounted to RMB73.7 million, RMB104.7 million and RMB82.1 million for the year ended December 31, 2023 and 2024 and four months ended April 30, 2025, respectively. We did not realize revenue for the four months ended April 30, 2024. Other than our Core Product, GFH925, which received NDA approval from the NMPA in August 2024, our other drug candidates and GFH925 in jurisdictions beyond China had not been approved for commercialization and had not generated any revenue from product sales. We had not been profitable and had incurred operating losses during the Track Record Period. For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, we had total loss for the year/period of RMB508.3 million and RMB677.6 million, RMB404.7 million and RMB66.6 million, respectively. Our total loss for the year/period mainly resulted from research and development costs and change in fair value of redemption liabilities on equity shares.

As GFH925 has been approved for commercialization in China, we anticipate to realize revenues from sales of GFH925 pursuant to our agreement with Innovent. For additional licensing information about the agreement, see “Business — Major Collaboration and Licensing Arrangements.” However, we also anticipate incurring an increased amount of research and development costs and operating expenses for the next several years as we continue to advance our pipeline products in China and overseas. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a [REDACTED]. We expect that our financial performance will fluctuate from period to period due to the development status of our pipeline products, timeline and terms of potential collaboration with our partners, regulatory approval timeline and commercialization of our drug candidates after approval.

BASIS OF PRESENTATION AND PREPARATION

Our consolidated financial information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”) (which include all IFRSs, International Accounting Standards (“IASs”) and Interpretations) issued by the International Accounting Standards Board (the “IASB”), and accounting principles generally accepted in Hong Kong. All IFRSs effective for the accounting period commencing from January 1, 2025, together with the relevant transitional provisions, have been adopted by us in the preparation of the consolidated financial information for the Track Record Period.

The consolidated financial information has been prepared under the historical cost convention, except for redemption liabilities on equity shares and wealth management products that have been measured at fair value, as explained in the respective accounting policies in the Accountants’ Report in Appendix I to this Document. Our consolidated financial information is presented in RMB and all values are rounded to the nearest thousand except when otherwise indicated. The preparation of the consolidated financial information in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires our management to exercise its judgment in the process of applying our accounting policies.

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The Directors further assessed whether we have sufficient working capital to meet our present obligations, taking into account the financial resources available to us. We have prudently prepared a full-speed budget based for clinical trials of our Core Products and other pipelines for 2025 assuming we are able to raise [REDACTED] from the [REDACTED] as well as a backbone budget plan to advance all necessary R&D activities for our Core Products assuming we are unable to raise [REDACTED] from the [REDACTED]. Based on the rigorous review of the budget under either full-speed or backbone scenario, the Directors are satisfied that we would have sufficient working capital to meet our present obligations, taking into account the financial resources available to us for next twelve months from 30 April 2025.

Based on the above factors, our historical performance and our management’s operating and financing plans, the Directors concluded that it is appropriate to prepare the consolidated financial information for the Track Record Period on a going concern basis.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations and financial condition have been, and are expected to continue to be, principally affected by a number of factors, many of which may be beyond our control. A discussion of the key factors is set out below.

Development and Commercialization of Our Pipeline Products

Our business and results of operations depend on our ability to successfully develop, as well as our receipt of regulatory approval for and successful commercialization of, our drug candidates. For pipeline products that we out license certain rights, including commercialization rights, in certain jurisdictions to collaborators, our results of operations will likely depend on the collaborators’ promotional and marketing efforts once those products are approved in the relevant jurisdictions. As of the Latest Practicable Date, we had established a diverse and innovative pipeline featuring eight pipeline products. A substantial part of our pipeline programs revolves around therapies targeting RAS family members, which are key regulators during cellular signaling transduction to stimulate or silence downstream proteins to effectuate regulation on cell growth, differentiation and survival. For more information on the development status of our Core Products and other drug candidates, see “Business — Our Product Pipeline.” Our business and results of operations depend on our drug candidates demonstrating favorable safety and efficacy profiles in clinical trials and our or our collaborators’ ability to obtain the requisite regulatory approvals for the drug candidates.

While GFH925 has received NDA approval from the NMPA, which we expect to bring us revenue from drug sales, GFH375 and other pipeline products have not been approved for commercial sale, and we had not generated any revenue from product sales during the Track Record Period. We expect to incur significant research and development costs and further advance the pipeline products to the commercialization stage over the coming years. However, our ability to generate revenue from our pipeline products to cover research and developments costs and other expenses will depend on multiple factors, including but not limited to our ability to obtain regulatory approvals, secure adequate manufacturing capacity, collaboration

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with competent third-party partners, as well as making our products accessible to, affordable for and accepted by the addressable patient population who are in need of high-quality products that bring comprehensive benefits for oncology and immunology diseases.

Our Existing and Future Collaboration and Licensing Arrangements

In the past, we entered into a number of collaboration and licensing arrangements with respect to our pipeline products, including our Core Products GFH925 and GFH375. We generated revenue in the amount of RMB73.7 million, RMB104.7 million and RMB82.1 million in 2023, 2024 and April 30, 2025, respectively. Most of the revenue that we recognized during the Track Record Period was generated from licenses of intellectual property under such collaboration and out-licensing arrangements. We are eligible to receive further payments upon the achievement of specified development, regulatory and commercial milestones, subject to terms and conditions of these agreements. For additional information about the relevant agreements, see “Business — Major Collaboration and Licensing Arrangements.” These strategic collaborations empower us to maximize the global value of our assets and provide capital support for our other pipeline assets and sustainable long-term growth. We may also enter into new collaboration and licensing arrangements to serve our best interests. We anticipate our existing and future collaboration and licensing arrangements to contribute a substantial part of our revenue and cash inflows going forward, and payments associated with such arrangements may influence and result in fluctuations in our revenue, profit and results of operations from period to period.

Our Cost Structure

Our results of operations are significantly affected by our cost structure, of which our research and development costs and administrative expenses are a major component.

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 quality drug candidates requires significant investments of financial resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, we have invested a significant amount of financial resources in research and development to advance and expand our pipeline of clinical- and preclinical-stage drug candidates. The research and development costs we incurred for the years ended December 31, 2023 and 2024 and the four months ended April 30, 2024 and 2025 amounted to RMB312.7 million, RMB332.1 million, RMB142.3 million and RMB69.8 million, respectively. See “— Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income — Research and Development Costs” for detailed information.

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We expect our research and development costs to continue to be a major component in our cost structure. As we expand the indications and explore combination therapies of our Core Products, advance more drug candidates along clinical trials and conduct additional preclinical studies, we expect to incur additional costs in relation to, among other things, preclinical study and clinical trial expenses, CMC expenses, raw materials procurements, manufacturing and sales and marketing.

Our administrative expenses, which primarily consisted of staff costs and professional services expenses, among others, amounted to RMB49.9 million, RMB58.1 million, RMB13.9 million and RMB23.7 million for the years ended December 31, 2023 and 2024 and the four months ended April 30, 2024 and 2025, respectively. Our administrative expenses increased during the Track Record Period mainly due to the increase in [REDACTED]. We expect our administrative expenses to increase in coming years to support our growing operations, expanding product development efforts and entry into future collaboration and licensing arrangements.

The change in fair value of redemption liabilities on equity shares also had a significant impact on our financial position during the Track Record Period. We have recognized the equity shares that we issued in the several rounds of investments that we historically received as redemption liabilities on equity shares. Upon [REDACTED], we do not expect to recognize any further change in fair value of redemption liabilities on equity shares, as the redemption right will be automatically terminated upon [REDACTED], which we anticipate to allow us to turn into a net assets, rather than net liabilities, position.

We expect our cost structure to evolve as we continue to develop and expand our business. Beyond research and development costs and administrative expenses, we anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a [REDACTED] in Hong Kong.

Funding for Our Operations

During the Track Record Period, we funded our operations primarily through equity financing. Going forward, in the event of the successful commercialization of one or more of our pipeline products, we expect to primarily fund our operations with revenue generated from sales of the commercialized drug products. However, with the continuing expansion of our business, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Any fluctuation in the funding for our operations will impact our cash flow and our results of operations.

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MATERIAL ACCOUNTING POLICIES AND SIGNIFICANT ACCOUNTING JUDGMENTS 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. 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.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates and judgments used in the preparation of our consolidated financial statements. Our material accounting policies and estimates, which are important for an understanding of our financial condition and results of operations, are set forth in detail in Notes 2 and 3 to the Accountants’ Report in Appendix I to this Document.

Revenue Recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognized when control of the goods or services is transferred to the customer at an amount that reflects the consideration to which our 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 recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

Our revenue is generated from the collaboration agreements with Innovent and SELLAS, which generally contain multiple performance obligations including (1) grants of licenses to intellectual property rights and (2) the research and development services.

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Collaboration revenue

At contract inception, we analyze the collaboration arrangements to assess whether they are within the scope of IFRS 11 *Joint Arrangements* to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and are exposed to significant risks and rewards dependent on the commercial success of such activities.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of the collaboration agreements, our management performs the five-step model under IFRS 15. The collaboration arrangements may contain more than one unit of account or performance obligation, including grants of licenses to intellectual property rights (the “Licenses”), agreements to provide research and development services and other deliverables. The collaborative arrangements typically do not include a right of return for any deliverable. In general, the consideration allocated to each performance obligation is recognized when the obligation is satisfied either by delivering a good or rendering a service, limited to the consideration that is not constrained. Non-refundable payments received before all of the relevant criteria for revenue recognition are satisfied are recorded as contract liabilities.

(a) Licenses of intellectual property

Upfront non-refundable payments for Licenses are evaluated to determine if they are distinct from the other performance obligations identified in the arrangements. For the Licenses determined to be distinct, we recognize revenues from non-refundable up-front fees allocated to the licenses at a point in time, when the Licenses are transferred to the licensee and the licensee is able to use and benefit from the Licenses.

Milestone payments

At the inception of each arrangement that includes development milestone payments and commercial milestone payments, our management evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestones related to development-based activities may include initiation of various phases of clinical trials. Due to the uncertainty involved in meeting these development-based targets, they are generally fully constrained at contract inception. Our management assesses whether the variable consideration is fully constrained for each reporting period based on the facts and circumstances surrounding the clinical trials. Upon changes to constraint associated with the developmental milestones, variable consideration is included in the transaction price when a significant reversal of revenue recognized is not expected to occur and allocated to the separate performance obligations. Due to the inherent uncertainty with the approval process,

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regulatory milestones are fully constrained until the period in which those regulatory approvals are achieved. Regulatory milestones are included in the transaction price in the period regulatory approval is obtained.

Royalties

For arrangements that include sales-based royalties, we recognize revenue when the related sales occur.

(b) Research and development services

We provide our customer with a project team of scientists and technical staff dedicated to the customer’s studies for a specific period of time and charges the customer at a fixed rate per employee. We have assessed that the customers simultaneously receive and consume benefit provided by our performance. Therefore, the performance obligation of research and development services is satisfied over time and revenue is recognized over the service period.

(c) Drug supply manufacturing services

We provide drug supply manufacturing services to customers. We recognize revenue at point in time when such services are rendered. The drug supply manufacturing services revenue is recognized on a net basis as we are acting as an agent because we did not obtain control of those drugs goods before they are transferred to the customers. Accordingly, during Track Record Period, we did not recognize any revenues for the drug supply manufacturing services.

Other Income

Bank 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.

Research and Development Costs

All research costs are charged to profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when our 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. Determination of the amounts to be capitalized requires management to make judgments on the technical feasibility of existing pipelines to be successfully commercialized and bring economic benefits to our Company.

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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 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 capitalized 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, our Group recognizes 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 for this purpose are as follows:

Computer and office equipment	19% to 32%
Machinery and equipment.	19%
Motor vehicles	19%
Leasehold improvements	Shorter of remaining lease terms and estimated useful lives

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 the end of the reporting periods.

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in profit or loss in the year the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

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.

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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Right-of-use Assets

Right-of-use assets are recognized 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 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 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 terms and the estimated useful lives of the assets as follows:

Office premises 2 to 10 years

If ownership of the leased asset transfers to our 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.

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 our Group and payments of penalties for termination of a lease, if the lease term reflects our Group exercising the option to terminate the lease.

In calculating the present value of lease payments, we use our 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 used to determine such lease payments) or a change in assessment of an option to purchase the underlying asset.

Our lease liabilities are presented in a separate line on the consolidated statements of financial position.

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Short-term leases and leases of low-value assets

We apply the short-term lease recognition exemption to its short-term leases of office premises (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 25 short-term leases and leases of low-value assets are recognized as an expense on a straight-line basis over the lease term.

Share-based Payments

We operate restricted share units schemes. Employees (including directors) of our Group receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments (“equity-settled transactions”). 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, further details of which are given in Note 29 to the Accountants’ Report in Appendix I to this Document.

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 reporting period until the vesting date reflects the extent to which the vesting period has expired and our 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 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 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 restricted shares 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.

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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 canceled, 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.

Contract Liabilities

A contract liability is recognized when a payment is received or a payment is due (whichever is earlier) from a customer before our Group transfers the related goods or services. Contract liabilities are recognized as revenue when our Group performs under the contract (i.e., transfers control of the related goods or services to the customer).

Impairment of Non-financial Assets

Where an indication of impairment exists, or when annual impairment testing for a non-financial asset is required, 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. In testing a cash-generating unit for impairment, a portion of the carrying amount of a corporate asset (e.g., a headquarters building) is allocated to an individual cash-generating unit if it can be allocated on a reasonable and consistent basis or, otherwise, to the smallest group of cash-generating units.

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 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 profit or loss in the period in which it arises unless the asset is carried at a revalued amount, in which case the reversal of the impairment loss is accounted for in accordance with the relevant accounting policy for that revalued asset.

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Fair Value Measurement

We measure our financial instruments 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 our 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.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

We use 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 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 statement 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 the reporting periods.

During the Track Record Period, we had certain financial liabilities categorized within Level 3 of fair value measurement (“**Level 3 Financial Liabilities**”). Our Level 3 Financial liabilities include redemption liabilities on equity shares. Our finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At the end of the reporting periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the finance manager.

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	Fair value measurement of liabilities using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	(RMB in thousands)			
As of December 31, 2023				
Redemption liabilities on				
equity shares	—	—	1,636,508	1,636,508
As of December 31, 2024				
Redemption liabilities on				
equity shares	—	—	2,214,121	2,214,121
As of April 30, 2025				
Redemption liabilities on				
equity shares	—	—	2,264,813	2,264,813

During the Track Record Period, there were no transfers between Level 1 and Level 2, or transfers into or out of Level 3 for both financial assets and financial liabilities.

The fair value of redemption liabilities on equity shares have been estimated using a discounted cash flow and back-solve method based on unobservable inputs including risk-free interest rate, volatility and discount for lack of marketability (DLOM). We believe that the estimated fair values resulting from the valuation technique are reasonable, and that they were the most appropriate values at the end of reporting periods.

In relation to the valuation of the Level 3 Financial Liabilities, our Directors had reviewed the valuation works and results and the financial statements prepared in accordance with IFRS, and had obtained sufficient understanding of the valuation model, methodologies and techniques on which the valuation is based. Based on the above, our Directors are of the view that the valuation analysis performed during the Track Record Period is fair and reasonable, and our financial statements are properly prepared. In addition, our Directors are satisfied with the valuation work for the Level 3 Financial Liabilities performed during the Track Record Period.

Our Reporting Accountants have conducted their work in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” (“**HKSIR 200**”) issued by the Hong Kong Institute of Certified Public Accountants in order to express an opinion on the Historical Financial Information (as defined in the Appendix I to this Document) as a whole. The Reporting Accountants’ opinion on the Historical Financial Information for the Track Record Period as a whole is set out in Appendix I to this Document.

FINANCIAL INFORMATION

DESCRIPTION OF SELECTED COMPONENTS OF CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

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

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
REVENUE	73,734	104,703	—	82,149
Cost of sales	(684)	(20,095)	—	(8,693)
Gross profit	73,050	84,608	—	73,456
Other income and gains	39,964	28,531	6,534	6,122
Research and development costs	(312,738)	(332,124)	(142,262)	(69,818)
Administrative expenses	(49,946)	(58,081)	(13,881)	(23,684)
Other expenses	(176)	(10)	(2)	(3)
Finance costs	(1,485)	(17,963)	(13,615)	(2,005)
Loss before change in fair value of redemption liabilities on equity shares	(251,331)	(295,039)	(163,226)	(15,932)
Change in fair value of redemption liabilities on equity shares	(256,993)	(382,602)	(241,461)	(50,692)
LOSS BEFORE TAX	(508,324)	(677,641)	(404,687)	(66,624)
Income tax expense	—	—	—	—
LOSS FOR THE YEAR/PERIOD	(508,324)	(677,641)	(404,687)	(66,624)
Attributable to:				
Owners of the parent	(508,324)	(677,641)	(404,687)	(66,624)
OTHER COMPREHENSIVE (EXPENSE)/INCOME				
Other comprehensive income (expense) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	734	(1,111)	(624)	470
OTHER COMPREHENSIVE (EXPENSE)/INCOME FOR THE YEAR	734	(1,111)	(624)	470
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(507,590)	(678,752)	(405,311)	(66,154)

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Revenue

During the Track Record Period, our revenue was mainly derived from our collaboration with Innovent regarding our Core Product GFH925, collaboration with Verastem regarding our Core Product GFH375 and SELLAS regarding GFH009. For additional information about the relevant agreements, see “Business — Major Collaboration and Licensing Arrangements.” Most of the revenue that we recognized during the Track Record Period was generated from licenses of intellectual property under such collaboration and out-licensing arrangements. We also generated a small portion of revenue from provision of research and development services, clinical and regulatory support in connection with the collaboration with SELLAS, including medical monitoring, data management, statistics and clinical pharmacology. The following table sets forth components of our revenue.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Licenses of intellectual property	71,779	90,035	—	80,742
Sales of goods ⁽¹⁾	—	14,668	—	127
Research and development services	1,955	—	—	1,280
Total	73,734	104,703	—	82,149

The following table sets forth of our revenue by Core Products and other products.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
GFH925	71,779	104,703	—	4,310
GFH375	—	—	—	77,618
Other products	1,955	—	—	221
Total	73,734	104,703	—	82,149

Note:

- (1) The sales of goods in 2024 was derived from our supply of GFH925 to Innovent. The sales of goods in the first four months in 2025 was derived from the resale of redundant consumables.

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Cost of Sales

For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, our cost of sales was RMB0.7 million, RMB20.1 million, nil and RMB8.7 million, respectively. Our cost of sales primarily consists of costs related to licenses of intellectual property, costs related to sales of goods and cost related to research and development services. Costs related to intellectual property licenses primarily consist of fees paid to a third-party patent holder under licensing arrangements enabled us to proactively mitigate potential infringement risks associated with GFH925. Under these arrangements, we have agreed to pay one of the patent holders mid-teen percentage royalties upon the achievement of specified regulatory and commercialization milestones and receipt of royalty payments for GFH925 in China, commencing after the execution of the agreement in 2024. See “Business — Intellectual Property.” Costs related to licenses of intellectual property increased in the four months ended April 30, 2025 compared to that of the same period of 2024 was primarily due to the increased royalty payments we received from Innovent in the first four months of 2025, whereas we did not receive any such payments in the first four months of 2024. Such costs increased in 2024 compared to 2023 was due to the regulatory milestones and royalties we received from Innovent in late 2024. As such, we had made corresponding royalties payments to the license holder in late 2024 and the first four months in 2025.

The cost of goods sold primarily reflects the costs incurred in connection with our fulfillment of drug supply arrangements. During the Track Record Period, the cost related to sales of goods primarily reflected costs incurred in fulfilling drug supply arrangements for GFH925. These costs exceeded the corresponding revenue from the sale of GFH925, mainly because production was based on the first-generation CMC process, which had a higher cost profile than the selling price to Innovent. We expect the cost of sales to be significantly reduced once the second-generation CMC process is successfully implemented For details on how we fulfill our drug supply arrangement, including manufacturing the GFH925 supplied to Innovent, see “Business — Chemistry, Manufacturing & Controls (“CMC”) — Collaboration with CDMO Partners.” The following table sets forth components of our cost of sales.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Costs related to licenses of				
intellectual property	—	12,425	—	595
Cost related to research and				
development services	684	—	—	—
Cost related to sales of goods	—	7,670	—	8,098
Total	684	20,095	—	8,693

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Gross Profit

Our gross profit represents our revenue less our cost of sales. For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, our gross profit was RMB73.1 million, RMB84.6 million, nil and RMB73.5 million, respectively. The fluctuation of our gross profit was primarily driven by the fluctuation of the revenue we recognized, which in turn resulted from the timing of our entry into collaboration agreements and the payment schedule stipulated in those collaboration agreements.

Other Income and Gains

Our other income and gains primarily consists of (i) government grants, (ii) bank interest income, (iii) net foreign exchange differences and (iv) fair value gains on financial assets at fair value through profit and loss (“FVTPL”).

The following table sets forth a breakdown of our other income and gains for the periods indicated.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Other income				
Government grants	21,786	6,869	678	242
Bank interest income	<u>10,767</u>	<u>17,228</u>	<u>4,186</u>	<u>4,986</u>
Gains				
Foreign exchange				
differences, net	3,818	3,539	959	894
Fair value gains on financial				
assets at FVTPL	3,587	402	222	—
Gain on lease reassessment . . .	—	488	488	—
Others	<u>6</u>	<u>5</u>	<u>1</u>	<u>—</u>
Total	<u>39,964</u>	<u>28,531</u>	<u>6,534</u>	<u>6,122</u>

Our government grants mainly represent incentives we received from the local governments. Such incentives are generally one-off in nature and granted primarily for compensating expenditure arising from our various preclinical and clinical research activities, as well as our general business operations. Fair value gains on financial assets at FVTPL mainly represents gains resulting from changes in the fair value of our structured deposits purchased from reputable banks.

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Research and Development Costs

The following table sets forth a breakdown of our research and development costs for the periods indicated.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
CMC, materials costs and preclinical development costs	99,468	83,438	18,132	16,023
Clinical development costs . .	85,961	57,223	23,085	22,320
Staff costs	78,198	68,992	22,206	19,114
Share-based payment	20,283	21,518	7,479	6,965
Depreciation and amortization	15,289	12,595	4,246	3,048
IP management expenses	4,300	4,921	1,501	1,060
Termination fee	—	45,404	45,404	—
Patent licensing agreements . .	3,774	28,774	18,868	—
Others	5,465	9,259	1,341	1,288
Total	312,738	332,124	142,262	69,818

Our CMC, materials costs and preclinical development costs relate to our process development of our pipeline products, the costs of materials used in our CMC development and the costs related to our preclinical development of pipeline product candidates, including costs related to engaging third-party service providers. Our clinical development costs related to clinical development of pipeline products, including costs related to engaging third-party service providers. In the twelve months ended December 31, 2024, we incurred the expenses of RMB45.4 million to Innovent in relation to the termination of ex-China option for GFH925. No such costs incurred in the first four months of 2025. Depreciation and amortization includes depreciation of property, plant and equipment and right-of-use assets and amortization of intangible assets. IP management expenses primarily relate to our costs related to preparing and filing patent applications and maintenance of issued patents. Others primarily relates to utilities and miscellaneous fees for translation, training, transportation, communications and office expenses, among others. For the years ended December 31, 2023 and 2024, and the four months ended April 30, 2024, we incurred one-time payments of RMB3.8 million, RMB28.8 million and RMB18.9 million, respectively, related to patent licensing agreements we entered. No such costs in the first four months of 2025. For additional information, see “Risk Factors — Risks Related to Intellectual Property Rights — If we or our collaborators are unable to obtain and maintain adequate patent and other intellectual property protection for our pipeline products throughout the selected markets in the world, our ability to successfully commercialize our pipeline products may be adversely affected.”

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For the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, we recorded major items of research and development costs attributable to our Core Products, consisting of (i) CMC, material costs and preclinical development costs, (ii) clinical development costs, and termination fee and (iii) staff costs, of RMB121.1 million, RMB143.3 million, RMB78.1 million and RMB27.2 million, respectively, representing 38.7%, 43.1%, 54.9% and 39.0% of our total research and development costs in the corresponding periods, respectively.

The major items of research and development costs attributable to the Core Product GFH925, consisting of (i) CMC, material costs and preclinical development costs, (ii) clinical development costs, and termination fee and (iii) staff costs, are RMB81.5 million, RMB101.2 million, RMB73.3 million and RMB13.9 million for the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, respectively. Such research and development costs expressed as a percentage of the total operating expense, defined as the sum of research and development costs and administrative expenses, are 22.5%, 25.9%, 47.0% and 14.8% for the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, respectively.

The following table sets forth major items of research and development costs attributable to the Core Product GFH925 during the Track Record Period.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
CMC, material costs and preclinical development costs	38,579	16,341	11,224	825
Clinical development costs and termination fee	29,208	71,414	56,415	10,521
Staff costs	13,684	13,406	5,673	2,508
Subtotal of major items	81,471	101,161	73,312	13,854
Add: others*	8,979	4,955	4,561	2,428
Exclude: termination fee** . . .	—	(45,404)	(45,404)	—
Total	90,450	60,712	32,469	16,282

* Others mainly include IP management expenses, depreciation and amortisation expense and share-based compensation.

** The termination fee stands for RMB45.4 million to Innovent in connection with the termination of the ex-China option previously granted to Innovent.

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The major items of research and development costs attributable to the Core Product GF375 expressed as a percentage of the total operating expense, defined as the sum of research and development costs and administrative expenses, are 10.9%, 10.8%, 3.1 % and 14.3% for the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, respectively.

The following table sets forth major items of research and development costs attributable to the Core Product GFH375 during the Track Record Period.

	For the year ended December 31,		For the four months ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
CMC, material costs and preclinical development costs	30,228	27,506	2,279	(85)
Clinical development costs . . .	—	5,893	—	9,092
Staff costs	9,436	8,712	2,555	4,335
Subtotal of major items . . .	39,664	42,111	4,834	13,342
Others*	2,779	7,933	1,797	2,717
Total	42,443	50,044	6,631	16,059

* Others mainly include IP management expenses, depreciation and amortisation expense and share-based compensation.

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The following table sets forth the research and development costs attributable to each of our major drug candidates during the Track Record Period:

	For the year ended December 31,		For the year ended April 30,	
	2023	2024	2024	2025
	<i>(unaudited)</i>			
	<i>(RMB in thousands)</i>			
GFH925	90,450	60,712	32,469	16,282
GFH375	42,443	50,044	6,631	16,059
GFH018	48,818	20,887	7,800	821
GFH009	39,550	23,317	9,805	2,202
Other candidates	87,703	102,986	21,285	34,454
Subtotal	308,964	257,946	77,990	69,818
Payment made to pre-empt potential issues*	3,774	28,774	18,868	—
Terminations fee**	—	45,404	45,404	—
Total	312,738	332,124	142,262	69,818

* The payment was made to pre-empt potential issues over GFH925 in China with third-party patent holders such that these third-party patent holders’ patents in China would not affect the Company’s freedom to operate GFH925 and its commercialization in China.

** The termination fee stands for RMB45.4 million to Innovent in connection with the termination of the ex-China option previously granted to Innovent.

The following table sets forth the clinical development costs (including termination fee) as part of the R&D expenses incurred for the Core Products at different jurisdictions where the clinical trials are conducted in each year during the Track Record Period.

For the year ended December 31,										
(RMB in thousands)	2023					2024				
	CHN	AUS	U.S.	EU	total	CHN	AUS	U.S.	EU	TOTAL
Core Products										
GF925	—	—	432	28,776	29,208	—	—	794	70,620	71,414
GF375	—	—	—	—	—	5,893	—	—	—	5,893
For the four months ended April 30,										
(RMB in thousands)	2024					2025				
	CHN	AUS	U.S.	EU	TOTAL	CHN	AUS	U.S.	EU	total
Core Products										
GF925	—	—	591	55,824	56,415	—	—	45	10,476	10,521
GF375	—	—	—	—	—	9,092	—	—	—	9,092

FINANCIAL INFORMATION

Administrative Expenses

During the Track Record Period, our administrative expenses primarily consisted of (i) staff costs, including wages, bonus, social insurance and other welfare for our administrative personnel, (ii) professional services expenses primarily in relation to our equity financing and business collaboration activities, and annual retainer fees of our legal counsels, (iii) office, traveling and business-related expenses, a vast majority of which consisted of office expenses and traveling expenses, (iv) depreciation of property, plant and equipment and right-of-use assets and amortization of intangible assets, (v) Share-based payment compensation, (vi) [REDACTED] expense and (vii) others. The following table sets forth a breakdown of our administrative expenses for the periods indicated.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Staff costs	18,771	19,739	6,638	6,004
Share-based payment compensation	16,685	5,367	2,107	1,810
Professional services expenses	6,853	7,306	2,428	4,626
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Office, traveling and business- related expenses	3,818	4,436	1,664	1,155
Depreciation and amortization.	2,747	1,697	712	459
Others	1,072	1,173	332	402
Total	49,946	58,081	13,881	23,684

Other Expenses

During the Track Record Period, we incurred a small amount of other expenses, which was primarily attribute to the loss on disposals of property, plant and equipment. Other expenses for the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025 were RMB176 thousand, RMB10 thousand, RMB2 thousand and RMB3 thousand, respectively.

FINANCIAL INFORMATION

Finance Costs

Our finance costs consist of (i) transaction cost on issue of redemption liabilities on equity shares, (ii) interest on lease liabilities; (iii) imputed interest expense on other payables and (iv) interest on bank borrowings. The following table sets forth the components of our finance costs for the periods indicated.

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
	<i>(unaudited)</i>			
	<i>(RMB in thousands)</i>			
Transaction costs on issue of redemption liabilities on equity shares	–	11,840	11,840	–
Interest on lease liabilities . . .	1,366	1,112	389	271
Imputed interest expenses on other payables	–	4,134	1,334	1,116
Interest on bank borrowings . .	119	877	52	618
Total	1,485	17,963	13,615	2,005

The transaction costs on issue of redemption liabilities on equity shares mainly represent the consulting service fees in connection with our equity financing. We incurred imputed interest expenses on other payables for the twelve months ended December 31, 2024 primarily because we are committed to pay Innovent in several installments in relation to the termination of ex-China option for GFH925.

Change in Fair Value of Redemption Liabilities on Equity Shares

We have recognized the equity shares that we issued in the several rounds of investments that we historically received as redemption liabilities on equity shares. For additional information about those historical investments, see “History, Development and Corporate Structure” in this Document. Change in fair value of redemption liabilities on equity shares represents changes in fair value of the equity shares issued by us. The change in the fair value of our issued equity shares is charged to profit or loss.

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We used the discounted cash flow and back-solve method to determine the underlying share value of our Company and performed an equity allocation based on the option pricing model to arrive at the fair value of the redemption liabilities on equity shares as of the end of each reporting period with reference to valuation report carried out by an independent valuer. For additional information, see Note 25 of the Accountants’ Report set out in Appendix I to this Document.

Upon [REDACTED], we do not expect to recognize any further change in fair value of redemption liabilities on equity shares, as the redemption right, and the related compulsory liquidation rights, will be automatically terminated upon [REDACTED]. For additional information, see “History, Development and Corporate Structure” in this Document.

Income Tax

We are subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of our Group are domiciled and operate.

PRC

Under the Law of the PRC on Enterprise Income Tax (the “**EIT Law**”) and Implementation Regulation of the EIT Law, the Enterprise Income Tax (“**EIT**”) rate of the PRC subsidiaries was 25% during the Track Record Period except for certain members of the Group, which was subject to tax concession set out below.

Our Company was accredited as a “High and New Technology Enterprise” (“**HNTE**”) in 2022. Therefore, our Company was entitled to a preferential EIT rate of 15% during the Track Record Period. The qualification as a HNTE Enterprise is subject to review by the relevant tax authority in the PRC every three years.

In 2022, the Ministry of Finance and the State Administration of Taxation issued the Notice on the Further Implementation of Preferential Income Tax for Small and Micro Enterprises (Cai Shui [2022] No. 13), which provides that the portion of annual taxable income of small and micro enterprises exceeding RMB1.0 million but not exceeding RMB3.0 million shall be deducted to 25% of the taxable income and subject to income tax at a rate of 20% for the period from January 1, 2022 to December 31, 2027. GenFleet Zhejiang, GenFleet Beijing and GenFleet Shanghai were recognized as Small and Micro Enterprises and were entitled to a preferential tax rate of 20% during the Track Record Period.

Australia

GenFleet Australia, which was incorporated in Australia with less than AUD50.0 million of turnover, was subject to income tax at the rate of 25% on the estimated assessable profits during the Track Record Period.

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The United States

GenFleet U.S., the subsidiary incorporated and operated in the United States, was subject to the federal corporate income tax rate at 21% during the Track Record Period.

PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Four Months Ended April 30, 2024 Compared to Four Months Ended April 30, 2025

Revenue

For the four months ended April 30, 2025, we recognized RMB77.6 million revenue related to GFH375 in connection with Verastem’s exercise of its option under the Verastem Agreement in January 2025. We also recognized RMB4.3 million royalty related to GFH925 from Innovent. We have also recognized small amount of revenue from sale of goods and R&D services for the first four months in 2025. We did not recognize any revenue in the four months ended April 30, 2024.

Cost of Sales

For the four months ended April 30, 2025, we recognized cost of sales of RMB8.7 million, which was primarily attributable to cost related to sales of goods of RMB8.1 million in relation to the fulfillment of drug supply arrangement. We did not recognize any cost of sales for the four months ended April 30, 2024.

Gross Profit

For the four months ended April 30, 2025, we recognized gross profit of RMB73.5 million. As we did not recognize any revenue or incur cost of sales for the four months ended April 30, 2024, our gross profit was nil for the same period.

Other Income and Gains

Our other income and gains remained relatively stable at RMB6.1 million for the four months ended April 30, 2025 compared to RMB6.5 million for the four months ended April 30, 2024. The decrease was primarily attributable to the decrease of RMB0.4 million in government grants, and decrease of RMB0.7 million in gains on (i) fair value gains on financial assets at FVTPL and (ii) lease reassessment in the first four months of 2025, partially offset by the increase of bank interest income of RMB0.8 million in the four months ended April 30, 2025.

Research and Development Costs

Our research and development costs decreased by 50.9% from RMB142.3 million for the four months ended April 30, 2024 to RMB69.8 million for the four months ended April 30, 2025, primarily due to incurred expenses of RMB45.4 million on termination of Ex-China option and RMB18.9 million under the patent licensing agreements, each in the first four months of 2024. No such costs incurred in the first four months of 2025.

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Administrative Expenses

Our administrative expenses increased by 70.5% from RMB13.9 million for the four months ended April 30, 2024 to RMB23.7 million for the four months ended April 30, 2025. The increase was mainly driven by an increase of [REDACTED] related expenses incurred in 2025.

Finance Costs

Our finance costs decreased significantly from RMB13.6 million for the four months ended April 30, 2024 to RMB2.0 million for the four months ended April 30, 2025. The decrease was primarily attributable to the decrease of transaction cost on issue of redemption liabilities on equity shares by RMB11.8 million as a result of professional fees in connection with our series C+ financing with redemption features in the first four months of 2024. We did not recognize such transaction cost in the first four months of 2025.

Change in Fair Value of Redemption Liabilities on Equity Shares

Our change in fair value of redemption liabilities on equity shares decreased from RMB241.5 million for the four months ended April 30, 2024 to RMB50.7 million for the four months ended April 30, 2025, primarily due to the moderate growth in value of our Company.

Loss for the Period

For the reasons described above, our loss for the period decreased from RMB404.7 million for the four months ended April 30, 2024 to RMB66.6 million for the four months ended April 30, 2025.

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

Revenue

Our revenue increased from RMB73.7 million for the year ended December 31, 2023 to RMB104.7 million for the year ended December 31, 2024. Most of the revenue that we recognized during the Track Record Period was generated from licenses of intellectual property under such collaboration and out-licensing arrangements, and the increase in revenue was in line with the timing of our entry into the relevant licensing agreements and the payment schedules stipulated in those agreements and whether milestones triggering the payments were reached.

Cost of Sales

Our cost of sales increased significantly from RMB0.7 million in 2023 to RMB20.1 million in 2024, which was primarily attributable to the cost of GFH925 we supplied to Innovent.

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Gross Profit

As a result of the foregoing, our gross profit increased from RMB73.1 million for the year ended December 31, 2023 to RMB84.6 million for the year ended December 31, 2024.

Other Income and Gains

Our other income and gains decreased from RMB40.0 million for the year ended December 31, 2023 to RMB28.5 million for the year ended December 31, 2024. The decrease was primarily attributable to the decrease in government grants of RMB14.9 million and the decrease in fair value gains on financial assets at FVTPL by RMB3.2 million because the structured deposits reached maturity in 2023 and the reduced amount of new structured deposits we purchased in the year ended December 31, 2024, partially offset by the increase of bank interest income of RMB6.5 million in the year ended December 31, 2024.

Research and Development Costs

Our research and development costs increased from RMB312.7 million for the year ended December 31, 2023 to RMB332.1 million for the year ended December 31, 2024, primarily due to an increase of RMB28.8 million in others, primarily attributable to an one-time payment of RMB28.8 million under the patent licensing agreements, and was partially offset by a decrease of RMB9.2 million in staff costs.

Administrative Expenses

Our administrative expenses increased from RMB49.9 million for the year ended December 31, 2023 to RMB58.1 million for the year ended December 31, 2024. The increase was mainly driven by an increase of [REDACTED] by RMB[REDACTED].

Finance Costs

Our finance costs increased significantly from RMB1.5 million for the year ended December 31, 2023 to RMB18.0 million for the year ended December 31, 2024. The increase was primarily attributable to the increase of transaction cost on issue of redemption liabilities on equity shares by RMB11.8 million as a result of professional fees in connection with our series C+ financing with redemption features in 2024.

Change in Fair Value of Redemption Liabilities on Equity Shares

Our change in fair value of redemption liabilities on equity shares increased from RMB257.0 million for the year ended December 31, 2023 to RMB382.6 million for the year ended December 31, 2024, primarily due to the increase in value of our Company.

Loss for the Period

For the reasons described above, our loss for the period increased from RMB508.3 million for the year ended December 31, 2023 to RMB677.6 million for the year ended December 31, 2024.

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DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The following table sets forth our consolidated statements of financial position as of the dates indicated.

	As of December 31,		As of April 30,
	2023	2024	2025
	(RMB in thousands)		
NON-CURRENT ASSETS			
Property, plant and equipment	20,601	12,328	10,325
Right-of-use assets	23,361	15,412	14,212
Intangible assets	1,401	1,257	1,198
Prepayments, other receivables and other assets	8,275	9,576	9,730
Time deposits	31,752	—	—
Total non-current assets	85,390	38,573	35,465
CURRENT ASSETS			
Inventories	2,058	5,586	918
Trade receivables	72,353	109,153	97,518
Prepayments, other receivables and other assets	44,136	58,594	56,013
Time deposits	—	32,790	—
Cash and cash equivalents	332,197	362,125	390,766
Total current assets	450,744	568,248	545,215
CURRENT LIABILITIES			
Trade and other payables	82,847	181,733	159,406
Interest-bearing bank borrowings	5,312	51,128	85,117
Contract liabilities	101,914	42,204	12,348
Redemption liabilities on equity shares	1,636,508	2,214,121	2,264,813
Lease liabilities	5,526	4,243	3,345
Total current liabilities	1,832,107	2,493,429	2,525,029
Net current liabilities	(1,381,363)	(1,925,181)	(1,979,814)
Total assets less current liabilities	(1,295,973)	(1,886,608)	(1,944,349)
NON-CURRENT LIABILITIES			
Lease liabilities	20,835	13,977	12,861
Deferred income	503	—	—
Trade and other payables	—	55,676	56,429
Total non-current liabilities	21,338	69,653	69,290
Net liabilities	(1,317,311)	(1,956,261)	(2,013,639)
DEFICIENCY IN EQUITY			
Equity attributable to owners of the Company			
Paid-in capital/Share capital	22,027	26,774	26,774
Reserves	(1,339,338)	(1,983,035)	(2,040,413)
Controlling interests	(1,317,311)	(1,956,261)	(2,013,639)
Net deficits	(1,317,311)	(1,956,261)	(2,013,639)

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The following table sets forth our current assets and current liabilities as of the dates indicated.

	As of December 31,		As of April 30,	As of July 31,
	2023	2024	2025	2025
	(RMB in thousands)			(unaudited)
Current assets				
Inventories	2,058	5,586	918	892
Trade receivables	72,353	109,153	97,518	93,363
Prepayments, other receivables and other assets	44,136	58,594	56,013	55,231
Time deposits	–	32,790	–	–
Cash and cash equivalents . .	332,197	362,125	390,766	358,310
Total current assets	450,744	568,248	545,215	507,796
Current liabilities				
Trade and other payables . . .	82,847	181,733	159,406	183,607
Interest-bearing bank borrowings	5,312	51,128	85,117	74,209
Contract liabilities	101,914	42,204	12,348	32,759
Redemption liabilities on equity shares	1,636,508	2,214,121	2,264,813	3,199,126
Lease liabilities	5,526	4,243	3,345	3,419
Total current liabilities	1,832,107	2,493,429	2,525,029	3,493,120
NET CURRENT				
LIABILITIES	(1,381,363)	(1,925,181)	(1,979,814)	(2,985,324)

During the Track Record Period, we had net liabilities position, which was primarily due to the significant total comprehensive loss for the year/period in each year/period of the Track Record Period caused by the significant redemption liabilities on equity shares and increased research and development costs in each year/period of the Track Record Period. The increase of net liabilities from RMB1,956.3 million as of December 31, 2024 to RMB2,013.6 million as of April 30, 2025 was primarily due to the loss for the period year of RMB66.6 million mainly driven by the research and development costs we incurred and an increase in fair value of the Shares held by [REDACTED] Investors. The increase of net liabilities from RMB1,317.3 million as of December 31, 2023 to RMB1,956.3 million as of December 31, 2024 was primarily due to the loss for the year of RMB677.6 million mainly driven by the research and development costs we incurred and an increase in fair value of the Shares held by [REDACTED] Investors.

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The increase of net current liabilities by RMB543.8 million from RMB1,381.4 million as of December 31, 2023 to RMB1,925.2 million as of December 31, 2024 was primarily driven by an increase of (i) redemption liabilities on equity shares by RMB577.6 million, (ii) trade and other payables of RMB98.9 million primarily from the payables under the termination of the ex-China option and (iii) interest-bearing bank borrowings of RMB45.8 million, partially offset by an increase of (i) time deposits and cash and cash equivalents of RMB62.7 million and (ii) trade receivables of RMB36.8 million as well as a decrease in contract liabilities of RMB59.7 million, primarily attributable to the termination in January 2024 of the ex-China option previously granted to Innovent for GFH925, as well as the recognition of contractual obligations under the Verastem Agreement following the receipt of payments in 2024.

Our net current liabilities as of April 30, 2025 remained relatively stable and increased by 2.8% to RMB1,979.8 million, primarily due to the increase of interest-bearing bank borrowings of RMB34.0 million and redemption liabilities on equity shares by RMB50.7 million, partially offset by a decrease in trade and other payables of RMB22.3 million and contract liabilities of RMB29.9 million.

The increase of net liabilities by RMB639.0 million from December 31, 2023 to December 31, 2024 was primarily driven by our total comprehensive loss for the year in 2024 of RMB678.8 million, which was further driven by the significant amount of research and development costs of RMB332.1 million and change in fair value of redemption liabilities on equity shares of RMB382.6 million.

Our net liabilities as of April 30, 2025 remained relatively stable and increased by RMB57.3 million to RMB2,013.6 million, primarily due to our total comprehensive loss for the period in the first four months of 2025 of RMB66.2 million, which was further driven by the significant amount of research and development costs of RMB69.8 million and change in fair value of redemption liabilities on equity shares of RMB50.7 million.

Upon the [REDACTED], we expect to record equity shares issued in connection with [REDACTED] Investments as equity and do not expect to recognize any redemption liabilities on these equity shares, or recognize any future loss or gains in connection with such redemption liabilities on our consolidated statements of profit or loss and other comprehensive income. We therefore expect to have a net asset position rather than a net liability position upon the [REDACTED]. We will also take additional measures to improve our financial position. For additional information, see “— Liquidity and Capital Resources.”

Property, plant and equipment

Our property, plant and equipment primarily consists of machinery and equipment, computer and office equipment, motor vehicles and leasehold improvements. The following table sets forth a breakdown of the net carrying amount of our property, plant and equipment as of the dates indicated.

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	As of December 31,		As of April 30,
	2023	2024	2025
	<i>(RMB in thousands)</i>		
Machinery and equipment	17,812	11,419	9,581
Computer and office equipment	1,280	576	492
Motor vehicles	575	333	252
Leasehold improvements	934	—	—
Total	20,601	12,328	10,325

Our property, plant and equipment decreased from RMB20.6 million as of December 31, 2023 to RMB12.3 million as of December 31, 2024, primarily attributable to the depreciation of machinery and equipment of RMB6.4 million for the year ended December 31, 2024.

Our property, plant and equipment decreased from RMB12.3 million as of December 31, 2024 to RMB10.3 million as of April 30, 2025, primarily attributable to the depreciation of machinery and equipment of RMB1.8 million for the four months ended April 30, 2025.

Right-of-use assets

Our right-of-use assets are primarily related to our leased office premises used in our operations. Leases of office premises generally have lease terms between two and 10 years. Our right-of-use assets decreased from RMB23.4 million as of December 31, 2023 to RMB15.4 million as of December 31, 2024, primarily due to a depreciation charge of RMB5.4 million and reassessment of a lease term arising from a decision not to exercise the extension option, which decreased the right-of-use assets by RMB2.5 million in the year ended December 31, 2024. Our right-of-use assets decreased from RMB15.4 million as of December 31, 2024 to RMB14.2 million as of April 30, 2025, primarily due to a depreciation charge of RMB1.4 million in the four months ended April 30, 2025.

Intangible assets

Our intangible assets include computer software related to our business operations. The net carrying amount of our intangible assets slightly decreased from RMB1.4 million as of December 31, 2023 to RMB1.3 million as of December 31, 2024, primarily attributable to the amortization of our compute software in the year ended December 31, 2024. The net carrying amount of our intangible assets slightly decreased to RMB1.2 million as of April 30, 2025, primarily attributable to the amortization of our compute software of RMB59 thousand in the four months ended April 30, 2025.

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Trade receivables

During the Track Record Period, our trade receivables consisted of receivables from our collaboration partners for payment (including milestone payment) obligations set out in the relevant agreements. The following table sets forth the details of our trade receivables as of the dates indicated.

	As of December 31,		As of April 30,
	2023	2024	2025
<i>(RMB in thousands)</i>			
Trade receivables	72,353	109,153	97,518
Impairment	—	—	—
Total	72,353	109,153	97,518

Our trade receivables increased from RMB72.4 million as of December 31, 2023 to RMB109.2 million as of December 31, 2024 and decreased to RMB97.5 million as of April 30, 2025, generally in line with the research and development activities of our collaborators in relation to the out-license and collaboration programs, as well as the milestones achieved within such periods.

The following table sets forth an aging analysis of our trade receivables as of the dates indicated.

	As of December 31,		As of April 30,
	2023	2024	2025
<i>(RMB in thousands)</i>			
Within 1 year	72,353	109,153	97,518
Total	72,353	109,153	97,518

As of July 31, 2025, RMB7.6 million, or 7.8% of our trade receivables as of April 30, 2025 had been subsequently settled. The Company does not expect any material recoverability issues with respect to the Company’s trade receivables. As of April 30, 2025, approximately 92.6% of the trade receivables were due from Innovent, arising from the licensing and collaboration agreements. Innovent is a limited liability company listed on the Hong Kong Stock Exchange. Based on the financial information disclosed in its latest annual report, there are no indications of concerns regarding its ability to meet repayment obligations. In addition, Innovent has been consistently fulfilling its payment obligations, with trade receivables being settled on an ongoing basis.

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Prepayments, other receivables and other assets

Our prepayments, other receivables and other assets primarily consisted of (i) prepayments for research and development services; (ii) value-added tax recoverable, representing value-added tax paid by us on purchases that are deductible against future value-added tax payable; (iii) rental and other deposits, with deposits mainly in connection with our offices as well as third-party research and development services; (iv) other prepayments including our prepayments for various business-related activities, such as patent filing, legal consulting and financing; and (v) other receivables including disbursement on behalf of Innovent and SELLAS, which are to be borne by Innovent and SELLAS, in connection with our research and/or manufacturing activities.

The following table sets forth the components of our prepayments, other receivables and other assets as of the dates indicated:

	As of December 31,		As of April 30,
	2023	2024	2025
	(RMB in thousands)		
Non-current			
Rental and other deposits	1,480	1,514	1,514
Value-added tax recoverable	6,635	7,865	8,017
Others	160	197	199
Subtotal	8,275	9,576	9,730
Current			
Prepayments for research and development and other services	26,755	22,194	26,176
Rental and other deposits	7,375	7,139	3,576
Value-added tax recoverable	4,537	10,719	16,771
Deferred [REDACTED] expense	[REDACTED]	[REDACTED]	[REDACTED]
Other receivables	5,469	15,420	4,816
Subtotal	44,136	58,594	56,013
Total	52,411	68,170	65,743

Our prepayments, other receivables and other assets increased from RMB52.4 million as of December 31, 2023 to RMB68.2 million as of December 31, 2024, primarily due to the increase of value-added tax recoverable by RMB7.4 million and payment advances for certain CMC activities of RMB15.0 million.

Our prepayments, other receivables and other assets decreased from RMB68.2 million as of December 31, 2024 to RMB65.7 million as of April 30, 2025, primarily due to the decrease of other receivables of RMB10.6 million, partially offset by the increase of value-added tax recoverable of RMB6.1 million and prepayments for research and development services and other services of RMB4.0 million.

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As of July 31, 2025, RMB5.0 million, or 9.0% of the current portion of our prepayments, other receivables and other assets as of April 30, 2025 had been subsequently settled.

Time deposits

All time deposits held at bank with original maturities over three months and less than one year with corresponding interest receivables are classified as our current assets. Time deposits held at bank with original maturities over one year with corresponding interest receivables are classified as our non-current assets. Most of our time deposits were denominated in the U.S. dollar.

	As of December 31,		As of April 30,
	2023	2024	2025
	(RMB in thousands)		
Time deposits over three months but less than one year	–	32,790	–
Time deposits over one year	31,752	–	–
Total	31,752	32,790	–

Our time deposits remained relatively stable at RMB31.8 million as of December 31, 2023 and RMB32.8 million as of December 31, 2024, respectively.

We do not have time deposits as of April 30, 2025.

Inventories

During the Track Record Period, we had a relatively insignificant amount of inventories, which primarily consisted of reagents and consumables for preclinical activities. Our inventories increased from RMB2.1 million as of December 31, 2023 to RMB5.6 million as of December 31, 2024, generally in line with our R&D activities. Our inventories further decreased to RMB0.9 million as of April 30, 2025, generally in line with our R&D activities.

As of July 31, 2025, RMB0.2 million, or 18.8% of our inventories as of April 30, 2025 had been consumed.

Financial assets at FVTPL

Our financial assets at FVTPL during the Track Record Period represents the structured deposits we purchased as part of our wealth management to generate reasonable low risk returns. The purchases of structured deposits were approved by our senior management team. Such structure deposits were principal guaranteed and purchased from reputable banks in the PRC. We had financial assets at FVTPL of nil, nil and nil as of December 31, 2023 and December 31, 2024 and April 30, 2025, respectively, since our financial assets at FVTPL reached maturity in 2023, and our financial assets at FVTPL purchased in 2024 reached maturity before December 31, 2024, and we did not purchase such financial assets in the first four months of 2025.

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With regards to the purchase of wealth management products, we have formulated the investment policy of diversifying risks and generating steady returns on the premise of ensuring the safety of funds. Our finance manager 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 internal control measures to control our process of investment in wealth management products;
- Our Board authorizes and supervises the finance manager to approve through a strict review and decision-making process, and our General Manager and/or Chairman of the Board are responsible for the approval of our material investments in wealth management products;
- Our finance department is responsible for the analysis and research of investments in wealth management products, as well as the long-term routine management of such investments; and
- 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 evaluate the sufficiency of our remaining working capital for our business needs, operating activities, research and development and capital expenditures following the proposed investment. We adopt a prudent approach in selecting financial assets. Our investment strategy related to financial assets focuses on minimizing the financial risks by reasonably and conservatively matching the maturities of the portfolio to anticipated operating cash needs, while generating desirable investment returns for the benefits of our shareholders. We make investment decisions related to financial assets on a case-by-case basis after thoroughly considering a number of factors, including but not limited to the macro-economic environment, general market conditions, risk control and credit of invested subjects, our own working capital conditions, and the expected profit or potential loss of the investment. 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.

To the extent that we will have surplus cash that is not required for our short-term working capital purposes, we will continue to consider investing in wealth management products taking into account the considerations above as appropriate to be in our best interest. Our investments in wealth management products after the [REDACTED] will be subject to compliance with Chapter 14 of the Listing Rules.

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Cash and cash equivalents

Our cash and cash equivalents primarily consisted of cash at banks. The following table sets forth a breakdown of our cash and cash equivalents by currency type as of the dates indicated.

	As of December 31,		As of April 30,
	2023	2024	2025
<i>(RMB in thousands)</i>			
Denominated in:			
– Renminbi	75,183	24,714	74,224
– U.S. dollar	238,818	319,040	303,165
– Australian dollar	18,196	18,371	13,377
Total	332,197	362,125	390,766

Our cash and cash equivalents increased from RMB332.2 million as of December 31, 2023 to RMB362.1 million as of December 31, 2024 and further to RMB390.8 million as of April 30, 2025. For an analysis on cash flows during the Track Record Period, see “—Liquidity and Capital Resources.”

Trade and other payables

Our trade and other payables primarily related to our purchases of materials and third-party contracting services in relation to our research and development activities. The following table sets forth a breakdown of our trade and other payables.

	As of December 31,		As of April 30,
	2023	2024	2025
<i>(RMB in thousands)</i>			
Current:			
Trade payables	8,355	6,292	10,836
Payroll payables	19,656	17,711	8,561
Accrued expenses for research and development services	49,335	73,704	63,964
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Other taxes payables	1,088	987	684
Other payables			
– License-out agreement option termination fee	–	68,573	69,112
– Accrued expenses	3,910	1,216	688
– Others	503	544	181
Total	82,847	181,733	159,406

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	As of December 31,		As of April 30,
	2023	2024	2025
<i>(RMB in thousands)</i>			
Non-current:			
License-out agreement option			
termination fee	—	55,676	56,429
Total	—	55,676	56,429

The current portion of our trade and other payables increased from RMB82.8 million as of December 31, 2023 to RMB181.7 million as of December 31, 2024, primarily due to the license-out agreement option termination fee of RMB68.6 million as of December 31, 2024 primarily in relation to our agreement with Innovent in January 2024 to terminate the ex-China option previously granted to Innovent regarding GFH925. We also had a non-current portion of the trade and other payables of RMB55.7 million due to the same reason. For additional information about the agreement, see “Business — Major Collaboration and Licensing Arrangements — Supplementary Agreement with Innovent.”

The current portion of our trade and other payables decreased from RMB181.7 million as of December 31, 2024 to RMB159.4 million as of April 30, 2025, primarily due to (i) the increase in trade payables of RMB4.5 million, (ii) the decrease in payroll payables of RMB9.2 million and (iii) the decrease in accrued [REDACTED] expense of RMB[REDACTED]. We had a non-current portion of the trade and other payables, representing license-out agreement option termination fee of RMB56.4 million as of April 30, 2025 primarily in relation to our agreement with Innovent in January 2024 to terminate the ex-China option previously granted to Innovent regarding GFH925. For additional information about the agreement, see “Business — Major Collaboration and Licensing Arrangements — Supplementary Agreement with Innovent.”

The following table sets forth an aging analysis of our trade payables based on the invoice date as of the dates indicated.

	As of December 31,		As of April 30,
	2023	2024	2025
<i>(RMB in thousands)</i>			
Within 3 months	8,355	6,292	10,836
Total	8,355	6,292	10,836

Our trade payables are non-interest-bearing and are typically settled on terms of one to three months of the invoice date.

As of July 31, 2025, RMB10.8 million, or 100.0%, of our trade payables as of April 30, 2025 had been subsequently settled.

FINANCIAL INFORMATION

Contract liabilities

Our contract liabilities primarily represented the obligations to transfer the ex-China right of GFH925 pursuant to an ex-China option to Innovent and the obligations to transfer the ex-China right of GFH375 pursuant to an option granted to Verastem, respectively.

In January 2024, we entered into an agreement with Innovent to terminate the ex-China option of GFH925. In January 2025, Verastem exercised the ex-China option of GFH375. We have gradually fulfilled our contractual obligations under the aforementioned contracts in the Track Record Period, which is the primarily underlying reason for a decrease of contractual liabilities from RMB101.9 million as of December 31, 2023 to RMB42.2 million as of December 31, 2024 and further to RMB12.3 million as of April 30, 2025. For additional information about our agreements with Innovent, see “Business — Major Collaboration and Licensing Arrangements.”

As of July 31, 2025, RMB0.4 million, or 3.3% of our outstanding contract liabilities as of April 30, 2025 has been subsequently recognized as revenue.

Redemption liabilities on equity shares

We have recognized the equity shares that we issued in the several rounds of investments that we historically received as redemption liabilities on equity shares. For additional information about those historical investments, see “History, Development and Corporate Structure” and Note 25 of the Accountants’ Report set out in Appendix I to this Document.

During the Track Record Period, we had increased redemption liabilities on equity shares from RMB1,636.5 million as of December 31, 2023 to RMB2,214.1 million as of December 31, 2024 and further to RMB2,264.8 million as of April 30, 2025. Such increments were in line with our issuance of additional equity shares with redemption features to raise capital and the increase in value of Shares held by [REDACTED] Investors.

Lease liabilities

The following table sets forth our lease liabilities as of the dates indicated.

	As of December 31,		As of April 30,
	2023	2024	2025
	(RMB in thousands)		
Current	5,526	4,243	3,345
Non-current	20,835	13,977	12,861
Total	26,361	18,220	16,206

FINANCIAL INFORMATION

Our lease liabilities decreased from RMB26.4 million as of December 31, 2023 to RMB18.2 million as of December 31, 2024, primarily attributable to (i) our lease payments in the year ended December 31, 2024 of RMB6.3 million and (ii) a reassessment of a lease term arising from a decision not to exercise the extension option, which decreased our lease liabilities by RMB3.0 million as of December 31, 2024.

Our lease liabilities further decreased to RMB16.2 million as of April 30, 2025 primarily due to our lease payments in the first four months of 2025 of RMB2.5 million.

Deferred income

Our deferred income decreased from RMB0.5 million as of December 31, 2023 to nil as of December 31, 2024, primarily due to recognizing RMB6.9 million of government grants as income in 2024, partially offset by a receipt of government grants of RMB6.4 million during the same period.

We had RMBnil deferred income as of April 30, 2025.

LIQUIDITY AND CAPITAL RESOURCES

Overview

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 addition, we monitor the utilization of borrowings and, from time to time, evaluate the options to renew the borrowings upon expiry based on our actual business requirement. We relied on equity financing as the major sources of liquidity during the Track Record Period.

During the Track Record Period, we incurred negative cash flows from our operations and our operating cash outflows mainly resulted from our research and development costs. Our operating activities used RMB202.1 million, RMB206.4 million, RMB136.9 million and RMB34.0 million for the years ended December 31, 2023 and 2024 and four months ended April 30, 2024 and 2025, respectively. We expect to generate more cash flow from our operating activities, through income from launching and commercializing GFH925, forging productive collaboration agreements with third parties, advancing the development and eventually commercializing GFH925 overseas and other pipeline products, and enhancing our cost containment capacity and operating efficiency. In order to bring to fruition our research and development objectives, we will ultimately need additional funding sources and there can be no assurances that they will be made available.

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Cash Flows

The following table sets forth key items of our consolidated statements of cash flows for the periods indicated:

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Operating activities				
Cash used in operating activities	(211,792)	(222,266)	(140,384)	(38,670)
Interest received	9,732	15,866	3,439	4,625
Net cash flows used in operating activities	(202,060)	(206,400)	(136,945)	(34,045)
Investing activities				
Purchases of items of property, plant and equipment	(594)	(236)	(5)	(11)
Purchases for other intangible assets	—	(32)	—	—
Purchases of financial assets at FVTPL	(480,000)	(170,000)	(110,000)	—
Withdrawal of financial assets at FVTPL	744,024	170,402	90,222	—
Proceeds from disposal of property, plant and equipment	13	4	4	—
Proceeds from withdrawal of time deposits with original maturity of more than three months	—	124,560	16,290	33,151
Purchases of time deposits with original maturity of more than three months	—	(123,968)	(119,227)	—
Net cash flows from/(used in) investing activities	263,443	730	(122,716)	33,140
Financing activities				
New bank borrowings	5,312	56,928	5,800	54,900
Repayment of bank borrowings	(22,767)	(11,112)	—	(21,128)

FINANCIAL INFORMATION

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
	(unaudited)			
	(RMB in thousands)			
Interest paid on bank borrowings	(119)	(877)	(52)	(401)
Principal portion of lease payments	(5,402)	(5,144)	(1,627)	(2,187)
Interest paid for lease liabilities	(1,366)	(1,112)	(389)	(271)
Proceeds on issue of shares . .	–	207,871	207,871	–
Payment of [REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Issued costs paid	(4,717)	(11,840)	(6,698)	–
Net cash flows (used in)/from financing activities	(29,059)	233,438	204,905	28,182
Net increase/(decrease) in cash and cash equivalents . .	32,324	27,768	(54,756)	27,277
Cash and cash equivalents at beginning of year/period . . .	295,321	332,197	332,197	362,125
Effects of foreign exchange rate changes, net	4,552	2,160	585	1,364
Cash and cash equivalents at end of year/period	332,197	362,125	278,026	390,766

Operating Activities

In the four months ended April 30, 2025, our net cash used in operating activities was RMB34.0 million, which was primarily attributable to our loss before tax of RMB66.6 million, primarily adjusted for (i) fair value loss on redemption liabilities on equity shares of RMB50.7 million, (ii) decrease in trade and other payables of RMB21.5 million, (iii) decrease in inventories of RMB4.7 million, (iv) decrease in contract liabilities of RMB29.9 million.

In 2024, our net cash used in operating activities was RMB206.4 million, which was primarily attributable to our loss before tax of RMB677.6 million, primarily adjusted for (i) fair value loss on redemption liabilities on equity shares of RMB382.6 million, (ii) increase in trade and other payables of RMB148.6 million, (iii) decrease in contract liabilities of RMB59.7 million, (iv) share-based payment compensation of RMB26.9 million and (v) finance costs of RMB18.0 million.

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In 2023, our net cash used in operating activities was RMB202.1 million, which was primarily attributable to our loss before tax of RMB508.3 million, primarily adjusted for (i) fair value loss on redemption liabilities on equity shares of RMB257.0 million, (ii) share-based payment compensation of RMB37.0 million, (iii) increase in trade receivables of RMB32.9 million and (iv) decrease in prepayments, other receivables and other assets of RMB14.7 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:

- rapidly advancing our pipeline products towards commercialization to generate revenue from product sales. For our Core Product GFH925, we expect to generate inflow of cash from the commercialization of GFH925 in China. We are conducting and planning to conduct further clinical development of GFH925 in overseas jurisdictions, such as in the United States and Europe to pave the way for launching and commercializing GFH925 overseas to maximize its value. We also plan to advance GFH375 clinical trial in China to further validate its clinical safety and efficacy profiles. In addition to our Core Products, we have been optimizing our product portfolio and propelling it from preclinical stage toward clinical studies. As we achieve regulatory approvals for more pipeline products, we expect to generate a steady inflow of cash from sales of pipeline products in the foreseeable future;
- entering into collaboration and licensing agreements with major pharmaceutical companies for the co-development of our pipeline products, and activity pursuing business development opportunities at every stage of the development of our product candidates; and
- adopting comprehensive measures to effectively control our cost and operating expenses. For example, we plan to continue to regularly evaluate our existing and future arrangements and actively seek mutually beneficial strategic cooperations to control our research and development costs.

Investing Activities

For the four months ended April 30, 2025, our net cash from investing activities was RMB33.1 million, primarily as a result of proceeds from withdrawal of time deposits with original maturity of more than three months of RMB33.2 million.

In 2024, our net cash generated from investing activities was RMB0.7 million, primarily as a result of the offsetting effect of purchases and withdrawal of financial assets at FVTPL, and purchases and proceeds from time deposits with original maturity of more than three months.

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In 2023, our net cash generated from investing activities was RMB263.4 million, which was primarily attributable to disposal of financial assets at FVTPL of RMB744.0 million, partially offset by purchases of financial assets at FVTPL of RMB480.0 million.

Financing Activities

In the four months ended April 30, 2025, we had RMB28.2 million of net cash inflow from financing activities, primarily attributable to the proceeds from new bank borrowings of RMB54.9 million, offset by repayment of bank borrowings of RMB21.1 million.

In 2024, we had RMB233.4 million of net cash inflow from financing activities, primarily attributable to the capital contributions from investors of RMB207.9 million in connection with our series C+ equity financing round and proceeds from new bank borrowings of RMB56.9 million.

In 2023, we had RMB29.1 million of net cash outflow from financing activities, primarily attributable to our repayment of bank borrowings of RMB22.8 million.

CASH OPERATING COSTS

The following table sets forth information on our cash operating costs for the periods indicated.

Research and development costs	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	

Research and development costs for Core Products

– Clinical development costs and termination fee .	26,449	43,406	20,435	9,596
– staff costs	23,322	22,798	11,284	8,138
– CMC and Preclinical development costs	70,976	58,082	25,088	20,069

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Research and development costs	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Research and development costs for other product candidates				
– Clinical development costs	57,626	24,767	10,013	2,017
– staff costs	55,560	48,316	20,112	18,547
– CMC and Preclinical development costs	31,562	43,808	11,030	3,839
Workforce employment costs	19,087	19,345	7,619	7,849
	284,582	260,522	105,581	70,055

WORKING CAPITAL CONFIRMATION

Our Directors are of the opinion that, taking into account the financial resources available, including cash and cash equivalents, the expected income from commercialization of GFH925 in China, and the estimated net [REDACTED] from the [REDACTED], as well as our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses for at least the next 12 months from the date of this Document.

Our cash burn rate refers to the average monthly amount of net cash used in operating activities, capital expenditures and lease payments. Assuming an average cash burn rate going forward of 1.1 times the level in 2024, we estimate that our cash at bank and on hand and other financial assets as of September 30, 2025 will be able to maintain our financial viability for [REDACTED] from September 30, 2025 taking into account the estimated net [REDACTED] from the [REDACTED]; or we estimate that we will be able to maintain our financial viability for [REDACTED] from September 30, 2025 without taking into account the estimated net [REDACTED] from the [REDACTED]. 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.

FINANCIAL INFORMATION

[REDACTED]

FINANCIAL INFORMATION

CAPITAL EXPENDITURES

The following table sets forth our capital expenditures for the periods indicated:

	For the Year Ended December 31,		For the Four Months Ended April 30,	
	2023	2024	2024	2025
	<i>(RMB in thousands)</i>			

Purchase of property, plant and equipment	594	236	5	11

Our historical capital expenditures during the Track Record Period primarily included purchases of property, plant and equipment. We funded our capital expenditure requirements during the Track Record Period mainly from equity financing. We plan to fund our planned capital expenditures using our cash at bank and the net [REDACTED] received from the [REDACTED]. Please refer to the section headed “Use of [REDACTED]” in this document for more details. We may reallocate the fund to be utilized on capital expenditure based on our ongoing business needs.

CONTRACTUAL COMMITMENTS

We had the following contractual commitments as of the dates indicated:

	As of December 31,		As of April 30,
	2023	2024	2025
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Property, plant and equipment	5	1	—

CONTINGENT LIABILITIES

As of December 31, 2023 and 2024 and April 30, 2025, we did not have any contingent liabilities. We confirm that as of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

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RELATED PARTY TRANSACTIONS

During the Track Record Period, we had one transaction with a related party in accordance with the terms agreed with the counterparty. Details of our transaction with the related party during the Track Record Period are set out in Note 33 to the Accountants’ Report included in Appendix I to this Document. Our Directors confirm that the material related party transaction during the Track Record Period was conducted on an arm’s length basis, and would not distort our results of operations over the Track Record Period or make our historical results over the Track Record Period not reflective of our expectations for our future performance.

KEY FINANCIAL RATIOS

The table below sets forth the current ratio of our Group as of the dates indicated:

	As of December 31,		As of April 30,
	2023	2024	2025
Current ratio ⁽¹⁾	0.25	0.23	0.22

Note:

(1) Current ratio equals current assets divided by current liabilities as of the end of the year/period.

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 36 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 financing activities by subsidiaries in currencies other than the subsidiaries’ functional currencies. For further details, including relevant sensitivity analysis, see Note 36 to the Accountants’ Report in Appendix I to this Document.

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Credit Risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss. Our credit risk is primarily attributable to trade and other receivables. We trade only with recognized and creditworthy third parties. Management has a credit policy in place and the exposure to credit risk is monitored on an ongoing basis. 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.

Our management has assessed that during the Track Record Period, trade receivables have not had a significant increase in credit risk since initial recognition. Our management has applied the simplified approach to provide for ECLs prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade and other receivables. Our management expects the occurrence of losses from non-performance by counterparties of trade and other receivables to be remote and no loss allowance for impairment of trade and other receivables is provided as of April 30, 2025.

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 further details, see Note 36 to the Accountants’ Report set out in Appendix I to this Document.

DIVIDEND

We have never declared or paid any dividends on our ordinary shares or any other securities. As of the Latest Practicable Date, we did not have a formal dividend policy. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not intend to declare or pay any dividends in the foreseeable future. [REDACTED] should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Directors subject to our Articles of Association and the PRC Company Law, and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China.

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As confirmed by our PRC Legal Advisor, 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.

DISTRIBUTABLE RESERVES

As of April 30, 2025, our Company did not have any distributable reserves.

[REDACTED]-RELATED EXPENSE INCURRED AND TO BE INCURRED

Our [REDACTED] expenses represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. Assuming an [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED], we estimated that the total [REDACTED] expenses for the [REDACTED] are approximately HK\$[REDACTED], accounting for approximately [REDACTED] of the gross [REDACTED] from the [REDACTED] (assuming no H Shares are issued pursuant to the [REDACTED] or the [REDACTED]), of which approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss and other comprehensive income upon the completion of [REDACTED], and approximately HK\$[REDACTED] is expected to be accounted for as a deduction from equity upon the completion of [REDACTED]. The above expenses comprise of (i) [REDACTED], including [REDACTED] and other expenses, of HK\$[REDACTED]; and (ii) [REDACTED] expenses of HK\$[REDACTED], including (a) fee paid and payable to legal advisors and reporting accountants of HK\$ [REDACTED], and (b) other fees and expenses of HK\$[REDACTED]. HK\$[REDACTED] of [REDACTED] expenses has been recognized in profit or loss during the Track Record Period. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

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[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 April 30, 2025 (being the date on which the latest consolidated financial information of our Group was prepared) and there has been no event since April 30, 2025 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, 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

For further details of our future plans, please see the section headed “Business — Strategies” in this Document.

USE OF [REDACTED]

We estimate that the aggregate net [REDACTED] to our Company from the [REDACTED] will be approximately HK\$[REDACTED], after deducting [REDACTED] fees and estimated expenses in connection with the [REDACTED] payable by us and assuming that the [REDACTED] the [REDACTED] are not exercised and an [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED] stated in this Document.

We intend to apply such net [REDACTED] from the [REDACTED] for the following purposes:

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund further development of our Core Products GFH925 and GFH375, which includes:
 - approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the clinical development of GFH925.
 - approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the Phase III clinical trial to evaluate the safety and efficacy of the GFH925/cetuximab combination therapy as a first-line treatment for NSCLC harboring the KRAS G12C mutation, which we plan to initiate in United States in the fourth quarter of 2025. The planned Phase III clinical trial in the U.S. is designed to be part of a multi-regional study in U.S. and EU, and may support future global registration in multiple regions. In EU, we plan to conduct the Phase III trial in Spain, Italy and Greece. We would also consider conducting the Phase III trial in other EU member states where there are extensive experience in conducting clinical trials and KRAS testing capacity for lung cancers.
 - approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund other costs associated with the clinical development of GFH925, including CMC and staff costs. To reduce the production cost, we are actively developing a second-generation manufacturing process for GGH925, which we expect to adopt in 2026. Compared with the first-generation manufacturing process, the

FUTURE PLANS AND USE OF [REDACTED]

second-generation manufacturing process is expected to generate products of the same quality while achieving over 50% of cost reduction. We are taking full responsibility for the entire process, including vendor selection.

The [REDACTED] allocated for GFH925 is only in relation to our clinical trials in ex-Greater China and the process development; they are not related to the our collaboration or arrangement with Innovent.

We have incurred RMB81.5 million, RMB101.2 million, RMB73.3 million and RMB13.9 million major items of research and development costs attributable to GFH925 in 2023, 2024 and four months ended April 30, 2024 and 2025.

We anticipate completing the KROCUS Phase II trial in the fourth quarter of 2025. We plan to leverage the clinical results of the KROCUS trial to apply for a Phase III clinical trial in the United States to evaluate the safety and efficacy of the GFH925/cetuximab combination therapy as a first-line treatment for NSCLC harboring the KRAS G12C mutation.

For further details, please see the section headed “Business — Our RAS Matrix Pipeline Products — Core Product GFH925: A Small Molecule Inhibitor of KRAS G12C — Clinical Development Plan” in this Document.

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the clinical development of GFH375 in China.
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the Phase II part of the Phase I/II clinical trial of GFH375 in patients with advanced solid tumors harboring the KRAS G12D mutation, which we initiated in China in February 2025.
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the planned GFH375X1201 study, which is a separate Phase II clinical trial of GFH375 in patients with metastatic PDAC harboring the KRAS G12D mutation. The purpose of initiating the GFH375X1201 study is to evaluate GFH375 as a potential treatment for PDAC, the lead indication of GFH375.
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the planned Phase III clinical trial of GFH375 in patients with advanced solid tumors (expected to include PDAC, NSCLC and CRC) harboring the KRAS G12D mutation.

FUTURE PLANS AND USE OF [REDACTED]

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund other costs associated with the clinical development of GFH375, including CMC and staff costs. We expect our GFH375 once entering into commercialization stage will require the use of our in-house manufacturing facility under construction in Zhejiang Province, which has a designed annual capacity of 100 million tablets.

We have incurred RMB39.7 million, RMB42.1 million, RMB4.8 million and RMB13.3 million major items of research and development costs attributable to GFH375 in 2023, 2024 and four months ended April 30, 2024 and 2025.

We have initiated the Phase II part of the Phase I/II clinical trial in patients with advanced solid tumors harboring the KRAS G12D mutation in China in February 2025. We expect to submit to the NMPA a pre-pivotal study communication request in the third quarter of 2025 and initiate a pivotal clinical study of GFH375 as a treatment of PDAC in the fourth quarter of 2025.

For further details, please see the section headed “Business — Our RAS Matrix Pipeline Products — GFH375: A Small Molecule Inhibitor of KRAS G12D — Clinical Development Plan” in this Document.

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund the development of our other product candidates such as GFH312, GFS202A, GFH276, GFS784 and other preclinical candidates. In particular, approximately HK\$[REDACTED], representing around [REDACTED]% of the net [REDACTED], is expected to be allocated to fund the clinical and regulatory costs associated with the Phase II and Phase III trials of GFH312 as monotherapy for PBC in China. For further details, please see the section headed “Business — Other Pipeline Products” in this Document; and

We submitted an IND application for a Phase II clinical trial of GFH312 for the treatment of PBC to the NMPA in March 2025 and obtained NMPA’s approval in May 2025. We plan to initiate a Phase II clinical trial of GFH312 for the treatment of PBC in the first half of 2026.

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used for our working capital and other general corporate purposes.

The net [REDACTED] from the [REDACTED] will not be used to finance the outstanding payment of the Supplementary Agreement with Innovent or any potential patent disputes.

FUTURE PLANS AND USE OF [REDACTED]

If the [REDACTED] and the [REDACTED] are exercised in full, the net [REDACTED] of the [REDACTED] would increase to approximately HK\$[REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED] stated in this Document). We intend to apply the additional net [REDACTED] to the above uses in the proportion stated above.

In the event that the [REDACTED] is set at the maximum [REDACTED] or the minimum [REDACTED] of the indicative [REDACTED], the net [REDACTED] of the [REDACTED] will increase or decrease by approximately HK\$[REDACTED], respectively. To the extent that the net [REDACTED] from the [REDACTED] (including the net [REDACTED] from the exercise of the [REDACTED] and the [REDACTED]) are either more or less than expected, we will adjust our allocation of the net [REDACTED] for the above purposes on a pro rata basis.

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.

If the net [REDACTED] of the [REDACTED] are not immediately applied to the above purposes, we will only deposit those net [REDACTED] into short-term interest-bearing accounts at licensed commercial banks and/or other authorized financial institutions (as defined under the SFO or the applicable laws and regulations in other jurisdictions) so long as it is deemed to be in the best interests of our Company. We will issue an appropriate announcement if there is any material change to the above proposed use of [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report received from the independent reporting accountants, Ernst & Young, Certified Public Accountants, Hong Kong, prepared for the purpose of incorporation in this Document.

[To insert the firm’s letterhead]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF GENFLEET THERAPEUTICS (SHANGHAI) INC. AND CITIC SECURITIES (HONG KONG) LIMITED

Introduction

We report on the historical financial information of GENFLEET THERAPEUTICS (SHANGHAI) INC. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-4 to I-67, which comprises the consolidated statements of profit or loss and other comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2023 and 2024, and the four months ended 30 April 2025 (the “Relevant Periods”), and the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2023 and 2024 and 30 April 2025 and material accounting policy information and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages I-4 to I-67 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [REDACTED] (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 (the “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 and the Company as at 31 December 2023 and 2024 and 30 April 2025 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.

Review of interim comparative financial information

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the four months ended 30 April 2024 and other explanatory information (the “Interim Comparative Financial Information”). The directors of the Company are responsible for the preparation and presentation of the Interim Comparative Financial Information in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Interim Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Interim Comparative Financial Information, for the purposes of the accountants’ report, is not prepared, in all material respects, 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 13 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

[●]

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 AND OTHER COMPREHENSIVE INCOME

	<i>Notes</i>	Year ended 31 December		Four months ended 30 April	
		2023	2024	2024	2025
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i>
REVENUE	5	73,734	104,703	–	82,149
Cost of sales		(684)	(20,095)	–	(8,693)
Gross profit		73,050	84,608	–	73,456
Other income and gains	6	39,964	28,531	6,534	6,122
Research and development costs		(312,738)	(332,124)	(142,262)	(69,818)
Administrative expenses		(49,946)	(58,081)	(13,881)	(23,684)
Other expenses	8	(176)	(10)	(2)	(3)
Finance costs	7	(1,485)	(17,963)	(13,615)	(2,005)
Loss before change in fair value of redemption liabilities on equity shares		(251,331)	(295,039)	(163,226)	(15,932)
Change in fair value of redemption liabilities on equity shares	25	(256,993)	(382,602)	(241,461)	(50,692)
LOSS BEFORE TAX	9	(508,324)	(677,641)	(404,687)	(66,624)
Income tax expense	12	–	–	–	–
LOSS FOR THE YEAR/PERIOD		(508,324)	(677,641)	(404,687)	(66,624)
Attributable to:					
Owners of the parent		(508,324)	(677,641)	(404,687)	(66,624)
OTHER COMPREHENSIVE INCOME/(EXPENSE)					
Other comprehensive income (expense) that may be reclassified to profit or loss in subsequent periods:					
Exchange differences on translation of foreign operations		734	(1,111)	(624)	470
OTHER COMPREHENSIVE INCOME/(EXPENSE) FOR THE YEAR/PERIOD		734	(1,111)	(624)	470
TOTAL COMPREHENSIVE LOSS FOR THE YEAR/PERIOD		(507,590)	(678,752)	(405,311)	(66,154)
Attributable to:					
Owners of the Company		(507,590)	(678,752)	(405,311)	(66,154)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY (expressed in RMB)					
Basic and diluted	14	(23.08)	(26.20)	(16.86)	(2.49)

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

		As at 31 December	As at 31 December	As at 30 April
	Notes	2023	2024	2025
		RMB’000	RMB’000	RMB’000
NON-CURRENT ASSETS				
Property, plant and equipment	15	20,601	12,328	10,325
Right-of-use assets	16	23,361	15,412	14,212
Intangible assets	17	1,401	1,257	1,198
Prepayments, other receivables and other assets	19	8,275	9,576	9,730
Time deposits	20	31,752	–	–
Total non-current assets		85,390	38,573	35,465
CURRENT ASSETS				
Inventories		2,058	5,586	918
Trade receivables	18	72,353	109,153	97,518
Prepayments, other receivables and other assets	19	44,136	58,594	56,013
Time deposits	20	–	32,790	–
Cash and cash equivalents	20	332,197	362,125	390,766
Total current assets		450,744	568,248	545,215
CURRENT LIABILITIES				
Trade and other payables	21	82,847	181,733	159,406
Interest-bearing bank borrowings	22	5,312	51,128	85,117
Contract liabilities	24	101,914	42,204	12,348
Redemption liabilities on equity shares	25	1,636,508	2,214,121	2,264,813
Lease liabilities	16	5,526	4,243	3,345
Total current liabilities		1,832,107	2,493,429	2,525,029
NET CURRENT LIABILITIES		(1,381,363)	(1,925,181)	(1,979,814)
TOTAL ASSETS LESS CURRENT LIABILITIES		(1,295,973)	(1,886,608)	(1,944,349)
NON-CURRENT LIABILITIES				
Lease liabilities	16	20,835	13,977	12,861
Deferred income	23	503	–	–
Trade and other payables	21	–	55,676	56,429
Total non-current liabilities		21,338	69,653	69,290
Net liabilities		(1,317,311)	(1,956,261)	(2,013,639)
DEFICIENCY IN EQUITY				
Equity attributable to owners of the Company				
Paid-in capital/Share capital	27	22,027	26,774	26,774
Reserves	28	(1,339,338)	(1,983,035)	(2,040,413)
Controlling interests		(1,317,311)	(1,956,261)	(2,013,639)
Net deficits		(1,317,311)	(1,956,261)	(2,013,639)

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2023

	<u>Paid-in capital</u>	<u>Share premium</u>	<u>Share- based payment reserve</u>	<u>Other reserves</u>	<u>Foreign currency translation reserve</u>	<u>Accumulated losses</u>	<u>Net deficits</u>
	<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>RMB'000</i>
At 1 January 2023	22,027	1,246,080	1,555	(1,264,082)	(1,098)	(851,171)	(846,689)
Exchange translation differences	–	–	–	–	734	–	734
Loss for the year	–	–	–	–	–	(508,324)	(508,324)
Total comprehensive loss for the year	–	–	–	–	734	(508,324)	(507,590)
Share-based payment compensation (<i>note 29</i>) . . .	–	–	36,968	–	–	–	36,968
At 31 December 2023	<u>22,027</u>	<u>1,246,080</u>	<u>38,523</u>	<u>(1,264,082)</u>	<u>(364)</u>	<u>(1,359,495)</u>	<u>(1,317,311)</u>

Year ended 31 December 2024

	<u>Paid-in capital/ Share capital</u>	<u>Share premium</u>	<u>Share- based payment reserve</u>	<u>Other reserves</u>	<u>Foreign currency translation reserve</u>	<u>Accumulated losses</u>	<u>Net deficits</u>
	<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>RMB'000</i>
At 1 January 2024	22,027	1,246,080	38,523	(1,264,082)	(364)	(1,359,495)	(1,317,311)
Exchange translation differences	–	–	–	–	(1,111)	–	(1,111)
Loss for the year	–	–	–	–	–	(677,641)	(677,641)
Total comprehensive loss for the year	–	–	–	–	(1,111)	(677,641)	(678,752)
Issue of new shares (<i>note 27</i>)	2,648	193,338	–	–	–	–	195,986
Capital contributions from employee incentive platform (<i>note 27</i>)	2,099	9,786	–	–	–	–	11,885
Conversion into a joint stock company (“Capitalisation Issue”) . .	–	(734,351)	–	–	–	734,351	–
Recognition of redemption liabilities on equity shares (<i>note 25</i>)	–	–	–	(195,011)	–	–	(195,011)
Share-based payment compensation (<i>note 29</i>) . .	–	–	26,942	–	–	–	26,942
At 31 December 2024	<u>26,774</u>	<u>714,853</u>	<u>65,465</u>	<u>(1,459,093)</u>	<u>(1,475)</u>	<u>(1,302,785)</u>	<u>(1,956,261)</u>

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ACCOUNTANTS’ REPORT

Four months ended 30 April 2024

	<u>Paid-in capital</u>	<u>Share premium</u>	<u>Share- based payment reserve</u>	<u>Other reserves</u>	<u>Foreign currency translation reserve</u>	<u>Accumulated losses</u>	<u>Net deficits</u>
	<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>RMB'000</i>
At 1 January 2024	22,027	1,246,080	38,523	(1,264,082)	(364)	(1,359,495)	(1,317,311)
Exchange translation differences	–	–	–	–	(624)	–	(624)
Loss for the period	–	–	–	–	–	(404,687)	(404,687)
Total comprehensive loss for the period	–	–	–	–	(624)	(404,687)	(405,311)
Issue of new shares (note 27)	2,648	193,338	–	–	–	–	195,986
Capital contributions from employee incentive platform (note 27)	2,099	9,786	–	–	–	–	11,885
Recognition of redemption liabilities on equity shares (note 25)	–	–	–	(195,011)	–	–	(195,011)
Share-based payment compensation (note 29)	–	–	9,584	–	–	–	9,584
At 30 April 2024	<u>26,774</u>	<u>1,449,204</u>	<u>48,107</u>	<u>(1,459,093)</u>	<u>(988)</u>	<u>(1,764,182)</u>	<u>(1,700,178)</u>

Four months ended 30 April 2025

	<u>Share capital</u>	<u>Share premium</u>	<u>Share- based payment reserve</u>	<u>Other reserves</u>	<u>Foreign currency translation reserve</u>	<u>Accumulated losses</u>	<u>Net deficits</u>
	<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>RMB'000</i>
At 1 January 2025	26,774	714,853	65,465	(1,459,093)	(1,475)	(1,302,785)	(1,956,261)
Exchange translation differences	–	–	–	–	470	–	470
Loss for the period	–	–	–	–	–	(66,624)	(66,624)
Total comprehensive loss for the period	–	–	–	–	470	(66,624)	(66,154)
Share-based payment compensation (note 29)	–	–	8,776	–	–	–	8,776
At 30 April 2025	<u>26,774</u>	<u>714,853</u>	<u>74,241</u>	<u>(1,459,093)</u>	<u>(1,005)</u>	<u>(1,369,409)</u>	<u>(2,013,639)</u>

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS

		Year ended 31 December		Four months ended 30 April	
	Notes	2023	2024	2024	2025
		RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		(508,324)	(677,641)	(404,687)	(66,624)
Adjustments for:					
Finance cost	7	1,485	17,963	13,615	2,005
Bank interest income	6	(10,767)	(17,228)	(4,186)	(4,986)
Amortisation of other intangible assets . .	17	186	176	58	59
Depreciation of property, plant and equipment	15	11,502	8,496	3,012	2,011
Depreciation of right-of-use assets	16	6,167	5,440	1,814	1,373
Share-based payment compensation	29	36,968	26,942	9,584	8,776
Fair value loss on redemption liabilities on equity shares.	25	256,993	382,602	241,461	50,692
Loss on the disposal of property, plant and equipment	8	137	9	2	3
Gain on lease reassessment	6	–	(488)	(488)	–
Fair value gains on financial assets at FVTPL	6	(3,587)	(402)	(222)	–
Net exchange difference	6	(3,818)	(3,539)	(959)	(894)
(Increase)/decrease in trade receivables . .		(32,945)	(36,800)	574	11,635
Decrease/(increase) in inventories		544	(3,528)	596	4,668
Decrease/(increase) in prepayments, other receivables and other assets		14,690	(12,637)	(6,905)	3,979
Increase/(decrease) in contract liabilities . .		14,361	(59,710)	(87,554)	(29,856)
Decrease in deferred income		(3,148)	(503)	(450)	–
Increase/(decrease) in trade and other payables		7,764	148,582	94,351	(21,511)
Cash used in operating activities		(211,792)	(222,266)	(140,384)	(38,670)
Interest received		9,732	15,866	3,439	4,625
Net cash flows used in operating activities .		(202,060)	(206,400)	(136,945)	(34,045)
CASH FLOWS FROM INVESTING ACTIVITIES					
Purchases of items of property, plant and equipment		(594)	(236)	(5)	(11)
Purchases for other intangible assets		–	(32)	–	–
Purchases of financial assets at FVTPL . . .		(480,000)	(170,000)	(110,000)	–
Withdrawal of financial assets at FVTPL . .		744,024	170,402	90,222	–
Proceeds from disposal of property, plant and equipment.		13	4	4	–
Proceeds from withdrawal of time deposits with original maturity of more than three months		–	124,560	16,290	33,151
Purchases of time deposits with original maturity of more than three months. . . .		–	(123,968)	(119,227)	–
Net cash flows generated from/(used in) investing activities		263,443	730	(122,716)	33,140

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		Year ended 31 December		Four months ended 30 April	
	Notes	2023	2024	2024	2025
		RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
CASH FLOWS FROM FINANCING ACTIVITIES					
New bank borrowings		5,312	56,928	5,800	54,900
Repayment of bank borrowings		(22,767)	(11,112)	–	(21,128)
Interest paid on bank borrowings		(119)	(877)	(52)	(401)
Principal portion of lease payments		(5,402)	(5,144)	(1,627)	(2,187)
Interest paid for lease liabilities		(1,366)	(1,112)	(389)	(271)
Proceeds on issue of shares		–	207,871	207,871	–
Payment of [REDACTED] expenses		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Issued costs paid		(4,717)	(11,840)	(6,698)	–
Net cash flows (used in)/from financing activities		(29,059)	233,438	204,905	28,182
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS					
		32,324	27,768	(54,756)	27,277
Cash and cash equivalents at beginning of year/period		295,321	332,197	332,197	362,125
Effect of foreign exchange rate changes, net.		4,552	2,160	585	1,364
CASH AND CASH EQUIVALENTS AT END OF YEAR/PERIOD.	20	332,197	362,125	278,026	390,766
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS					
Cash and bank balances		332,197	255,226	278,026	308,644
Non-pledged time deposits with original maturity of less than three months when acquired.		–	106,899	–	82,122
Cash and cash equivalents as stated in the statement of cash flows		332,197	362,125	278,026	390,766

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ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

		As at 31 December	As at 31 December	As at 30 April
	Notes	2023	2024	2025
		RMB’000	RMB’000	RMB’000
NON-CURRENT ASSETS				
Property, plant and equipment	15	18,080	10,866	9,096
Intangible assets	17	1,401	1,257	1,198
Right-of-use assets	16	23,286	15,412	14,072
Investments in subsidiaries	30	303,526	398,352	411,740
Prepayments, other receivables and other assets	19	1,640	1,711	1,713
Amounts due from subsidiaries		152,490	199,491	206,990
Time deposits	20	31,752	—	—
Total non-current assets		532,175	627,089	644,809
CURRENT ASSETS				
Inventories		1,677	5,586	918
Trade receivables	18	72,353	109,153	97,518
Prepayments, other receivables and other assets	19	9,626	39,081	35,117
Time deposits	20	—	32,790	—
Cash and cash equivalents	20	241,962	313,454	361,804
Total current assets		325,618	500,064	495,357
CURRENT LIABILITIES				
Interest-bearing bank borrowings	22	5,312	51,128	85,117
Trade and other payables	21	60,410	166,859	156,003
Amounts due to subsidiaries		1,548	96,548	101,048
Contract liabilities	24	101,914	42,204	12,348
Redemption liabilities on equity shares	25	1,636,508	2,214,121	2,264,813
Lease liabilities	16	5,499	4,243	3,171
Total current liabilities		1,811,191	2,575,103	2,622,500
NET CURRENT LIABILITIES		(1,485,573)	(2,075,039)	(2,127,143)
TOTAL ASSETS LESS CURRENT LIABILITIES		(953,398)	(1,447,950)	(1,482,334)
NON-CURRENT LIABILITIES				
Lease liabilities	16	20,835	13,977	12,861
Deferred income		503	—	—
Trade and other payables	21	—	55,676	56,429
Total non-current liabilities		21,338	69,653	69,290
Net liabilities		(974,736)	(1,517,603)	(1,551,624)
EQUITY				
Paid-in capital/Share capital		22,027	26,774	26,774
Reserves	28	(996,763)	(1,544,377)	(1,578,398)
Net deficits		(974,736)	(1,517,603)	(1,551,624)

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II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE AND GROUP INFORMATION

GENFLEET THERAPEUTICS (SHANGHAI) INC. (the “Company”) was established in Mainland China on 23 August 2017. The registered office address of the Company is 2, 3, 4 and 5 floor, Building 8, 1206 Zhangjiang Road, China (Shanghai) Pilot Free Trade Zone, PRC.

The Company is a clinical-stage biotechnology company. The Company and its subsidiaries (the “Group”) are principally engaged in the research, development and commercialisation of pharmaceutical products.

As at the date of this report, the Company had direct interests in its subsidiaries, all of which are private limited liability companies, the particulars of which are as follows:

Name	Place and date of incorporation/ registration and place of operations	Issued ordinary share/ registered capital	Issued ordinary share/registered capital		Principal activities
			Direct	Indirect	
Zhejiang GenFleet Therapeutics Co., Ltd (浙江勁方藥業有限公司)* (note a)	PRC/Mainland China 8 April 2018	RMB60,000,000	100%	–	Research and development of innovative drugs
GenFleet Therapeutics (Hangzhou) Co., Ltd (勁方藥業(杭州)有限公司)* (note a)	PRC/Mainland China 26 September 2023	RMB50,000,000	100%	–	Technical services, technology development and production of drugs
GenFleet Therapeutics (Zhuhai) Co., Ltd (勁方藥業(珠海)有限公司)* (note a)	PRC/Mainland China 1 November 2023	RMB50,000,000	100%	–	Technical services, technology development and production of drugs
GENFLEET THERAPEUTICS INC. (note a)	United States 13 April 2020	United States Dollars (“USD”) 15,000,000	100%	–	Research and development of innovative drugs
GENFLEET THERAPEUTICS (AUSTRALIA) PTY LTD (note a)	Australia 15 July 2020	AUD100	100%	–	Research and development of innovative drugs

* These entities are limited liability enterprises established under the PRC law. The English names of these entities represent the best effort made by the directors of the Company, as they had not been registered with official English names.

Note:

(a) No audited financial statements have been prepared for the entities for Relevant Periods, as the entities were not subject to any statutory audit requirements under the relevant rules and regulations in their jurisdictions of incorporation/registration.

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 (the “IASB”). All IFRSs effective for the accounting period commencing from 1 January 2025, 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.

These financial statements have been prepared under the historical cost convention, except for Redemption liabilities on equity shares which have been measured at fair value. These financial statements are presented in Renminbi and all values are rounded to the nearest thousand except when otherwise indicated.

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The Group incurred losses continually during the Relevant Periods due to the pre-revenue stage of its new drug research and development businesses. The Group recorded net current liabilities of RMB1,979,814,000 and net liabilities of RMB2,013,639,000 as at 30 April 2025, primarily due to the significant amount of the redemption liabilities on equity shares of RMB2,264,813,000 arising from the financing with redemption feature from [REDACTED] investors. The redemption liabilities on equity shares will not result in future cash payments within the next twelve months from 30 April 2025 because as set out in the paragraph headed “Rights of the [REDACTED] Investors — HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE” to this document, pursuant to a supplemental agreement entered into by the Company with, among others, the then shareholders of the Company dated 26 December 2024, the redemption feature has ceased to be effective from the date before the submission of [REDACTED] for an [REDACTED] on the Main Board of the Stock Exchange (the “[REDACTED]”) and shall be reinstated in the event where (i) the [REDACTED] of the [REDACTED] not being accepted (including being rejected or returned); (ii) the Company withdrawing its [REDACTED] of the [REDACTED]; (iii) the Company failing to complete the [REDACTED] within two years after date of the [REDACTED]; or (iv) the listing committee of the Stock Exchange not approving the [REDACTED] of the [REDACTED]. In this regard, the directors of the Company are of the opinion that the Company is not obligated to settle the redemption liabilities in next twelve months from 30 April 2025.

The directors of the Company further assessed whether the Group have sufficient working capital to meet its present obligations, taking into account the financial resources available to the Group.

The Company has prudently prepared a full-speed budget based for clinical trials of its core products and other pipelines for 2025 assuming the Company is able to raise [REDACTED] from the [REDACTED] as well as a backbone budget plan to advance all necessary R&D activities for its core products assuming the Company is unable to raise [REDACTED] from the [REDACTED]. Based on the rigorous review of the budget under either full-speed or backbone scenario, the directors of the Company are satisfied that the Group would have sufficient working capital to meet its present obligations, taking into account the financial resources available to the Group for next twelve months from 30 April 2025.

Based on the above factors and our Group’s historical performance and our management’s operating and financing plans, the directors of the Company concluded that it is appropriate to prepare the Historical Financial Information on a going concern basis, which contemplates the realization of assets and settlement of liabilities in the normal course of business.

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).

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 periods 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 parent of the Group 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.

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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 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 INTERNATIONAL FINANCIAL REPORTING STANDARDS

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.

IFRS 18	<i>Presentation and Disclosure in Financial Statements²</i>
IFRS 19	<i>Subsidiaries without Public Accountability: Disclosures²</i>
Amendments to IFRS 9 and IFRS 7 . . .	<i>Amendments to the Classification and Measurement of Financial Instruments¹</i>
Amendments to IFRS 10 and IAS 28 . .	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture³</i>
Amendments to IFRS 9 and IFRS 7 . . .	<i>Contracts Referencing Nature-dependent Electricity</i>
Annual Improvements to IFRS Accounting Standards – Volume 11 . .	<i>Amendments to IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7¹</i>

1 Effective for annual periods beginning on or after 1 January 2026

2 Effective for annual/reporting periods beginning on or after 1 January 2027

3 No mandatory effective date yet determined but available for adoption

The application of IFRS 18 will have no impact on the consolidated statements of financial position of the Group, but will have impact on the presentation of the consolidated statements of profit or loss and other comprehensive income and consolidated statements of cash flows. Except for IFRS 18, the directors of the Company anticipate that the application of these amendments to IFRS Accounting Standards will have no material impact on the Group’s financial performance and financial position in the foreseeable future.

2.3 MATERIAL ACCOUNTING POLICIES

Fair value measurement

The Group measures its financial instruments 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.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

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.

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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 statement 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 the reporting periods.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required, 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. In testing a cash-generating unit for impairment, a portion of the carrying amount of a corporate asset (e.g., a headquarters building) is allocated to an individual cash-generating unit if it can be allocated on a reasonable and consistent basis or, otherwise, to the smallest group of cash-generating units.

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 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 profit or loss in the period in which it arises unless the asset is carried at a revalued amount, in which case the reversal of the impairment loss is accounted for in accordance with the relevant accounting policy for that revalued asset.

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;

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- (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 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 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 for this purpose are as follows:

Computer and office equipment	19% to 32%
Machinery and equipment	19%
Motor vehicles	19%
Leasehold improvements	Shorter of remaining lease terms and estimated useful lives

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 the end of the reporting periods.

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 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.

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.

Software	10 years

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Purchased software is stated at cost less any impairment losses and is amortised on the straight-line basis over its estimated useful life of 10 years. The estimated useful life of 10 years for software is determined by considering the period of the economic benefits to the Group as well as by referring to the industry practice.

Research and development costs

All research costs are charged to 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 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 premises	2 to 10 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.

(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.

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 used to determine such lease payments) or a change in assessment of an option to purchase the underlying asset.

The Group’s lease liabilities are presented in a separate line on the consolidated statements of financial position.

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(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 premises (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 recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset.

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 recognised in profit or loss when the asset is derecognised, 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 recognised in the profit or loss.

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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 the end of each reporting period, 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.

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.

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 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.

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- 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 general 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 financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade and other payables, interest-bearing bank borrowings and redemption liabilities on equity shares.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost

After initial recognition, trade and other payables and interest-bearing bank 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 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 profit or loss.

Financial liabilities measured at FVTPL

Financial liabilities measured at FVTPL include redemption liabilities on equity shares.

Financial liabilities designated upon initial recognition as at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. Gains or losses on liabilities designated at FVTPL are recognised in profit or loss, except for the gains or losses arising from the Group’s own credit risk which are presented in other comprehensive income with no subsequent reclassification to the profit or loss. The net fair value gain or loss recognised in the profit or loss does not include any interest charged on these financial liabilities.

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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 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 realizable value. Cost is determined on the first-in, first-out basis or on a weighted average method and, in the case of work in progress and finished goods, comprises direct materials, direct labour and an appropriate proportion of overheads. 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.

Provisions

A provision is recognised when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

If Group has a contract that is onerous, the present obligation under the contract will be recognised and measured as a provision.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside 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 periods, 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 periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

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Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability 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 difference; 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.

Deferred tax assets are recognised for all deductible temporary differences, and the carry forward 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 carry forward 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 difference; 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 the reporting periods 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 the reporting periods 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 periods.

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 or deducted from the carrying amount of the asset and released to the statement of profit or loss by way of a reduced depreciation charge.

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Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of the goods or services is transferred to the customer 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.

The Group’s revenue is generated from the collaboration agreements with Innovent Biologics, Inc. and SELLAS Life Sciences Group, Inc., which generally contain multiple performance obligations including (1) grants of licenses to intellectual property rights and (2) the research and development services.

Collaboration revenue

At contract inception, the Group analyses the collaboration arrangements to assess whether they are within the scope of IFRS 11 *Joint Arrangements* to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and are exposed to significant risks and rewards dependent on the commercial success of such activities. After Group’s assessment, no collaboration arrangement was within the scope of IFRS11 Joint Arrangements during the Relevant Periods.

In determining the appropriate amount of revenue to be recognised as the Group fulfils its obligations under each of the collaboration agreements, the management of the Company perform the five-step model under IFRS 15. The collaboration arrangements may contain more than one unit of account or performance obligation, including grants of licenses to intellectual property rights (the “Licenses”), agreements to provide research and development services and other deliverables. The collaborative arrangements typically do not include a right of return for any deliverable. In general, the consideration allocated to each performance obligation is recognised when the obligation is satisfied either by delivering a good or rendering a service, limited to the consideration that is not constrained. Non-refundable payments received before all of the relevant criteria for revenue recognition are satisfied are recorded as contract liabilities.

(a) Licenses of intellectual property

Upfront non-refundable payments for Licenses are evaluated to determine if they are distinct from the other performance obligations identified in the arrangements. For the Licenses determined to be distinct, the Group recognises revenues from non-refundable up-front fees allocated to the licenses at a point in time, when the Licenses are transferred to the licensee and the licensee is able to use and benefit from the Licenses.

Milestone payments

At the inception of each arrangement that includes development milestone payments and commercial milestone payments, the management of the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestones related to development-based activities may include initiation of various phases of clinical trials. Due to the uncertainty involved in meeting these development-based targets, they are generally fully constrained at contract inception. The management of the Company assesses whether the variable consideration is fully constrained for each reporting period based on the facts and circumstances surrounding the clinical trials. Upon changes to constraint associated with the developmental milestones, variable consideration is included in the transaction price when a significant reversal of revenue recognised is not expected to occur and allocated to the separate performance obligations. Due to the inherent uncertainty with the approval process, regulatory milestones are fully constrained until the period in which those regulatory approvals are achieved. Regulatory milestones are included in the transaction price in the period regulatory approval is obtained.

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Royalties

For arrangements that include sales-based royalties, the Group recognises revenue when the related sales occur.

(b) Research and development services

The Group provides a customer with a project team of scientists and technical staff dedicated to the customer’s studies for a specific period of time and charges the customer at a fixed rate per employee and the Group has assessed that the customer simultaneously receives and consumes benefit provided by the Group’s performances. Therefore, the performance obligation of research and development services is satisfied over time and revenue is recognised over the service period.

(c) Drug supply manufacturing services

The Group provides drug supply manufacturing services to customers and the Group recognises revenue at point in time when such services are rendered. The drug supply manufacturing services revenue is recognised on a net basis as the Group is acting as an agent because the Group didn’t obtain control of those drugs goods before they are transferred to the customers.

Other income

Bank 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 Group operates restricted share units schemes. 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”). 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, further details of which are set out in Note 29 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 restricted shares 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.

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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.

Other employee benefits

Pension schemes

The employees of the Group which operates in Mainland China are required to participate in a central pension scheme operated by the local municipal government. The subsidiaries operating in Mainland China are 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 subsidiary in the United States maintains multiple qualified contributory savings plans as allowed under Section 401(k) of the Internal Revenue Code in the US. These plans are defined contribution plans covering substantially all its qualifying employees of that subsidiary and provide for voluntary contributions by employees, subject to certain limits. The contributions are made by both the employees and the employer. The employees’ contributions are primarily based on specified dollar amounts or percentages of employee compensation. The only obligation of the subsidiaries in the US with respect to the retirement benefit plans is to make the specified contributions under the plans.

Housing fund — Mainland China

The Group contributes on a monthly basis to a defined contribution housing fund plan operated by the local municipal government. Contributions to this plan by the Group are expensed as incurred.

Borrowing costs

All borrowing costs are recognised in profit or loss in the period in which they are incurred.

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 periods. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

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 recognised in other comprehensive income or profit or loss is also recognised 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 certain overseas subsidiaries are currencies other than RMB. As at the end of the Relevant Periods, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of the reporting periods and their statements of profit or loss and other comprehensive income are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

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The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the cumulative amount in the reserve relating to that particular foreign operation is recognised in profit or loss.

For the purpose of the consolidated statement of cash flows, the cash flows of the overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of the overseas subsidiaries which arise throughout the reporting periods are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group’s 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 profit or loss as incurred. Expenses incurred on each pipeline to develop new products are only capitalised and deferred in accordance with the accounting policy for research and development expenses in Note 2.3 to the Historical Financial Information. Determining the amounts to be capitalised requires management to make judgements on the technical feasibility of existing pipelines to be successfully commercialised and bring economic benefits to the Company.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of the reporting periods, 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.

Leases — Estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate (“IBR”) to measure lease liabilities. The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as a subsidiary’s stand-alone credit rating).

Impairment of property, plant and equipment, intangible assets and right-of-use assets

At the end of each reporting period, the Group reviews the carrying amounts of its property, plant and equipment, intangible assets and right-of-use assets to determine whether there is any indication that these assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss.

The recoverable amount of property, plant and equipment, intangible assets and right-of-use assets are estimated individually. When it is not possible to estimate the recoverable amount individually, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs. Recoverable amount is the higher of fair value less costs of disposal and value in use. 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 (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted. If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognized immediately in profit or loss.

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Group assess whether there are any indicators of impairment for all non-financial assets (including property, plant and equipment, intangible assets and right-of-use assets) at the end of each period comprising the Relevant Periods by reviewing the internal and external sources of information.

As of 31 December 2023 and 2024 and 30 April 2025, no indicators of impairment for non-financial assets of the Group were identified, given that (i) non-financial assets of the Group were neither obsolete nor physically damaged, and (ii) Group actual losses incurred for the years ended 31 December 2023 and 2024 and the four months ended 30 April 2025 did not exceed the estimated losses for the same periods.

Fair value of financial instruments

The redemption liabilities on equity shares issued by the Group are not traded in an active market and the respective fair value is determined by using valuation techniques, including the back-solve method. Such valuation is based on key parameters about risk-free rate, discounts for lack of marketability (“DLOM”) and volatility, which are subject to uncertainty and might materially differ from the actual results.

The fair values of redemption liabilities on equity shares of the Group as at 31 December 2023 and 2024 and 30 April 2025 were RMB1,636,508,000, RMB2,214,121,000, and RMB2,264,813,000, respectively. Further details are set out in Note 25 to the Historical Financial Information.

Recognition of income taxes and deferred tax assets

Determining income tax provision involves judgment on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation. Deferred tax assets are recognised in respect of deductible temporary differences and unused tax losses. As those deferred tax assets can only be recognised to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilised, management’s judgment is required to assess the probability of future taxable profits. Management’s assessment is revised as necessary and deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

Share-based payment expenses

The Group estimates the number of share awards contingently issuable when determining the share-based expenses, which depends on the achievement of certain non-market performance targets of the Group under the Employee Incentive Scheme (as defined in Note 29 to the Historical Financial Information). This requires an estimation of the performance targets to be achieved by the Group, including completion of [REDACTED]. The Group recorded RMB36,968,000, RMB26,942,000 and RMB8,776,000 share-based payment compensation expenses during the Relevant Periods.

4. OPERATING SEGMENT INFORMATION

Operating segment information

The Group is engaged in biopharmaceutical research and development, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group’s directors for purposes of resource allocation and performance assessment. Therefore, no further operating segment analysis thereof is presented.

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Geographical information

(a) Revenue from external customers

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Overseas	1,955	—	—	77,618
Mainland China	71,779	104,703	—	4,531
Total	73,734	104,703	—	82,149

The revenue information above is based on the locations of headquarters of the Group’s customers.

(b) Non-current assets

Since all of the Group’s non-current assets were located in Mainland China, no geographical information in accordance with IFRS 8 *Operating Segments* is presented.

Information about major customers

Revenue from one customer (2023: two), which accounted for 100% of the Group’s revenue during the year end 31 December 2024 and 2023, and revenue from two major customers which accounted for 99.73% of the Group’s revenue during the four months ended 30 April 2025, is set out below:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Customer A	1,955	—	—	—
Customer B	71,779	104,703	—	4,310
Customer C	—	—	—	77,618
Total	73,734	104,703	—	81,928

5. REVENUE

An analysis of revenue is as follows:

Revenue from contracts with customers

(a) Disaggregated revenue information

Type of services	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Licenses of intellectual property . . .	71,779	90,035	—	80,742
Sale of goods	—	14,668	—	127
Research and development services .	1,955	—	—	1,280
Total	73,734	104,703	—	82,149

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	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Timing of revenue recognition				
Transferred at a point in time	71,779	104,703	—	80,869
Transferred overtime	1,955	—	—	1,280
Total	<u>73,734</u>	<u>104,703</u>	<u>—</u>	<u>82,149</u>

(b) **Performance obligations**

Information about the Group’s performance obligations is summarised below:

License-out of GFH925

On 1 September 2021, the Group entered into a license and option agreement (the “GFH925 License Agreement”) with Innovent Biologics, Inc. (“Innovent”). According to the GFH925 License Agreement, the Group grant to Innovent (i) an exclusive, royalty-bearing and sublicensable license to develop and commercialize GFH925 for the treatment, prevention or diagnosis of any disease in humans in Mainland China, Hong Kong, Macau and Taiwan (the “Greater China”); and (ii) an exclusive option (the “Ex-China Option”) to develop and commercialize GFH925 in the all countries and regions in the world other than Greater China (the “Ex-China Territory”).

In November 2021, Innovent paid the Group a one-time and non-refundable upfront payment of USD8,500,000 (equivalent to RMB55,126,000) for GFH925 license in Great China, and an ex-China Option payment of USD13,500,000 (equivalent to RMB87,553,000). The Group recognised collaboration revenue related to GFH925 of RMB55,126,000 during the year ended 31 December 2021 and recorded contract liability of RMB87,553,000 as of 31 December 2021.

In December 2022, Innovent paid the Group a development milestone payment of USD5,000,000 (equivalent to RMB35,884,000) for the first patient dosed in the first pivotal trial in Great China for the licensed product. According to the agreement of the development milestone payment, the Group recognised revenue of licenses of intellectual property related to GFH925 of RMB35,884,000 during the year ended 31 December 2022.

In 2023, Innovent paid the Group a development milestone payment of USD10,000,000 (equivalent to RMB71,779,000) for the NDA filing completed in Great China for the first indication for the licensed products. According to the agreement of the development milestone payment, the Group recognised revenue of licenses of intellectual property related to GFH925 of RMB71,779,000 during the year ended 31 December 2023.

In January 2024, the Group entered into a supplementary agreement with Innovent to terminate the Ex-China Option under the GFH925 License Agreement. Subject to the terms and conditions of the agreement, the group is required to pay non-refundable termination fees of USD20,000,000 in instalments and certain revenue sharing payments to Innovent based on the annual net sales of GFH925 outside Great China. Following the termination, the Group took back Ex-China option and has the exclusive rights to develop and commercialize the licensed product and the licensed compounds for any indication in the Ex-China Territory. As of 30 April 2025, the Group had paid USD2,000,000 (equivalent to RMB14,165,000) to Innovent. The remaining USD18,000,000 will be paid by the Group to Innovent in instalments by 1 December 2026.

During the four months ended 30 April 2025, the Group didn’t recognised any milestone revenue of GFH925.

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License-out of GFH009

In March 2022, the Group entered into an exclusive license agreement with Sellas Life Sciences Group, Inc. (“Sellas”), to use, have used, develop, have developed, manufacture, have manufactured, commercialize, have commercialized, and otherwise Exploit Compounds and Products in the world outside of Greater China. Pursuant to the Agreement, the Group is entitled to receive upfront payment, development milestone payments, commercial Milestone payments. Details of the agreement please refer to “BUSINESS” to this document. Sellas paid the Group a non-creditable and non-refundable initial payment of USD4,500,000 (equivalent to RMB28,567,000) and USD5,500,000 (equivalent to RMB39,144,000) in 2022 and 2023, respectively. The Group recognised revenue of licenses of intellectual property related to GFH009 of RMB68,040,000 during the year ended 31 December 2022, and recognised trade receivables of RMB38,305,000 at the end of 31 December 2022, which had been fully collected in 2023.

License-out of GFH375

In August 2023, the Group entered into a collaboration and option agreement (the “Verastem Agreement”) with Verastem, Inc. (“Verastem”), a pharmaceutical company headquartered in Massachusetts and listed on Nasdaq (stock code: VSTM). Verastem specializes in developing treatment for cancers and is a member of Nasdaq Biotechnology Index.

Under the Verastem Agreement, the Group granted Verastem options to obtain an exclusive, royalty-bearing and sublicensable licenses to develop, manufacture, commercialize and otherwise exploit the certain compounds and products in territories other than Greater China. As the Verastem Agreement implicates three programs, Verastem obtained three options from the Group and the exercise of option is on a program-by-program basis. Verastem paid the Group the upfront payments of USD2,000,000 (equivalent to RMB14,360,000) and USD3,500,000 (equivalent to RMB24,893,000) for the options of three product candidates, including GFH375 in 2023 and 2024, respectively. Therefore, the upfront payment received from Verastem was presented as contract liabilities as of 31 December 2023 and 2024. In January 2025, Verastem exercised one of three options and the Group recognised RMB77,618,000 revenue related to GFH375 during four months ended 30 April 2025.

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December are as follow:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Amounts expected to be recognised as revenue:				
Within one year	87,554	32,631	–	–
After one year	14,360	9,573	14,360	12,348
Total	<u>101,914</u>	<u>42,204</u>	<u>14,360</u>	<u>12,348</u>

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognised as revenue after one year relate to the exercise of the option, of which the performance obligations are to be satisfied within two years. All the other amounts of transaction prices allocated to the remaining performance obligations are expected to be recognised as revenue within one year. The amounts disclosed above do not include variable consideration which is constrained.

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6. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i>
<u>Other income</u>				
Government grants	21,786	6,869	678	242
Bank interest income	10,767	17,228	4,186	4,986
<u>Gains</u>				
Foreign exchange differences, net . .	3,818	3,539	959	894
Fair value gains on financial assets at FVTPL	3,587	402	222	—
Gain on lease reassessment	—	488	488	—
Others	6	5	1	—
<u>Total</u>	<u>39,964</u>	<u>28,531</u>	<u>6,534</u>	<u>6,122</u>

7. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i>
Interest on lease liabilities	1,366	1,112	389	271
Imputed interest expenses on other payable	—	4,134	1,334	1,116
Transaction cost on issue of redemption liabilities on equity shares	—	11,840	11,840	—
Interest on bank borrowings	119	877	52	618
<u>Total</u>	<u>1,485</u>	<u>17,963</u>	<u>13,615</u>	<u>2,005</u>

8. OTHER EXPENSES

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i>
Loss on disposals of property, plant and equipment	137	9	2	3
Others	39	1	—	—
<u>Total</u>	<u>176</u>	<u>10</u>	<u>2</u>	<u>3</u>

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9. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	<i>Notes</i>	Year ended 31 December		Four months ended 30 April	
		2023	2024	2024	2025
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i> <i>(unaudited)</i>	<i>RMB’000</i>
Cost of inventories sold		–	7,670	–	8,098
Cost of licenses of intellectual property		–	12,425	–	595
Cost of services provided . . .		684	–	–	–
Depreciation of property, plant and equipment*	15	11,502	8,496	3,012	2,011
Amortisation of intangible assets***	17	186	176	58	59
Depreciation of right-of-use assets**	16	6,167	5,440	1,814	1,373
Research and development costs		312,738	351,858	142,262	68,438
Gain on lease reassessment . .	6	–	(488)	(488)	–
Expenses relating to short-term and low-value leases .	16	1,540	961	375	387
[REDACTED] expense		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Staff costs (including directors’ emoluments):					
– Salaries, discretionary bonuses, allowances and benefits in kind		84,058	78,321	24,732	22,883
– Pension scheme contributions		5,750	5,709	1,968	1,863
– Share-based payment compensation	29	36,968	26,942	9,584	8,776
Total		<u>126,776</u>	<u>110,972</u>	<u>36,284</u>	<u>33,522</u>

* The depreciation of property, plant and equipment for the Relevant Periods is included in “Research and development costs” and “Administrative expenses” in the consolidated statements of profit or loss.

** The depreciation of right-of-use assets for the Relevant Periods is included in “Research and development costs” and “Administrative expenses” in the consolidated statements of profit or loss.

*** The amortisation of intangible assets for the Relevant Periods is included in “Research and development costs” and “Administrative expenses” in the consolidated statements of profit or loss.

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10. DIRECTORS’ AND SUPERVISORS’ REMUNERATION

Directors’ and supervisors’ remuneration for the Relevant Periods, disclosed pursuant to the Listing Rules, section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, is as follows:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Salaries, allowances and benefits in kind	14,238	13,302	4,124	4,755
Performance related bonuses	8,647	9,942	1,898	1,707
Pension scheme contributions	210	241	72	115
Equity-settled share award expense	33,548	9,386	3,752	3,222
Total fees and other emoluments	<u>56,643</u>	<u>32,871</u>	<u>9,846</u>	<u>9,799</u>

Directors and supervisors:

	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Share-based payment compensation	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Year ended 31 December 2023					
Directors:					
Dr. Lu Qiang (<i>Note a</i>)	1,310	1,444	—	16,785	19,539
Dr. Lan Jiong (<i>Note b</i>)	1,447	1,444	—	14,305	17,196
Mr. Li Bin (<i>Note c</i>)	—	—	—	—	—
Ms. Zhou Yi (<i>Note d</i>)	—	—	—	—	—
Ms. Shen Haige (<i>Note e</i>)	2,505	1,142	70	406	4,123
Mr. Wang Yu (<i>Note f</i>)	4,305	2,780	70	1,104	8,259
Mr. Stephen Hui Wang (<i>Note g</i>)	—	—	—	—	—
Mr. Song Gaoguang (<i>Note h</i>)	—	—	—	—	—
Mr. Zhu Jingyang (<i>Note i</i>)	—	—	—	—	—
Mr. Li Jingrong (<i>Note j</i>)	2,762	841	—	697	4,300
Mr. Chen Fanwei (<i>Note k</i>)	1,074	290	—	—	1,364
Mr. Peng Wei (<i>Note l</i>)	—	—	—	—	—
Ms. Qian Ranting (<i>Note m</i>)	—	—	—	—	—
Ms. Liu Dan (<i>Note o</i>)	—	—	—	—	—
Supervisors:					
Ms. Zhang Wei (<i>Note q</i>)	835	706	70	251	1,862
Mr. Wei Yufa (<i>Note r</i>)	—	—	—	—	—
Mr. Xue Mengjun (<i>Note s</i>)	—	—	—	—	—
Total	<u>14,238</u>	<u>8,647</u>	<u>210</u>	<u>33,548</u>	<u>56,643</u>

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	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Share-based payment compensation	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Year ended 31 December 2024					
Directors:					
Dr. Lu Qiang (<i>Note a</i>) . . .	998	1,663	—	—	2,661
Dr. Lan Jiong (<i>Note b</i>) . . .	998	1,665	—	—	2,663
Mr. Zhou Yi (<i>Note d</i>)	—	—	—	—	—
Ms. Shen Haige (<i>Note e</i>) . .	2,505	1,030	73	1,562	5,170
Mr. Wang Yu (<i>Note f</i>)	4,306	2,597	73	4,355	11,331
Mr. Song Gaoguang (<i>Note h</i>)	—	—	—	—	—
Mr. Zhu Jingyang (<i>Note i</i>) .	—	—	—	—	—
Mr. Li Jingrong (<i>Note j</i>) . .	2,763	1,673	—	2,322	6,758
Mr. Chen Fanwei (<i>Note k</i>) .	802	803	—	—	1,605
Mr. Peng Wei (<i>Note l</i>) . . .	—	—	—	—	—
Ms. Qian Ranting (<i>Note m</i>)	—	—	—	—	—
Mr. Gao Jieliang (<i>Note n</i>) .	—	—	—	—	—
Ms. Liu Dan (<i>Note o</i>)	—	—	—	—	—
Mr. Liu Erh Fei (<i>Note p</i>) . .	—	—	—	—	—
Ms. Tao Sha (<i>Note v</i>)	—	—	—	—	—
Ms. Zhang Wei (<i>Note q</i>) . .	139	111	12	190	452
Ms. Xu Xijin (<i>Note w</i>) . . .	—	—	—	—	—
Supervisors:					
Ms. Zhang Wei (<i>Note q</i>) . .	488	388	42	665	1,583
Mr. Wei Yufa (<i>Note r</i>) . . .	—	—	—	—	—
Mr. Xue Mengjun (<i>Note s</i>)	—	—	—	—	—
Ms. Ma Rui (<i>Note t</i>)	108	4	17	165	294
Mr. Lin Chonglan (<i>Note u</i>)	195	8	24	127	354
Total	<u>13,302</u>	<u>9,942</u>	<u>241</u>	<u>9,386</u>	<u>32,871</u>

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	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Share-based payment compensation	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Four months ended					
30 April 2024					
(unaudited)					
Directors:					
Dr. Lu Qiang (<i>Note a</i>) . . .	161	554	—	—	715
Dr. Lan Jiong (<i>Note b</i>) . . .	161	555	—	—	716
Mr. Zhou Yi (<i>Note d</i>)	—	—	—	—	—
Ms. Shen Haige (<i>Note e</i>) . .	835	157	24	625	1,641
Mr. Wang Yu (<i>Note f</i>)	1,436	366	24	1,742	3,568
Mr. Song Gaoguang (<i>Note h</i>)	—	—	—	—	—
Mr. Zhu Jingyang (<i>Note i</i>) .	—	—	—	—	—
Mr. Li Jingrong (<i>Note j</i>) . .	921	210	—	929	2,060
Mr. Chen Fanwei (<i>Note k</i>) .	331	—	—	—	331
Mr. Peng Wei (<i>Note l</i>) . . .	—	—	—	—	—
Ms. Qian Ranting (<i>Note m</i>)	—	—	—	—	—
Mr. Gao Jieliang (<i>Note n</i>) .	—	—	—	—	—
Ms. Liu Dan (<i>Note o</i>) . . .	—	—	—	—	—
Mr. Liu Erh fei (<i>Note p</i>) . .	—	—	—	—	—
Supervisors:					
Ms. Zhang Wei (<i>Note q</i>) . .	279	56	24	456	815
Mr. Wei Yufa (<i>Note r</i>) . . .	—	—	—	—	—
Mr. Xue Mengjun (<i>Note s</i>)	—	—	—	—	—
Total	4,124	1,898	72	3,752	9,846

	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Share-based payment compensation	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Four months ended					
30 April 2025					
Directors:					
Dr. Lu Qiang (<i>Note a</i>) . . .	497	421	—	—	918
Dr. Lan Jiong (<i>Note b</i>) . . .	497	421	—	—	918
Mr. Zhou Yi (<i>Note d</i>)	—	—	—	—	—
Ms. Shen Haige (<i>Note e</i>) . .	834	129	24	520	1,507
Mr. Wang Yu (<i>Note f</i>)	1,434	492	24	1,451	3,401
Mr. Song Gaoguang (<i>Note h</i>)	—	—	—	—	—
Mr. Zhu Jingyang (<i>Note i</i>) .	—	—	—	—	—
Mr. Li Jingrong (<i>Note j</i>) . .	920	224	—	774	1,918
Ms. Qian Ranting (<i>Note m</i>)	—	—	—	—	—
Ms. Tao Sha (<i>Note v</i>)	—	—	—	—	—
Ms. Zhang Wei (<i>Note q</i>) . .	275	10	24	380	689
Ms. Xu Xijin (<i>Note w</i>) . . .	—	—	—	—	—
Supervisors:					
Mr. Xue Mengjun (<i>Note s</i>)	—	—	—	—	—
Ms. Ma Rui (<i>Note t</i>)	105	3	19	55	182
Mr. Lin Chonglan (<i>Note u</i>)	193	7	24	42	266
Total	4,755	1,707	115	3,222	9,799

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Notes:

- (a) Dr. Lu Qiang was appointed as a director of the Company on November 2017.
- (b) Dr. Lan Jiong was appointed as a director of the Company with effect from November 2017.
- (c) Mr. Li Bin was appointed as a director of the Company with effect from October 2018 and has resigned as a director of the Company with effect from July 2023.
- (d) Mr. Zhou Yi was appointed as a director of the Company with effect from February 2020.
- (e) Ms. Shen Haige was appointed as a director of the Company with effect from December 2020.
- (f) Mr. Wang Yu was appointed as a director of the Company with effect from December 2020.
- (g) Mr. Stephen Hui Wang was appointed as a director of the Company with effect from December 2020 and has resigned as a director of the Company with effect from July 2023.
- (h) Mr. Song Gaoguang was appointed as a director of the Company with effect from December 2020.
- (i) Mr. Zhu Jingyang was appointed as a director of the Company with effect from August 2022.
- (j) Mr. Li Jingrong was appointed as a director of the Company with effect from March 2022.
- (k) Mr. Chen Fanwei was appointed as a director of the Company with effect from March 2022 and resigned in November 2024.
- (l) Mr. Peng Wei was appointed as a director of the Company with effect from July 2023 and resigned in July 2024.
- (m) Ms. Qian Ranting was appointed as a director of the Company with effect from July 2023.
- (n) Mr. Gao Jieliang was appointed as a director of the Company with effect from May 2024 and resigned in November 2024.
- (o) Ms. Liu Dan was appointed as a director of the Company with effect from February 2020 and has resigned as a director of the Company with effect from May 2024.
- (p) Mr. Liu Erh Fei was appointed as a director of the Company with effect from January 2024 and resigned in December 2024.
- (q) Ms. Zhang Wei was appointed as a supervisor of the Company with effect from February 2020 and resigned in July 2024. Ms. Zhang Wei was appointed as a director of the Company with effect from November 2024.
- (r) Mr. Wei Yufa was appointed as a supervisor of the Company with effect from February 2020 and resigned in July 2024.
- (s) Mr. Xue Mengjun was appointed as a supervisor of the Company with effect from August 2022.
- (t) Ms Ma Rui was appointed as a supervisor of the Company with effect from September 2024.
- (u) Mr. Lin Chonglan was appointed as a supervisor of the Company with effect from September 2024.
- (v) Ms. Tao Sha was appointed as a director of the Company with effect from November 2024.
- (w) Ms. Xu Xijin was appointed as a director of the Company with effect from July 2024.

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During the Relevant Period, restricted shares were granted to the non-director and non-chief executive highest paid employees in respect of their services to the Group, further details of which are included in the disclosures in Note 29 to the Historical Financial Information. The fair value of such restricted share units, which has been recognised in profit or loss over the vesting period, was determined as at the date of grant and the amount included in the Historical Financial Information for the Relevant Periods is included in the above non-director and non-chief executive highest paid employees’ remuneration disclosures.

During the Relevant Period, no highest paid employees waived or agreed to waive any remuneration, and no remuneration was paid by the Group to any of the five highest paid employees as an inducement to join or upon joining the Group or as compensation for loss of office.

11. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant Period, included five, three and five directors, details of whose remuneration are set out in Note 10 above. 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		Four months ended 30 April	
	2023	2024	2024	2025
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i>
Salaries, allowances and benefits in kind	–	2,827	1,368	–
Performance related bonuses	–	1,353	104	–
Pension scheme contributions	–	140	672	–
Equity-settled share award expense	–	6,034	71	–
Total	–	10,354	2,215	–
	=	=	=	=

The numbers of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands are as follows:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	<i>Number of employees</i>	<i>Number of employees</i>	<i>Number of employees</i> <i>(unaudited)</i>	<i>Number of employees</i>
HKD500,001 to HKD1,000,000 . . .	–	–	1	–
HKD1,000,001 to HKD1,500,000 . .	–	–	1	–
HKD4,500,001 to HKD5,500,000 . .	–	1	–	–
HKD5,500,001 to HKD6,500,000 . .	–	1	–	–

During the Relevant Periods, no highest paid employees waived or agreed to waive any remuneration and no remuneration was paid by the Group to any of the five highest paid employees as an inducement to join or upon joining the Group or as compensation for loss of office.

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12. INCOME TAX

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.

Mainland China

Under the Law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the Enterprise Income Tax (“EIT”) rate of the PRC subsidiaries was 25% during the Relevant Periods except for certain members of the Group which was subject to tax concession set out below.

The Company was accredited as a “High and New Technology Enterprise” (“HNTE”) in 2022. Therefore, the Company was entitled to a preferential EIT rate of 15% during the Relevant Periods. The qualification as a HNTE is subject to review by the relevant tax authority in the PRC every three years.

In 2022, the Ministry of Finance and the State Administration of Taxation issued the Notice on the Further Implementation of Preferential Income Tax for Small and Micro Enterprises (Cai Shui [2022] No. 13), which provides that the portion of annual taxable income of small and micro enterprises exceeding RMB1,000,000 but not exceeding RMB3,000,000 shall be deducted to 25% of the taxable income and subject to income tax at a rate of 20% for the period from 1 January 2022 to 31 December 2027. Zhejiang GenFleet Therapeutics Co., Ltd., GenFleet Therapeutics (Beijing) Co., Ltd. and GenFleet Biopharmaceutical (Shanghai) Co., Ltd. were recognised as Small and Micro Enterprises and were entitled to a preferential tax rate of 20% during the Relevant Periods.

Pursuant to Cai Shui [2018] circular No. 76, the Company and Zhejiang GenFleet Therapeutics Co., Ltd. which was accredited as “Technology-based Small and Medium-sized Enterprises” can carry forward their unutilised tax losses for up to ten years. This extension of the expiration period applies to all the unutilised tax losses that were carried forward by the entities at the effective date of the tax circular.

Australia

The subsidiary incorporated and operated in Australia with turnover of less than AUD50,000,000 was subject to income tax at the rate of 25% on the estimated assessable profits during the Relevant Periods.

USA

The subsidiary incorporated and operated in United States of America is subject to the federal corporate income tax rate at 21% during the Relevant Periods.

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Loss before tax	(508,324)	(677,641)	(404,687)	(66,624)
Tax at the statutory tax rate (15%) . .	(76,249)	(101,646)	(60,703)	(9,994)
Effect of different tax rates enacted by local authorities	(5,833)	(5,358)	(1,998)	(1,290)
Additional deductible allowance for research and development expenses	(34,871)	(32,719)	(10,796)	(7,351)
Tax losses utilised from previous periods	(196)	—	—	—
Income not subject to tax	(2,488)	(474)	—	—
Deductible temporary difference and tax losses not recognised	73,435	78,115	35,246	9,834
Expenses not deductible for tax . . .	46,202	62,082	38,251	8,801
Tax charge at the Group’s effective rate	—	—	—	—

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Deferred tax assets have not been recognised in respect of these losses and deductible temporary differences as the Company and its subsidiaries 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 can be utilised.

According to the EIT Law, an additional 100% of qualified research and development expenses incurred is allowed to be deducted from taxable income effective from 1 October 2022 for GenFleet Biopharmaceutical (Shanghai) Co., Ltd, and GenFleet Biopharmaceutical (Shanghai) Co., Ltd. while Zhejiang GenFleet Therapeutics Co., Ltd. has been eligible for this additional deduction since 1 January 2022.

13. DIVIDENDS

No dividend was paid or declared by the Company during the Relevant Periods.

14. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY

On 29 September 2024, the Company was converted to a joint stock limited liability company. A total of 26,774,063 shares of par value of RMB1.00 each were issued and allotted to the respective shareholders of the Company according to the paid-in capital registered under these shareholders on that day. The conversion of paid-in capital to share capital with par value of RMB1.00 each is applied retrospectively for the Relevant Periods and four months ended 30 April 2024 for the purpose of computation of basic earnings per share.

The calculation of the basic loss per share amounts is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average numbers of ordinary shares in issue during the Relevant Periods and four months ended 30 April 2024. The calculation of the basic loss per share amounts didn’t consider the [REDACTED] by the Company, where the Company [REDACTED] its Share from one Share of RMB1.0 each into [REDACTED] Shares of RMB[REDACTED] each, which will become effective immediately prior to the [REDACTED].

The Group had no potentially dilutive ordinary shares in issue during the Relevant Periods and four months ended 30 April 2024.

The calculation of basic and loss per share is based on:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Loss				
Loss attributable to ordinary equity holders of the parent	(508,324)	(677,641)	(404,687)	(66,624)
Shares				
Weighted average number of ordinary shares in issue during the year/period used in the basic loss per share calculation	22,027,034	25,859,402	24,007,405	26,774,063
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (Express in RMB)				
– Basic and diluted	(23.08)	(26.20)	(16.86)	(2.49)

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15. PROPERTY, PLANT AND EQUIPMENT

The Group

	Machinery and equipment	Computer and office equipment	Motor Vehicles	Leasehold improvements	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
31 December 2023					
At 1 January 2023:					
Cost	38,884	5,690	1,276	12,851	58,701
Accumulated depreciation .	(14,012)	(3,378)	(458)	(9,457)	(27,305)
Net carrying amount	<u>24,872</u>	<u>2,312</u>	<u>818</u>	<u>3,394</u>	<u>31,396</u>
At 1 January 2023, net of accumulated depreciation	24,872	2,312	818	3,394	31,396
Additions	547	169	–	141	857
Disposal	(88)	(62)	–	–	(150)
Depreciation provided during the year	<u>(7,519)</u>	<u>(1,139)</u>	<u>(243)</u>	<u>(2,601)</u>	<u>(11,502)</u>
At 31 December 2023, net of accumulated depreciation	<u>17,812</u>	<u>1,280</u>	<u>575</u>	<u>934</u>	<u>20,601</u>
At 31 December 2023:					
Cost	39,229	5,688	1,276	12,992	59,185
Accumulated depreciation	(21,417)	(4,408)	(701)	(12,058)	(38,584)
Net carrying amount	<u>17,812</u>	<u>1,280</u>	<u>575</u>	<u>934</u>	<u>20,601</u>
	Machinery and equipment	Computer and office equipment	Motor Vehicles	Leasehold improvements	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000

31 December 2024:

At 1 January 2024:					
Cost	39,229	5,688	1,276	12,992	59,185
Accumulated depreciation .	(21,417)	(4,408)	(701)	(12,058)	(38,584)
Net carrying amount	<u>17,812</u>	<u>1,280</u>	<u>575</u>	<u>934</u>	<u>20,601</u>
At 1 January 2024, net of accumulated depreciation	17,812	1,280	575	934	20,601
Additions	33	2	–	201	236
Disposal	(2)	(11)	–	–	(13)
Depreciation provided during the year	<u>(6,424)</u>	<u>(695)</u>	<u>(242)</u>	<u>(1,135)</u>	<u>(8,496)</u>
At 31 December 2024, net of accumulated depreciation	<u>11,419</u>	<u>576</u>	<u>333</u>	<u>–</u>	<u>12,328</u>
At 31 December 2024:					
Cost	39,221	5,578	1,276	13,523	59,598
Accumulated depreciation .	(27,802)	(5,002)	(943)	(13,523)	(47,270)
Net carrying amount	<u>11,419</u>	<u>576</u>	<u>333</u>	<u>–</u>	<u>12,328</u>

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	Machinery and equipment	Computer and office equipment	Motor Vehicles	Leasehold improvements	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
30 April 2025					
At 1 January 2025:					
Cost	39,221	5,578	1,276	13,523	59,598
Accumulated depreciation	(27,802)	(5,002)	(943)	(13,523)	(47,270)
Net carrying amount	<u>11,419</u>	<u>576</u>	<u>333</u>	<u>—</u>	<u>12,328</u>
At 1 January 2025, net of accumulated depreciation	11,419	576	333	—	12,328
Additions	11	—	—	—	11
Disposal	(3)	—	—	—	(3)
Depreciation provided during the period	<u>(1,846)</u>	<u>(84)</u>	<u>(81)</u>	<u>—</u>	<u>(2,011)</u>
At 30 April 2025, net of accumulated depreciation	<u>9,581</u>	<u>492</u>	<u>252</u>	<u>—</u>	<u>10,325</u>
At 30 April 2025:					
Cost	39,225	5,575	1,276	13,195	59,271
Accumulated depreciation	(29,644)	(5,083)	(1,024)	(13,195)	(48,946)
Net carrying amount	<u>9,581</u>	<u>492</u>	<u>252</u>	<u>—</u>	<u>10,325</u>

As at 31 December 2023 and 2024 and 30 April 2025, there were no pledged property, plant and equipment.

The Company

	Machinery and equipment	Computer and office equipment	Motor Vehicles	Leasehold improvements	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
31 December 2023					
At 1 January 2023:					
Cost	33,456	5,094	1,276	11,085	50,911
Accumulated depreciation	(11,967)	(3,058)	(458)	(7,692)	(23,175)
Net carrying amount	<u>21,489</u>	<u>2,036</u>	<u>818</u>	<u>3,393</u>	<u>27,736</u>
At 1 January 2023, net of accumulated depreciation	21,489	2,036	818	3,393	27,736
Additions	484	168	—	128	780
Disposal	(51)	(50)	—	—	(101)
Depreciation provided during the year	<u>(6,481)</u>	<u>(1,014)</u>	<u>(243)</u>	<u>(2,597)</u>	<u>(10,335)</u>
At 31 December 2023, net of accumulated depreciation	<u>15,441</u>	<u>1,140</u>	<u>575</u>	<u>924</u>	<u>18,080</u>
At 31 December 2023:					
Cost	33,792	5,109	1,276	11,213	51,390
Accumulated depreciation	(18,351)	(3,969)	(701)	(10,289)	(33,310)
Net carrying amount	<u>15,441</u>	<u>1,140</u>	<u>575</u>	<u>924</u>	<u>18,080</u>

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	Machinery and equipment	Computer and office equipment	Motor Vehicles	Leasehold improvements	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
31 December 2024					
At 1 January 2024:					
Cost	33,792	5,109	1,276	11,213	51,390
Accumulated depreciation	(18,351)	(3,969)	(701)	(10,289)	(33,310)
Net carrying amount	<u>15,441</u>	<u>1,140</u>	<u>575</u>	<u>924</u>	<u>18,080</u>
At 1 January 2024, net of accumulated depreciation	15,441	1,140	575	924	18,080
Additions	2	2	–	202	206
Disposal	(2)	(10)	–	–	(12)
Depreciation provided during the year	<u>(5,448)</u>	<u>(592)</u>	<u>(242)</u>	<u>(1,126)</u>	<u>(7,408)</u>
At 31 December 2024, net of accumulated depreciation	<u>9,993</u>	<u>540</u>	<u>333</u>	<u>–</u>	<u>10,866</u>
At 31 December 2024:					
Cost	33,752	5,001	1,276	11,745	51,774
Accumulated depreciation	(23,759)	(4,461)	(943)	(11,745)	(40,908)
Net carrying amount	<u>9,993</u>	<u>540</u>	<u>333</u>	<u>–</u>	<u>10,866</u>

	Machinery and equipment	Computer and office equipment	Motor Vehicles	Leasehold improvements	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
30 April 2025					
At 1 January 2025:					
Cost	33,752	5,001	1,276	11,745	51,774
Accumulated depreciation	(23,759)	(4,461)	(943)	(11,745)	(40,908)
Net carrying amount	<u>9,993</u>	<u>540</u>	<u>333</u>	<u>–</u>	<u>10,866</u>
At 1 January 2025, net of accumulated depreciation	9,993	540	333	–	10,866
Additions	10	–	–	–	10
Depreciation provided during the period	<u>(1,620)</u>	<u>(79)</u>	<u>(81)</u>	<u>–</u>	<u>(1,780)</u>
At 30 April 2025, net of accumulated depreciation	<u>8,383</u>	<u>461</u>	<u>252</u>	<u>–</u>	<u>9,096</u>
At 30 April 2025:					
Cost	33,762	5,001	1,276	–	40,039
Accumulated depreciation	(25,379)	(4,540)	(1,024)	–	(30,943)
Net carrying amount	<u>8,383</u>	<u>461</u>	<u>252</u>	<u>–</u>	<u>9,096</u>

As at 31 December 2023 and 2024 and 30 April 2025, there were no pledged property, plant and equipment.

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16. LEASES

The Group as a lessee

The Group has lease contracts for various items of office premises used in its operations. Leases of office premises generally have lease terms between 2 and 10 years. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group.

(a) Right-of-use assets

The carrying amounts of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Office premises
	<i>RMB’000</i>
As at 31 December 2023	
As at 1 January 2023	29,528
Depreciation charge	<u>(6,167)</u>
As at 31 December 2023.	<u>23,361</u>
	Office premises
	<i>RMB’000</i>
As at 31 December 2024	
As at 1 January 2024	23,361
Depreciation charge	(5,440)
Lease reassessment	<u>(2,509)</u>
As at 31 December 2024.	<u>15,412</u>
	Office premises
	<i>RMB’000</i>
As at 30 April 2025	
As at 1 January 2025	15,412
Addition	173
Depreciation charge	<u>(1,373)</u>
As at 30 April 2025.	<u>14,212</u>

(b) Lease liabilities

The carrying amount of lease liabilities and the movements during the Relevant Periods are as follows:

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount at 1 January.	31,763	26,361	18,220
New leases	–	–	173
Accretion of interest recognised during the year/period	1,366	1,112	271
Payments	(6,768)	(6,256)	(2,458)
Lease reassessment	–	(2,997)	–
Carrying amount.	<u>26,361</u>	<u>18,220</u>	<u>16,206</u>
Analysed into:			
Current portion.	5,526	4,243	3,345
Non-current portion	20,835	13,977	12,861

The maturity analysis of lease liabilities is disclosed in Note 36 to the Historical Financial Information.

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(c) The amounts recognised in profit or loss in relation to leases are as follows:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Depreciation of right-of-use assets . .	6,167	5,440	1,814	1,373
Interest on lease liabilities	1,366	1,112	389	271
Gain on lease reassessment	–	(488)	(488)	–
Expenses relating to short-term and low-value leases	1,540	961	375	387
Total amount recognised in profit or loss	<u>9,073</u>	<u>7,025</u>	<u>2,090</u>	<u>2,031</u>

(d) The total cash outflow for leases is disclosed in Note 31 to the Historical Financial Information.

The Company as a lessee

The Company has lease contracts for various items of office premises used in its operations. Leases of office premises generally have lease terms between 3 and 10 years. Generally, the Company is restricted from assigning and subleasing the leased assets outside the Company.

(a) Right-of-use assets

The carrying amounts of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Office premises
	RMB'000
As at 31 December 2023	
As at 1 January 2023	29,363
Depreciation charge	(6,077)
As at 31 December 2023	<u>23,286</u>
	Office premises
	RMB'000
As at 31 December 2024	
As at 1 January 2024	23,286
Depreciation charge	(5,365)
Lease reassessment	(2,509)
As at 31 December 2024	<u>15,412</u>
	Office premises
	RMB'000
As at 30 April 2025	
As at 1 January 2025	15,412
Depreciation charge	(1,340)
As at 30 April 2025	<u>14,072</u>

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(b) Lease liabilities

The carrying amounts of lease liabilities and the movements during the Relevant Periods are as follows:

	As at 31 December 2023 RMB'000	As at 31 December 2024 RMB'000	As at 30 April 2025 RMB'000
Carrying amount at 1 January	31,574	26,334	18,220
Accretion of interest recognised during the year/period	1,361	1,111	270
Payments	(6,601)	(6,228)	(2,458)
Lease reassessment	–	(2,997)	–
Carrying amount	<u>26,334</u>	<u>18,220</u>	<u>16,032</u>
Analysed into:			
Current portion	5,499	4,243	3,171
Non-current portion	<u>20,835</u>	<u>13,977</u>	<u>12,861</u>

The maturity analysis of lease liabilities is disclosed in Note 36 to the Historical Financial Information.

(c) The amounts recognised in profit or loss in relation to leases are as follows:

	Year ended 31 December		Four months ended 30 April	
	2023 RMB'000	2024 RMB'000	2024 RMB'000 (unaudited)	2025 RMB'000
Depreciation of right-of-use assets . .	6,077	5,365	1,814	1,340
Interest on lease liabilities	1,361	1,111	389	270
Lease reassessment	–	(488)	(489)	–
Expenses relating to short-term and low-value leases	<u>1,500</u>	<u>943</u>	<u>375</u>	<u>369</u>
Total amount recognised in profit or loss	<u>8,938</u>	<u>6,931</u>	<u>2,089</u>	<u>1,979</u>

17. INTANGIBLE ASSETS

The Group and the Company

	Software RMB'000
31 December 2023	
At 1 January 2023:	
Cost	1,567
Accumulated amortisation	<u>(167)</u>
Net carrying amount	<u>1,400</u>
At 1 January 2023, net of accumulated amortisation	1,400
Addition	187
Amortisation provided during the year	<u>(186)</u>
At 31 December 2023, net of accumulated amortisation	<u>1,401</u>
At 31 December 2023:	
Cost	1,754
Accumulated amortisation	<u>(353)</u>
Net carrying amount	<u>1,401</u>

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	Software
	<i>RMB’000</i>
31 December 2024	
At 1 January 2024:	
Cost	1,754
Accumulated amortisation	(353)
Net carrying amount	<u>1,401</u>
At 1 January 2024, net of accumulated amortisation	1,401
Addition	32
Amortisation provided during the year	(176)
At 31 December 2024, net of accumulated amortisation.	<u>1,257</u>
At 31 December 2024:	
Cost	1,786
Accumulated amortisation	(529)
Net carrying amount	<u>1,257</u>

	Software
	<i>RMB’000</i>
30 April 2025	
At 1 January 2025:	
Cost	1,786
Accumulated amortisation	(529)
Net carrying amount	<u>1,257</u>
At 1 January 2025, net of accumulated amortisation	1,257
Addition	–
Amortisation provided during the period	(59)
At 30 April 2025, net of accumulated amortisation.	<u>1,198</u>
At 30 April 2025:	
Cost	1,786
Accumulated amortisation	(588)
Net carrying amount	<u>1,198</u>

18. TRADE RECEIVABLE

The Group

	As at 31 December 2023	As at 31 December 2024	As at 30 April 2025
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade receivables	72,353	109,153	97,518
Impairment	–	–	–
Total	<u>72,353</u>	<u>109,153</u>	<u>97,518</u>

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ACCOUNTANTS’ REPORT

The Company

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Trade receivables	72,353	109,153	97,518
Impairment	—	—	—
Total	<u>72,353</u>	<u>109,153</u>	<u>97,518</u>

The Group’s trading terms with its customers are mainly on credit. The credit period is generally 30 to 60 days, depending on the contract terms. Each customer has a maximum credit limit. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

The Group

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Within 1 year.	72,353	109,153	97,518
Total	<u>72,353</u>	<u>109,153</u>	<u>97,518</u>

The Company

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Within 1 year.	72,353	109,153	97,518
Total	<u>72,353</u>	<u>109,153</u>	<u>97,518</u>

An impairment analysis is performed at each reporting date. The Group has applied the simplified approach to provide for ECLs prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. The directors of the Company are of the opinion that the ECL in respect of the balance of trade receivables is minimal. No loss allowance for impairment of trade receivables is provided as at 31 December 2023 and 2024 and 30 April 2025.

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19. PREPAYMENTS AND OTHER RECEIVABLES

The Group

	As at 31 December 2023 RMB'000	As at 31 December 2024 RMB'000	As at 30 April 2025 RMB'000
Non-current:			
Rental and other deposits	1,480	1,514	1,514
Value-added tax recoverable	6,635	7,865	8,017
Others	160	197	199
Total	8,275	9,576	9,730
Current:			
Prepayments for research and development			
services and other services	26,755	22,194	26,176
Rental and other deposits	7,375	7,139	3,576
Value-added tax recoverable	4,537	10,719	16,771
Other receivables	5,469	15,420	4,816
Deferred [REDACTED] expense	[REDACTED]	[REDACTED]	[REDACTED]
Total	44,136	58,594	56,013

The Company

	As at 31 December 2023 RMB'000	As at 31 December 2024 RMB'000	As at 30 April 2025 RMB'000
Non-current:			
Rental deposits	1,481	1,514	1,514
Others	159	197	199
Total	1,640	1,711	1,713
Current:			
Prepayments for research and development			
services and others	4,397	8,987	8,857
Rental and other deposits	373	337	61
Value-added tax recoverable	4,537	11,564	16,771
Other receivables	319	15,071	4,754
Deferred [REDACTED] expense	[REDACTED]	[REDACTED]	[REDACTED]
Total	9,626	39,081	35,117

The financial assets included in the above balances relate to receivables for which there were no recent history of default and past due amounts. In addition, there is no significant change in the economic factors based on the assessment of the forward-looking information, so the directors of the Company are of the opinion that the ECLs in respect of these balances are minimal. The balances are interest-free and are not secured with collateral.

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20. TIME DEPOSITS AND CASH AND CASH EQUIVALENTS

The Group

Cash and cash equivalents

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Cash at banks	332,197	255,226	308,644
Time deposits	31,752	139,689	82,122
Subtotal	363,949	394,915	390,766
Less:			
Time deposits over three months	(31,752)	(32,790)	—
Cash and cash equivalents	332,197	362,125	390,766
Denominated in:			
RMB	75,183	24,714	74,224
USD	238,818	319,040	303,165
AUD	18,196	18,371	13,377
Total	332,197	362,125	390,766

Time deposits

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Time deposits over three months but less than one year – current.	—	32,790	—
Time deposits over one year – non-current.	31,752	—	—
Total	31,752	32,790	—
Denominated in:			
RMB	31,752	32,790	—

The Company

Cash and cash equivalents

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Cash at banks	241,962	217,909	282,013
Time deposits	31,752	128,335	79,791
Subtotal	273,714	346,244	361,804
Less:			
Time deposits over three months	(31,752)	(32,790)	—
Cash and cash equivalents	241,962	313,454	361,804

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	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Denominated in:			
RMB	21,008	12,675	71,425
USD	220,954	300,779	290,379
Total	241,962	313,454	361,804

Time deposits

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Time deposits over three months but less than one year – current.	–	32,790	–
Time deposits over one year – non-current.	31,752	–	–
Total	31,752	32,790	–
Denominated in:			
RMB	31,752	32,790	–
USD	–	–	–
Total	31,752	32,790	–

The RMB is not freely convertible into other currencies, however, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, 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.

Cash at banks earns interest at floating rates based on daily bank deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default.

21. TRADE AND OTHER PAYABLES

The Group

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Current:			
Trade payables	8,355	6,292	10,836
Payroll payables	19,656	17,711	8,561
Accrued expenses for research and development services	49,335	73,704	63,964
Accrued [REDACTED] expense	[REDACTED]	[REDACTED]	[REDACTED]
Other taxes payables	1,088	987	684
Other payables			
– License-out agreement option termination fee (note a)	–	68,573	69,112
– Accrued expenses	3,910	1,216	688
– Others	503	544	181
Total	82,847	181,733	159,406

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	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Non-current:			
Other payables			
– License-out agreement option termination fee (note a)	–	55,676	56,429
Total	–	55,676	56,429

Note:

(a) The detail information of License-out option termination fee is described in Note 5.

An ageing analysis of the trade payables as at each end of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Within 3 months	8,355	6,292	10,836
Total	8,355	6,292	10,836

The trade payables are non-interest-bearing and payable on demand, which are normally settled on terms of 1 to 3 months.

The Company

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Current:			
Trade payables	8,270	6,164	9,451
Payroll payables	11,257	11,503	5,616
Accrued expenses for research and development services	36,267	66,938	58,450
Accrued [REDACTED] expense	[REDACTED]	[REDACTED]	[REDACTED]
Other taxes payables	566	675	415
Other payables			
– License-out agreement option termination fee (note a)	–	68,573	69,112
– Accrued expenses	3,874	706	375
– Others	176	535	7,204
Total	60,410	166,859	156,003
Non-current:			
Other payables			
– License-out agreement option termination fee (note a)	–	55,676	56,429
Total	–	55,676	56,429

Note:

(a) The detail information of License-out option termination fee is described in Note 5.

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An ageing analysis of the trade payables as at the end of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Within 3 months	8,270	6,164	9,451
Total	<u>8,270</u>	<u>6,164</u>	<u>9,451</u>

The trade payables are non-interest-bearing and payable on demand, which are normally settled on terms of 1 to 3 months.

22. INTEREST-BEARING BANK BORROWINGS

The Group and the Company

As at 31 December 2023			
	Effective interest rate per annum	Maturity	RMB'000
	%		
Current:			
Bank loans-unsecured.	2.85-2.95	2024	<u>5,312</u>

As at 31 December 2024			
	Effective interest rate per annum	Maturity	RMB'000
	%		
Current:			
Bank loans-unsecured.	2.50-2.90	2025	<u>51,128</u>

As at 30 April 2025			
	Effective interest rate per annum	Maturity	RMB'000
	%		
Current:			
Bank loans-unsecured.	2.50-2.75	2025-2026	<u>85,117</u>

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Bank loans repayable:			
Within one year	<u>5,312</u>	<u>51,128</u>	<u>85,117</u>

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23. DEFERRED INCOME

The Group

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Government grants	503	—	—
	<u>503</u>	<u>—</u>	<u>—</u>

* The movements in deferred income during the Relevant Periods are as follows:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
At beginning of the year/period	3,651	503	503	—
Grants received during the year/period	18,638	6,366	228	242
Amounts released to profit or loss during the year/period .	(21,786)	(6,869)	(678)	(242)
At end of the year/period . . .	<u>503</u>	<u>—</u>	<u>53</u>	<u>—</u>

24. CONTRACT LIABILITIES

The Group and the Company

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Contract liabilities.	101,914	42,204	12,348
	<u>101,914</u>	<u>42,204</u>	<u>12,348</u>

Contract liabilities represented the obligation to transfer the Ex-China Option of GFH925 to Innovent and the obligation to transfer the Ex-China Option of GFH375 to Verastem. The changes of contractual liabilities on GFH925 are mainly due to the addition or termination of options to develop and commercialize the licensed products and licensed compounds of GFH925 in the Ex-China Territory and the exercise of the Ex-China Option of GFH375 at the end of the year/period as detailed in Note 5.

25. REDEMPTION LIABILITIES ON EQUITY SHARES

From January 2018 to March 2024, the Company had received several rounds of investments as follows:

In January 2018, the Company issued 2,500,000 angel round equity shares with a par value of RMB1.00 per share (“Angel Round Shares”) to several independent investors for a cash consideration of RMB60,000,000 or RMB24.00 per share.

In January 2019, the Company issued first tranche of 2,647,059 series A equity shares with a par value of RMB1.00 per share (“Series A Shares”) to several independent investors for a cash consideration of RMB120,000,000 or RMB45.33 per share.

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In April 2019, the Company issued 322,129 series A + equity shares with a par value of RMB1.00 per share (“Series A+ Shares”) to one independent investors for a cash consideration of RMB20,000,000 or RMB62.09 per share.

In February and March 2020, the Company issued second tranche of 581,622 Series A Shares to several independent investors for a cash consideration of RMB30,000,000 or RMB51.58 per share.

In March 2020, the Company issued 5,122,199 series B equity shares with a par value of RMB1.00 per share (“Series B Shares”) to several independent investors for a cash consideration of RMB343,000,000 or RMB66.96 per share.

In March 2021, the Company issued 2,156,401 series B+ equity shares with a par value of RMB1.00 per share (“Series B+ Shares”) to several independent investors for a cash consideration of RMB200,000,000 or RMB92.75 per share.

In December 2022, the Company issued 3,889,673 series C equity shares with a par value of RMB1.00 per share (“Series C Shares”) to several independent investors for a cash consideration of RMB491,082,000 or RMB124.03 per share.

In March 2024, the Company issued 1,673,807 series C+ equity shares with a par value of RMB1.00 per share (“Series C+ Shares”) to several independent investors for a cash consideration of RMB195,011,000 or RMB116.68 per share.

Angel Round Shares, Series A Shares, Series A+ Shares, Series B Shares, Series B+ Shares, Series C Shares and Series C+ Shares are collectively referred as Shares.

The key terms of the Shares are summarized as follows:

(1) Voting rights

All shareholders, including the holders of ordinary shares and holders of Shares, are entitled to vote together as a single class on a pro-rata basis.

(2) Dividends rights

The Group’s capital reserve, surplus reserve and undistributed reserve (if any) are shared by all shareholders in proportion to their shareholding.

No dividend or distribution, whether in cash, in property, or in any other shares of the Group, shall be declared, paid, set aside or made with respect to the ordinary shares at any time unless a dividend or distribution in like amount is likewise declared, paid, set aside or made at the same time with respect to each issued and outstanding payable of Shares in cash when, as and if declared by the Group.

(3) Redemption features

Upon occurrence of the following events which cannot be controlled by the Company, the Shares shall be redeemable by the Company at the option of the shareholders:

- (a) The Company fails to achieve a qualified [REDACTED] or qualified overall sale of the Company before 31 December 2024;
- (b) the founders or controlling shareholders of the Company is changed or they have actually ceased to contribute their time and efforts to the Company;
- (c) The Company, GenFleet Therapeutics (H.K.) Limited, employee incentive platforms or the founders seriously violates the transaction documents (including but not limited to any breach of representations, warranties, commitments, full-time service and non-competition commitments, etc.);
- (d) The founders of the Company, engage in significant acts of dishonesty that may cause unknown off-balance liabilities or unknown off-balance cash income; or

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- (e) The Company or the Group undergoes events that may cause significant obstacles to the qualified [REDACTED] of the Company and the obstacles cannot be overcome according to the relevant provisions of PRC laws or any one of the Company, GenFleet Therapeutics (H.K.) Limited, employee incentive platforms or the founders refuse to correct these obstacles.

The redemption amount is calculated as the higher of (i) the original investment principal from investors with an annual compound interest rate of 12% of the original investment principal plus any dividends declared but unpaid for a period of time commencing from the actual investment payment date to the actual settlement of redemption amount date (referred as “P+I”) and (ii) the net assets of the Company at the time of transfer attributable to the shareholders according to share percentage.

(4) Liquidation preferences

In the event of any liquidation or deemed liquidation event, holders of the Shares shall be entitled to be paid out of the funds and assets available for distribution to the members of the Company, an amount per share equal to the original issue price for each series equity share with an annual compound interest rate of 12% or 10% plus any dividends declared but unpaid thereon in the sequence as follows:

- (1) Series C+ Shares
- (2) Series C Shares
- (3) Series B+ Shares
- (4) Series B Shares
- (5) Series A+ Shares
- (6) Series A Shares
- (7) Angel Round Shares

(5) Anti-dilution right

If the Company increases its paid-in capital at a price lower than the price paid by the investors on a per paid-in capital basis, the investors have a right to require the Company to issue additional paid-in capital at the lowest issue price permitted by law to the investors or receive cash compensation from the Company, and the investors also have a right to require the controlling shareholders to transfer shares to the investors at the lowest issue price permitted by law or receive cash compensation from the controlling shareholders, so that the total amount paid by the investors divided by the total amount of paid-in capital obtained is equal to the price per paid-in capital in the new issuance.

Presentation and classification

The Group and the Company have designated the Shares issued to investors as whole as financial liabilities carried at FVTPL and presented as “redemption liabilities on equity shares” in the consolidated statements of financial position. The change in fair value of the redemption liabilities on equity shares is charged to profit or loss except for the portion attributable to credit risk change that shall be charged to other comprehensive income. Management considered that the fair value change in the redemption liabilities on equity shares attributable to changes of own credit risk is not significant.

The redemption liabilities on equity shares were presented in current liabilities as at 31 December 2023 and 2024 and 30 April 2025 as the Company would be requested to redeem the Shares upon occurrence of the events which cannot be controlled by the Company as detailed above.

The redemption features and liquidation preferences will be automatically terminated upon [REDACTED].

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The movements in our redemption liabilities on equity shares are set out as follows:

The Group and the Company

	Angel Round Shares	Series A Shares	Series A+ Shares	Series B Shares	Series B+ Shares	Series C Shares	Series C+ Shares	Total Shares
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2023 . . .	113,668	190,990	20,941	360,557	194,262	499,097	–	1,379,515
Change in fair value . .	13,163	39,363	5,438	98,683	50,165	50,181	–	256,993
At 31 December 2023 .	126,831	230,353	26,379	459,240	244,427	549,278	–	1,636,508
Issue	–	–	–	–	–	–	195,011	195,011
Change in fair value . .	45,688	54,037	4,550	64,024	23,177	89,672	101,454	382,602
At 31 December 2024 .	172,519	284,390	30,929	523,264	267,604	638,950	296,465	2,214,121
Issue								
Change in fair value . .	10,268	14,426	1,337	19,639	6,498	(236)	(1,240)	50,692
At 30 April 2025	182,787	298,816	32,266	542,903	274,102	638,714	295,225	2,264,813

The Company used the discounted cash flow and back-solve method to determine the underlying share value of the Company and performed an equity allocation based on the Option Pricing model (“OPM model”) to arrive the fair value of the redemption liabilities on equity shares as at the end of each reporting period with reference to valuation report carried out by an independent valuer.

In addition to the underlying share value of the Company determined by the back-solve method, other key valuation assumptions used in the OPM model to determine the fair value are as follows:

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Risk-free interest rate	2.08%	1.14%	1.47%
DLOM	15.09%	14.70%	14.10%
Volatility	58.00%	56.00%	58.00%
Possibilities under liquidation scenario	30.00%	27.50%	25.00%
Possibilities under redemption scenario	30.00%	27.50%	25.00%
Possibilities under conversion scenario	40.00%	45.00%	50.00%

The Group estimated the risk-free interest rate based on the yield of China government bond with maturity close to the expected exit timing as of the valuation date. The DLOM was estimated based on the option-pricing method. Under the option-pricing method, the cost of put option, which can hedge the price change before the privately held share can be sold, was considered as a basis to determine DLOM. Volatility was estimated based on annualized standard deviation of daily shares price return of comparable companies for a period from the valuation date and with a similar span as time to expiration.

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26. DEFERRED TAX

Deferred tax liabilities

	Right-of-use assets	Total
	<i>RMB'000</i>	<i>RMB'000</i>
As at 1 January 2023	4,437	4,437
Credited to the consolidated statements of profit or loss and other comprehensive income	(929)	(929)
As at 31 December 2023	3,508	3,508
Credited to the consolidated statements of profit or loss and other comprehensive income	(1,196)	(1,196)
As at 31 December 2024	2,312	2,312
Credited to the consolidated statements of profit or loss and other comprehensive income	(173)	(173)
As at 30 April 2025	<u>2,139</u>	<u>2,139</u>

Deferred tax assets

	Tax Losses	Lease liabilities	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
As at 1 January 2023	–	4,437	4,437
(Credited)/charged to the consolidated statements of profit or loss and other comprehensive income	10	(939)	(929)
As at 31 December 2023	10	3,498	3,508
Charged to the consolidated statements of profit or loss and other comprehensive income	(10)	(1,186)	(1,196)
As at 31 December 2024	–	2,312	2,312
Charged to the consolidated statements of profit or loss and other comprehensive income	–	(173)	(173)
As at 30 April 2025	<u>–</u>	<u>2,139</u>	<u>2,139</u>

For presentation purposes, certain deferred tax assets and liabilities have been offset in the statements of financial position. The following is an analysis of the deferred tax balances of the Group for financial reporting purposes:

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Net deferred tax assets recognised in the consolidated statement of financial position . . .	–	–	–
Net deferred tax liabilities recognised in the consolidated statement of financial position . . .	–	–	–
Net deferred tax liabilities in respect of continuing operations	<u>–</u>	<u>–</u>	<u>–</u>

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27. PAID-IN CAPITAL/SHARE CAPITAL

The Group and the Company

Pursuant to the shareholders’ resolutions dated 25 July 2024, the then existing shareholders of the Company approved the conversion of the Company into a joint stock company with limited liabilities with 26,774,063 shares in a nominal value of RMB1.0 each. Upon the completion of registration with the Administration for Market Regulation of the Shanghai (上海市市場監督管理局) on 29 September 2024, the Company was converted into a joint stock company with limited liability.

Paid-in capital/Share capital

	Share capital
	<i>RMB’000</i>
As at 1 January 2023, 31 December 2023 and 1 January 2024	22,027
Issue of new shares (<i>note a</i>)	2,648
Capital contribution from employee incentive platforms (<i>note b</i>)	2,099
As at 31 December 2024, 1 January 2025 and 30 April 2025	26,774

Notes:

- (a) On 24 July 2023, the Company passed shareholders’ resolutions and approved the increase of the registered capital of the Company from RMB24,852,000 to RMB25,100,000 for employee incentive platforms. On 28 December 2023, the Company passed shareholders’ resolutions and approved, among other things, the increase of the registered capital of the Company from RMB25,100,000 to RMB26,774,000, the capital contribution by shareholders related to the increase of the registered capital was settled in March 2024.
- (b) In March 2024, the consideration of RMB12,860,000 for registered capital of RMB3,073,000 was settled by employee incentive platforms. As at 31 December 2024, the share capital of the Company was RMB26,774,000 and fully paid.

28. RESERVES

The Group

The amounts of the Group’s share premium and other reserves and the movements therein for the Relevant Periods are presented in the consolidated statement of changes in equity.

(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 share awards as set out in Note 29 to the Historical Financial Information.

(c) *Other reserves*

Other reserves of the Group represent the carrying amounts of the equity shares with redemption features as stipulated in Note 25 to the Historical Financial Information.

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(d) Foreign currency translation reserve

The foreign currency translation reserve is used to record exchange differences arising from the translation of the financial statements of entities of which the functional currency is not RMB.

The Company

	Share premium	Share-based payment 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>
At 1 January 2023	1,246,080	1,555	(1,264,082)	(621,076)	(637,523)
Loss for the year	—	—	—	(396,208)	(396,208)
Total comprehensive loss for the year	—	—	—	(396,208)	(396,208)
Share-based payment compensation	—	36,968	—	—	36,968
At 31 December 2023 and 1 January 2024	1,246,080	38,523	(1,264,082)	(1,017,284)	(996,763)
Loss for the year	—	—	—	(582,669)	(582,669)
Total comprehensive loss for the year	—	—	—	(582,669)	(582,669)
Issue of new shares	193,338	—	—	—	193,338
Capital contribution from employee incentive platforms	9,786	—	—	—	9,786
Capitalisation Issue (<i>note a</i>).	(734,351)	—	—	734,351	—
Recognition of redemption liabilities on equity shares	—	—	(195,011)	—	(195,011)
Share-based payment compensation	—	26,942	—	—	26,942
At 31 December 2024 and 1 January 2025	714,853	65,465	(1,459,093)	(865,602)	(1,544,377)
Loss for the period	—	—	—	(42,797)	(42,797)
Total comprehensive loss for the period	—	—	—	(42,797)	(42,797)
Share-based payment compensation	—	8,776	—	—	8,776
At 30 April 2025	714,853	74,241	(1,459,093)	(908,399)	(1,578,398)

Note:

- (a) On 29 September 2024, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC. The net assets of the Company under PRC Generally Accepted Accounting Principles as of the conversion base date, including paid-in capital, share premium and accumulated losses, amounting to RMB760,278,237 were converted into 26,774,063 share capital at RMB1.00 each.

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29. SHARE-BASED PAYMENTS

Employee Incentive Scheme

The Company adopted a share incentive plan (“Employee Incentive Scheme”) in 2020, as amended and restated in 2023, for the purpose of attracting and retaining the best talents who promote the success of the Group’s operations. Eligible participants of the Employee Incentive Scheme include the certain directors of the Company, and employees of the Group. Pursuant to the adopted Employee Incentive Scheme in 2023, 2,383,606 shares of the Company were allocated to four employee incentive platforms. The restricted shares granted to each grantee shall vest and tradeable upon one year anniversary of the [REDACTED] of the Company. The eligible participants would be repaid with original subscription price plus single digit interest if employment were terminated before the vesting date. After taking into consideration of the best estimation of the [REDACTED], the management determined the vesting period of the relevant restricted shares based on the above performance conditions and service requirements. As such, the share-based payment expenses are amortised during the vesting period.

The fair value of services received in return for shares granted to employees and directors was measured by reference to the fair value of the shares granted and the subscription price paid by employees and directors. During the Relevant Periods, the Company granted nil, 2,226,857 and 42,000 restricted shares, respectively, with fair values ranging from RMB24.67 to RMB60.83 per share.

Details of the granted shares are as follows:

Date of grant	Number of restricted shares	Subscription price per share	Fair value of the underlying shares
2020/12/21	246,000	RMB0.0000	RMB24.67
2023/10/31	1,098,607	RMB5.6658	RMB53.65
2023/10/31	128,250	RMB0.0000	RMB53.65
2023/9/30	1,000,000	RMB5.7562	RMB53.65
2024/2/29	8,000	RMB5.6658	RMB53.65
2024/4/30	10,000	RMB5.6658	RMB60.83
2024/5/31	16,000	RMB5.6658	RMB60.83
2024/6/7	2,000	RMB0.0000	RMB60.83
2024/6/7	6,000	RMB5.6658	RMB60.83
2024/7/12	8,000	RMB5.6658	RMB60.83
Total	<u>2,522,857</u>		

The following numbers of restricted shares were outstanding under the Employee Incentive Scheme during the Relevant Periods:

	As at 31 December 2023 RMB’000	As at 31 December 2024 RMB’000	As at 30 April 2025 RMB’000
At the beginning of the year/period	171,000	2,383,607	2,383,607
Granted during the year/period	2,226,857	50,000	–
Forfeited during the year/period	(14,250)	(50,000)	–
At the end of the year/period	<u>2,383,607</u>	<u>2,383,607</u>	<u>2,383,607</u>

During the Relevant Periods and the four months ended 30 April 2024, share-based payment compensation expenses of RMB36,968,000, RMB26,942,000, RMB8,776,000 and RMB9,584,000 (unaudited) were charged to profit or loss.

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The fair values of the restricted shares as at the grant date were determined with reference to the fair value of ordinary shares on the grant dates, using back-solve method. Major inputs used for the determination of the fair values of ordinary shares are listed as follows:

	At grant dates
Expected volatility	54%-58%
Risk-free interest rate.	2.08%-2.86%
Discount for lack of marketability	15.09%-22.24%

30. INVESTMENTS IN SUBSIDIARIES

The Company

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Investment Cost	303,526	398,352	411,740

31. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the Relevant Periods, the Group had non-cash additions to right-of-use assets of nil and nil and non-cash additions to lease liabilities of nil and nil, respectively, in respect of lease arrangements for office premises.

(b) Changes in liabilities arising from financing activities

	Lease liabilities	Interest-bearing bank borrowings	Redemption liabilities on equity shares	Accrued transaction cost on issue of redemption liabilities on equity shares in trade and other payables	Accrued [REDACTED] expenses included in trade and other payable
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2023	31,763	22,767	1,379,515	4,717	[REDACTED]
Changes from financing cash flows					
Additions	–	5,312	–	–	[REDACTED]
Payments	(6,768)	(22,886)	–	(4,717)	[REDACTED]
Accretion of interest recognised during the year.	1,366	119	–	–	[REDACTED]
Change in fair value of redemption liabilities on equity shares	–	–	256,993	–	[REDACTED]
At 31 December 2023 and 1 January 2024	26,361	5,312	1,636,508	–	[REDACTED]

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	Lease liabilities	Interest-bearing bank borrowings	Redemption liabilities on equity shares	Accrued transaction cost on issue of redemption liabilities on equity shares in trade and other payables	Accrued [REDACTED] expenses included in trade and other payable
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Changes from financing cash flows					
Additions	–	56,928	195,011	11,840	[REDACTED]
Payments	(6,256)	(11,989)	–	(11,840)	[REDACTED]
Accretion of interest recognised during the year.	1,112	877	–	–	[REDACTED]
Change in fair value of redemption liabilities on equity shares	–	–	382,602	–	[REDACTED]
Lease reassessment	(2,997)	–	–	–	[REDACTED]
At 31 December 2024 and 1 January 2025	18,220	51,128	2,214,121	–	[REDACTED]
Changes from financing cash flows.					
Additions	173	54,900	–	–	[REDACTED]
Payments.	(2,458)	(21,529)	–	–	[REDACTED]
Accretion of interest recognised during the period	271	618	–	–	[REDACTED]
Change in fair value of redemption liabilities on equity shares	–	–	50,692	–	[REDACTED]
At 30 April 2025	16,206	85,117	2,264,813	–	[REDACTED]

(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		Four months ended 30 April	
	2023	2024	2024	2025
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			(unaudited)	
Within operating activities.	1,540	961	375	387
Within financing activities.	6,768	6,256	2,016	2,458
Total	8,308	7,217	2,391	2,845

32. COMMITMENTS

The Group had the following contractual commitments at the end of the Relevant Periods:

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Property, plant and equipment	5	1	–
	=	=	=

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33. RELATED PARTY TRANSACTIONS

(a) Names and relationships

Name of related parties	Relationship with the Group
Hongyong Binde (Hong Kong) Limited (鴻永秉德(香港)有限公司) (“Hongyong”)	Shareholder of the Company*

* Hongyong has significant influence over the Group as Hongyong had a representation on the board of directors of the Company.

(b) Significant related party transactions

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Rendering of services				
Hongyong	–	1,191	1,191	–
	=	=	=	=

(c) Compensation of key management personnel of the Group:

	Year ended 31 December		Four months ended 30 April	
	2023	2024	2024	2025
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Salaries, allowances and benefits in kind	2,757	1,996	322	994
Performance related bonuses	2,888	3,328	1,109	842
Pension scheme contributions	–	–	–	–
Equity-settled share award expense	31,090	–	–	–
Total compensation paid to key management personnel	36,735	5,324	1,431	1,836
	=	=	=	=

Further details of directors’ and supervisors’ emoluments are included in Note 10 to the Historical Financial Information.

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34. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of the Relevant Periods are as follows:

The Group

Financial assets

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Financial assets at amortised cost:			
Trade receivables	72,353	109,153	97,518
Financial assets included in prepayments and other receivables	14,324	24,073	9,906
Cash and cash equivalents	332,197	362,125	390,766
Time deposits	31,752	32,790	–
Total	<u>450,626</u>	<u>528,141</u>	<u>498,190</u>

Financial liabilities

	As at 31 December	As at 31 December	As at 30 April
	2023	2024	2025
	RMB'000	RMB'000	RMB'000
Financial liabilities at FVTPL:			
Redemption liabilities on equity shares	<u>1,636,508</u>	<u>2,214,121</u>	<u>2,264,813</u>
Financial liabilities at amortised cost:			
Interest-bearing bank borrowings	5,312	51,128	85,117
Financial liabilities included in trade and other payables	<u>62,103</u>	<u>218,711</u>	<u>206,590</u>
Total	<u>67,415</u>	<u>269,839</u>	<u>291,707</u>

35. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Fair values

Management has assessed that the fair values of cash and cash equivalents, financial assets included in prepayments and other receivables (in the current portion), financial liabilities included in trade and other payables approximate to their carrying amounts largely due to the short-term maturities of these instruments. The fair values of the other non-current financial assets and financial liabilities have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

The Group’s finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At the end 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 valuation is reviewed and approved by the finance manager.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

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The Group invests in financial assets at fair value through profit or loss, which represent structured deposits products issued by banks. The fair values are based on cash flows discounted using the expected yield rate.

The fair values of the redemption liabilities on equity shares measured at FVTPL are determined using the OPM. Further details are set out in note 25 to the Historical Financial Information.

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

The Group

Liabilities measured at fair value:

	Fair value measurement using			Total
	Quoted prices in active markets	Significant observable inputs	Significant unobservable inputs	
	(Level 1)	(Level 2)	(Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
As at 31 December 2023				
Redemption liabilities on equity shares	–	–	1,636,508	1,636,508
	=	=	=	=
As at 31 December 2024				
Redemption liabilities on equity shares	–	–	2,214,121	2,214,121
	=	=	=	=
As at 30 April 2025				
Redemption liabilities on equity shares	–	–	2,264,813	2,264,813
	=	=	=	=

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.

Below is a summary of significant unobservable inputs to the valuation of financial instruments together with a quantitative sensitivity analysis as at the end of each of the Relevant Periods:

As at 31 December 2023:

	Valuation technique	Significant unobservable inputs	Range	Sensitivity of fair value to the input
Redemption liabilities on equity shares . .	Back-solve method	Risk-free interest rate	2.08%	1% increase/decrease in risk-free interest rate would result in decrease/increase fair value by RMB(962,000)/ RMB3,091,000
		Volatility	58.00%	1% increase/decrease in volatility would result in decrease/increase fair value by RMB(622,000)/ RMB611,000
		DLOM	15.09%	1% increase/decrease in DLOM would result in decrease/increase in fair value by RMB(18,917,000)/ RMB18,917,000

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As at 31 December 2024:

	<u>Valuation technique</u>	<u>Significant unobservable inputs</u>	<u>Range</u>	<u>Sensitivity of fair value to the input</u>
Redemption liabilities on equity shares . .	Back-solve method	Risk-free interest rate	1.14%	1% increase/decrease in risk-free interest rate would result in decrease/increase fair value by RMB(3,574,000)/RMB5,732,000
		Volatility	56.00%	1% increase/decrease in volatility would result in decrease/increase fair value by RMB(1,034,000)/RMB1,023,000
		DLOM	14.60%	1% increase/decrease in DLOM would result in decrease/increase in fair value by RMB(25,523,000)/RMB25,523,000

As at 30 April 2025:

	<u>Valuation technique</u>	<u>Significant unobservable inputs</u>	<u>Range</u>	<u>Sensitivity of fair value to the input</u>
Redemption liabilities on equity shares . .	Back-solve method	Risk-free interest rate	1.47%	1% increase/decrease in risk-free interest rate would result in decrease/increase fair value by RMB(1,962,000)/RMB2,647,000
		Volatility	58.00%	1% increase/decrease in volatility would result in decrease/increase fair value by RMB(807,000)/RMB795,000
		DLOM	14.10%	1% increase/decrease in DLOM would result in decrease/increase in fair value by RMB(26,121,000)/RMB26,121,000

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36. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from financing activities by subsidiaries in currencies other than the subsidiaries’ functional currencies.

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in the USD and AUD exchange rates, with all other variables held constant, of the Group’s loss before tax and equity (due to changes in the fair value of monetary assets and liabilities).

	Increase/(decrease) in rate of foreign currency	Increase/(decrease) in loss before tax	Increase/(decrease) in equity
	%	RMB’000	RMB’000
31 December 2023			
If RMB weakens against USD	5	(1,001)	1,001
If RMB strengthens against USD	(5)	1,001	(1,001)
If RMB weakens against AUD	5	(910)	910
If RMB strengthens against AUD	(5)	910	(910)
31 December 2024			
If RMB weakens against USD	5	(194)	194
If RMB strengthens against USD	(5)	194	(194)
If RMB weakens against AUD	5	(919)	919
If RMB strengthens against AUD	(5)	919	(919)
30 April 2025			
If RMB weakens against USD	5	(1,815)	1,815
If RMB strengthens against USD	(5)	1,815	(1,815)
If RMB weakens against AUD	5	(553)	553
If RMB strengthens against AUD	(5)	553	(553)

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. For transactions that are not denominated in the functional currency of the relevant operating unit, the Group does not offer credit terms without the specific approval of the head of credit control.

The Group’s credit risk is primarily attributable to trade receivables. The Group has applied the simplified approach to provide for ECLs prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. The directors of the Company are of the opinion that the ECL in respect of the balance of trade receivables is minimal. No loss allowance for impairment of trade receivables is provided as at 30 April 2025.

For other receivables and other non-current assets, management has assessed that during the years ended 31 December 2023 and 2024, and the four months ended 30 April 2025, other receivables and other non-current assets have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. The Group does not expect any losses from non-performance by the counterparties of other receivables and no loss allowance provision for other receivables and other non-current assets was recognized.

To measure the expected credit losses, other receivables have been grouped based on shared credit risk characteristics and the days past due. As at 31 December 2023 and 2024 and 30 April 2025, the Group has assessed that the expected loss rate for other receivables was immaterial. Thus no loss allowance provision for other receivables was recognized as at 31 December 2023 and 2024 and 30 April 2025.

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.

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The maturity profile of the Group’s financial liabilities as at the end of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

The Group

	As at 31 December 2023			
	Within 1 year	1 to 5 years	Over 5 years	Total
	RMB’000	RMB’000	RMB’000	RMB’000
Financial liabilities included in trade and other payables	62,103	–	–	62,103
Interest-bearing bank borrowings. . .	5,399	–	–	5,399
Redemption liabilities on equity shares	1,715,411	–	–	1,715,411
Lease liabilities	5,981	24,681	–	30,662
Total	<u>1,788,894</u>	<u>24,681</u>	<u>–</u>	<u>1,813,575</u>

	As at 31 December 2024			
	Within 1 year	1 to 5 years	Over 5 years	Total
	RMB’000	RMB’000	RMB’000	RMB’000
Financial liabilities included in trade and other payables	166,306	57,507	–	223,813
Interest-bearing bank borrowings. . .	51,637	–	–	51,637
Redemption liabilities on equity shares	2,082,681	–	–	2,082,681
Lease liabilities	5,014	15,015	–	20,029
Total	<u>2,305,638</u>	<u>72,522</u>	<u>–</u>	<u>2,378,160</u>

	As at 30 April 2025			
	Within 1 year	1 to 5 years	Over 5 years	Total
	RMB’000	RMB’000	RMB’000	RMB’000
Financial liabilities included in trade and other payables	153,063	57,611	–	210,674
Interest-bearing bank borrowings. . .	86,405	–	–	86,405
Redemption liabilities on equity shares	2,140,215	–	–	2,140,215
Lease liabilities	5,288	13,688	–	18,976
Total	<u>2,384,971</u>	<u>71,299</u>	<u>–</u>	<u>2,456,270</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 shareholders’ 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 shareholders, return capital to shareholders 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.

37. EVENT AFTER THE RELEVANT PERIOD

No significant events of the Group occurred after 30 April 2025.

38. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or any of the companies now comprising the Group in respect of any period subsequent to 30 April 2025.

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

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SUMMARY OF ARTICLES OF ASSOCIATION

The Articles of Association is considered and approved at the general meeting of the Company, which shall come into effective and be implemented upon the [REDACTED] of the [REDACTED] foreign shares of the Company and from the date of its [REDACTED] and [REDACTED] on the Hong Kong Stock Exchange.

GENERAL PROVISIONS

The Company is a joint stock company with perpetual existence.

All assets of the Company shall be divided into shares of equal value. The shareholders shall be liable to the Company to the extent of the shares they subscribed for. The Company shall be liable for its debts to the extent of all of its assets.

From the effective date of the Articles of Association, the Articles of Association shall be a legally binding document which regulates the Company’s organization and acts, governs the rights and obligations between the Company and the shareholders, and amongst the shareholders themselves, and shall be a legally binding document governing on the Company, its shareholders, directors, supervisors, and senior management. Pursuant to the Articles of Association, a shareholder may take legal actions against the other shareholders; a shareholder may take legal actions against the Company’s directors, supervisors and senior management; a shareholder may take legal actions against the Company; and the Company may take legal actions against its shareholders, directors, supervisors and senior management.

SHARES

Issuance of Shares

The shares of the Company shall take the form of share certificates.

The shares of the Company shall be issued in accordance with the principles of openness, fairness and impartiality. Each share of the same class shall carry the same rights.

Shares of the same class and in the same issuance shall be issued on the same conditions and at the same price. Any entity or individual shall pay the same price for each of the shares he/she subscribes for.

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INCREASE, REDUCTION AND REPURCHASE OF SHARES

Capital Increase

The Company may, based on its operational and developmental needs, increase its capital in accordance with applicable laws, administrative regulations, departmental rules, normative documents, the securities regulatory rules of the place where the Company’s shares are [REDACTED] and the requirements of relevant regulatory authorities, and subject to a resolution of the general meeting, by any of the following methods:

- (I) a [REDACTED] of shares;
- (II) a non-public offering of shares;
- (III) allotment bonus shares to existing shareholders;
- (IV) conversion of common reserve funds to share capital;
- (V) other methods permitted by the laws, administrative regulations as well as the CSRC and the securities regulatory authorities of the place where the Company’s shares are [REDACTED].

Capital Reduction

The Company may reduce its registered capital. If the Company reduces its registered capital, it shall do so by the procedures set forth in the Company Law, the securities regulatory rules of the place where the Company’s shares are [REDACTED], other relevant regulations and the Articles of Association.

Repurchase of Shares

The Company shall not acquire its shares, except under one of the following circumstances:

- (I) reducing the registered capital of the Company;
- (II) merging with other companies that hold shares in the Company;
- (III) using the shares for employee shareholding schemes or as share incentives;
- (IV) acquiring the shares of shareholders (upon their request) who vote against any resolution adopted at any general meetings on the merger or division of the Company;

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- (V) using the shares to satisfy the conversion of those corporate bonds convertible into share certificates issued by the Company;
- (VI) safeguarding corporate value and shareholders’ equity as the Company deems necessary;
- (VII) other circumstances as stipulated by the laws, administrative regulations, departmental rules, and the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules).

The Company may acquire its own shares through [REDACTED] or other ways specified by the laws, administrative regulations, the CSRC and the securities regulatory authorities of the place where the Company’s shares are [REDACTED], and in accordance with applicable laws, administrative regulations and departmental rules.

In the event that the Company acquires its own shares under the circumstances set forth in (I) and (II) above, this shall be resolved at a general meeting of shareholders; in the event that the Company acquires its own shares under the circumstances set forth in (III), (V) and (VI) above, this shall be resolved at a board meeting with more than two-thirds of directors present.

After the Company acquires its own shares, under the circumstance in (I) above, the shares so acquired shall be cancelled within 10 days from the date of acquisition. In the case of (II) or (IV) above, the shares so acquired shall be transferred or cancelled within 6 months.

In the event that the Company acquires its own shares under the circumstances set forth in (III), (V) or (VI) above, the shares so acquired shall not exceed 10% of the total issued shares of the Company, and they shall be transferred or cancelled within 3 years.

If the relevant laws and regulations, normative documents and the securities regulatory rules of the place where the Company’s shares are listed (including but not limited to the Hong Kong Listing Rules) otherwise have provisions in respect of matters related to the aforesaid repurchase of share, without prejudicing the Company Law and the Securities Law, such provisions shall prevail.

Transfer of Shares

The shares of the Company may be transferred in accordance with the laws.

The Company shall not accept any of its own shares as the subject of pledges.

Shares issued prior to the Company’s [REDACTED] of shares shall not be transferred for a period of 1 year from the date of [REDACTED] and [REDACTED] of the Company’s shares on the stock exchange.

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The directors, supervisors and senior management of the Company shall declare to the Company the numbers of the shares of the Company held by them and the changes thereof and shall not transfer in a given year during their terms of office determined at the time of their assumption of office more than 25% of the total number of shares of the Company they hold. The shares of the Company held by the said person shall not be transferred within 1 year from the date of [REDACTED] and [REDACTED] of the Company’s shares. Any of the aforesaid persons shall not transfer the shares of the Company held by him/her within 6 months from his/her termination of the office.

If the relevant provisions of the securities regulatory authorities of the place where the Company’s shares are [REDACTED] have any other provisions in respect of restrictions on transfer of overseas-[REDACTED] shares, such provisions shall prevail.

SHAREHOLDERS AND GENERAL MEETINGS

Shareholders

The Company shall establish a register of shareholders based on the requirements as stipulated by the Company Law, the securities regulatory rules of the place where the Company’s shares are [REDACTED], other relevant regulations and the Articles of Association. The register of shareholders shall be the sufficient evidence of the shareholders’ shareholding in the Company.

A shareholder is entitled to rights and assumes obligations as per the class of the shares held by them. Shareholders holding the same class of shares shall be entitled to the same rights and assume the same obligations.

When the Company convenes the general meeting, distributes dividends, goes into liquidation or is involved in other actions that require the confirmation of the shareholders’ identities, the Board or the convener of the general meeting shall determine a record date of shareholdings, and the shareholders whose names are registered on the register of shareholders at closing on the record date of shareholdings shall be the shareholders entitled to the relevant interests.

Rights and Obligations of Shareholders

The shareholders of the Company shall be entitled to the following rights:

- (I) to receive distribution of dividends and other forms of benefits in proportion according to the number of shares held;

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- (II) to legally require, convene, preside over, participate in or appoint a shareholder proxy to participate in the general meeting and exercise corresponding right to speak and voting right (except for situations where voting rights are required to be waived on relevant matters in accordance with the securities regulatory rules of the place where the Company’s shares are [REDACTED]);
- (III) to supervise the business operations of the Company, put forward proposals or raise enquiries;
- (IV) to transfer, give as gift or pledge the shares held in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the Company’s shares are [REDACTED], other relevant regulations and the Articles of Association;
- (V) to inspect the Articles of Association, register of shareholders, corporate bond stubs, minutes of general meetings, resolutions of the Board meetings, resolutions of meetings of the supervisory committee and financial accounting reports;
- (VI) in the event of the termination or liquidation of the Company, to participate in the distribution of the remaining assets of the Company in proportion to the number of shares held;
- (VII) with respect to shareholders who voted against any resolution adopted at any general meetings on the merger or division of the Company, to request the Company to buy back the shares held by them;
- (VIII) other rights as stipulated by the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) or the Articles of Association.

Where the content of a resolution of the general meeting or the meeting of the Board of the Company violates laws or administrative regulations, the shareholders shall be entitled to request the People’s Court to hold it invalid.

If the convening procedure or voting method of a general meeting or board meeting violates laws, administrative regulations or the Articles of Association, or if the content of a resolution violates the Articles of Association, the shareholders shall be entitled to request the People’s Court to revoke the resolution within 60 days from the date it was made, except for those with only minor defects in the convening procedure or voting method of the Board meetings and those without material impact on resolutions.

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Shareholders who have not been notified to attend the general meeting may apply to the People's Court for revocation within sixty days from the date they knew or should have known of the passing of the resolution of the general meeting; if the right to revoke is not exercised within one year from the date the resolution is made, the right to revoke shall be extinguished.

In the event of any loss caused to the Company as a result of violation of any laws, administrative regulations or the Articles of Association by the directors or senior management when performing their duties in the Company, the shareholders holding 1% or more shares of the Company separately or jointly for over 180 consecutive days may submit a written request to the supervisory committee to file an action with the People's Court. Where supervisors violate any laws, administrative regulations or the Articles of Association in their performance of duties and cause losses to the Company, the aforesaid shareholders may submit a written request to the Board to file an action with the People's Court.

In the event that the supervisory committee or the Board refuses to file an action upon receipt of the shareholders' written request specified in the preceding paragraph, or fails to file an action within 30 days upon receipt thereof, or in the event that the failure to immediately file an action in an emergency case will cause irreparable damage to the interests of the Company, the shareholders specified in the preceding paragraph may, in their own name, directly file an action with the People's Court for the interests of the Company.

In the event that any person infringes upon the legitimate rights and interests of the Company and causes losses thereto, the shareholders specified in paragraph 1 of this Article may file an action with the People's Court pursuant to the provisions of the preceding two paragraphs.

Where the directors, supervisors or senior management of a wholly-owned subsidiary of the Company violate any laws, administrative regulations or the Articles of Association in their performance of duties and cause losses to the wholly-owned subsidiary or the legitimate rights and interests of the wholly-owned subsidiary are infringed by others, the shareholders specified in paragraph 1 of this Article may request the supervisory committee or the Board of the wholly-owned subsidiary in writing to file an action with the People's Court or, in their own name, directly file an action with the People's Court pursuant to the provisions of the preceding three paragraphs.

Where the directors or senior management violate any laws, administrative regulations or the Articles of Association, thereby damaging the interests of the shareholders, the shareholders may file an action with the People's Court.

The shareholders of the Company shall have the following obligations:

- (I) to comply with the laws, administrative regulations, and the Articles of Association;
- (II) to pay subscription monies according to the number of shares subscribed and the method of subscription;

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- (III) not to withdraw shares unless required by the laws and regulations;
- (IV) not to abuse their shareholders' rights to harm the legitimate interests of the Company or other shareholders; and not to abuse the independent legal person status of the Company and the limited liability of shareholders to harm the legitimate interests of any creditor of the Company;
- (V) any other obligations imposed by the laws, administrative regulations, the securities regulatory rules of the place where the Company's shares are [REDACTED] and the Articles of Association.

Where shareholders of the Company who abuse their shareholders' rights and thereby cause losses to the Company or other shareholders shall be liable for indemnity according to the law; where shareholders of the Company who abuse the independent legal person status of the Company and the limited liability of shareholders for the purposes of evading repayment of debts, thereby materially impairing the interests of the creditors of the Company, such shareholders shall be jointly and severally liable for the debts owed by the Company.

If shareholders conduct any action stipulated in the preceding paragraph by using two or more companies controlled by him/her, each of the company shall assume joint and several liability for any one of the company's debts.

Where a shareholder holding 5% or more of the voting shares of the Company pledges any shares in his/her possession, he/she shall make a written report to the Company on the day on which he/she pledges his/her shares.

Restriction on Rights of the Controlling Shareholders

The controlling shareholders, de facto controllers, directors, supervisors and senior management of the Company shall not use their connections to harm the interests of the Company. Any person who violates this provision and causes losses to the Company shall be liable for compensation.

The controlling shareholders and de facto controllers of the Company shall have fiduciary duties towards the Company and the [REDACTED] of the Company. The controlling shareholders shall exercise their rights as contributors in strict compliance with the laws. The controlling shareholders shall not infringe the legitimate rights and interests of the Company and the [REDACTED] of the Company through profit distribution, asset restructuring, foreign investment, capital appropriation and loan guarantee, and shall not make use of their controlling status to jeopardize the interests of the Company and the [REDACTED] of the Company.

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General Rules of the General Meeting

The general meeting is the organ of authority of the Company and shall exercise the following functions and powers in accordance with the laws:

- (I) to elect and replace directors and supervisors and decide on matters relating to the remuneration of directors and supervisors;
- (II) to consider and approve reports of the Board;
- (III) to consider and approve reports of the supervisory committee;
- (IV) to consider and approve profit distribution plans and loss recovery plans of the Company;
- (V) to decide on any increase or reduction of the registered capital of the Company;
- (VI) to decide on the issuance of corporate bonds;
- (VII) to decide on merger, division, dissolution, liquidation and change of form of the Company;
- (VIII) to amend the Articles of Association;
- (IX) to decide on the engagement or dismissal of the accounting firm of the Company and determine its remuneration;
- (X) to consider and approve the guarantees as provided below;
- (XI) to consider the purchase or disposal of substantial assets of the Company with an amount exceeding 30% of the latest audited total assets of the Company within one year;
- (XII) to consider the proposals by the shareholders severally or jointly holding one percent or more of the voting shares of the Company;
- (XIII) to consider and approve transactions between the Company and connected persons that meet the requirements of the Hong Kong Listing Rules to be submitted to a general meeting for approval;
- (XIV) to consider other matters which are required to be determined at the general meeting as required by the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) or the Articles of Association.

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The following external guarantee offered by the Company shall be considered and approved by a general meeting after considering and approving by a meeting of the Board of Directors of the Company:

- (I) guarantee provided by the Company with a guaranteed amount exceeding 30% of the latest audited total assets of the Company within one year (excluding guarantee between the Company and the subsidiaries of the Company);
- (II) guarantee provided to shareholders, de facto controllers and their connected parties;
- (III) other external guarantee matters which are required to be considered at the general meeting as required by the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company's shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) or the Articles of Association.

The shareholders set forth in (II) above or the shareholders who are subject to the domination of the de facto controller set forth in (II) above shall not take part in the voting on the matters specified in (II) above, such voting shall be considered and approved by the other shareholders present at the meeting.

The Board shall resolve on all matters relating to external guarantees other than those approved at general meetings.

General meetings include annual general meetings and extraordinary general meetings. Annual general meetings shall be held once every year and within 6 months from the close of the preceding fiscal year.

The Company shall convene an extraordinary general meeting within 2 months upon the occurrence of the following events:

- (I) the number of directors is less than the number stipulated in the Company Law or less than two-thirds of the number as specified in the Articles of Association;
- (II) the unrecovered losses of the Company amount to one-third of the total amount of its paid-up share capital;
- (III) on request by the shareholder(s) individually or collectively holding 10% or more of the voting shares of the Company;
- (IV) when the Board considers it is necessary;
- (V) when the supervisory committee proposes to convene;

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- (VI) other circumstances as stipulated by the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company’s shares are [REDACTED] or the Articles of Association.

Convening of General Meetings

General meetings shall be called by the Board in accordance with the laws.

The independent non-executive directors shall have the right to propose to the Board to convene an extraordinary general meeting. In response to a proposal by an independent non-executive director to convene an extraordinary general meeting, the Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the Company’s shares are [REDACTED] and the Articles of Association, give a written response as to whether or not it agrees to convene an extraordinary general meeting within 10 days upon receipt of such proposal. Where the Board agrees to convene the extraordinary general meeting, a convening notice will be issued within 5 days after the resolution of the Board is made; where the Board disagrees to convene the extraordinary general meeting, reasons shall be specified.

The supervisory committee shall have the right to propose to the Board to convene an extraordinary general meeting and such proposal shall be made to the Board in writing. The Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the Company’s shares are [REDACTED] and the Articles of Association, give a written response as to whether or not it agrees to convene an extraordinary general meeting within 10 days upon receipt of such proposal.

Where the Board agrees to convene the extraordinary general meeting, a convening notice will be issued within 5 days after the resolution of the Board is made, and the changes made to the original proposal in the notice shall be approved by the supervisory committee.

Where the Board disagrees to convene the extraordinary general meeting, or fails to reply within 10 days upon the receipt of such proposal, the Board will be deemed as not being able to perform or not to perform its duty to convene a general meeting, and the supervisory committee may convene and preside over such meeting on their own.

The shareholder(s) severally or jointly holding 10% or more of the voting shares of the Company shall have the right to propose to the Board to convene an extraordinary general meeting and such proposal shall be made to the Board in writing. The written proposal shall state the subject of the meeting and present a complete proposal. The Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) and the Articles of Association, give a written response as to whether or not it agrees to convene an extraordinary general meeting within 10 days upon receipt of such proposal.

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Where the Board agrees to convene the extraordinary general meeting, a convening notice shall be issued within 5 days after the resolution of the Board is made, and the changes made to the original proposal in the notice shall be approved by the relevant shareholders. If the laws, administrative regulations, departmental rules and the securities regulatory rules of the place where the Company’s shares are [REDACTED] have any other provisions, such provisions shall prevail. The subject of the meeting proposed by the convening requestor shall be included in the agenda of the extraordinary general meeting.

Where the Board disagrees to convene the extraordinary general meeting, or fails to reply within 10 days upon receipt of such proposal, the shareholder(s) individually or collectively holding 10% or more of the voting shares of the Company shall have the right to propose to the supervisory committee to convene an extraordinary general meeting and such proposal shall be made to the supervisory committee in writing.

Where the supervisory committee agrees to convene the extraordinary general meeting, a convening notice shall be issued within 5 days upon receipt of the proposal, and the changes made to the original proposal in the notice shall be approved by the relevant shareholders. If the laws, administrative regulations, departmental rules and the securities regulatory rules of the place where the Company’s shares are [REDACTED] have any other provisions, such provisions shall prevail. The subject of the meeting proposed by the convening requestor shall be included in the agenda of the extraordinary general meeting.

Where the supervisory committee fails to issue the notice of the general meeting within the prescribed period, the supervisory committee will be deemed as not being able to convene or not to preside over the general meeting, and the shareholder(s) individually or collectively holding 10% or more of the voting shares of the Company for 90 or more consecutive days may convene and preside over such meeting on their own.

If the supervisory committee or the shareholder(s) decides to convene a general meeting on his/her/its own, he/she/it shall notify the Board in writing and shall give notice of such meeting to the shareholders in accordance with the applicable requirements such as the Hong Kong Listing Rules.

Prior to the formation of the resolutions adopted at such general meeting, the shareholders convening such meeting shall hold at least 10% of the voting shares of the Company.

Proposals of General Meetings

The Board, the supervisory committee, and shareholder(s) severally or jointly holding more than 1% of the voting shares of the Company shall have the right to make a proposal to the Company at a general meeting of the Company.

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The shareholder(s) severally or jointly holding more than 1% of the voting shares of the Company may make provisional proposals in writing to the convener of a general meeting 10 days prior to such meeting. The convener shall issue a supplementary notice of the general meeting and announce the contents of such provisional proposals within 2 days upon receipt thereof, unless the provisional proposal does not comply with the Articles of Association.

Except as provided by the preceding paragraph and laws, administrative regulations and the securities regulatory rules of the place where the Company’s shares are [REDACTED], the convener of a general meeting shall not amend the proposals already specified in the notice of the general meeting or add new proposals subsequent to the issue of the notice of the general meeting.

Proposals which are not specified in the notice of the general meeting or which do not comply with the Articles of Association shall not be voted on and resolved at the general meeting.

Notices of General Meetings

The convener shall notify all shareholders by written notice (including announcement) no later than 21 days prior to the date of convening the annual general meeting and no later than 15 days prior to the date of convening the extraordinary general meeting. If the laws, administrative regulations, departmental rules and the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) have any other provisions, such provisions shall prevail.

The date of the meeting shall be excluded when the Company calculates the starting date.

Holding of General Meetings

All shareholders or their proxies recorded in the register on the record date shall have the right to attend general meetings, and they are entitled to speak and vote at general meetings in accordance with the relevant laws, regulations, the securities regulatory rules of the place where the Company’s shares are [REDACTED] and the Articles of Association. Shareholders may attend general meetings in person or appoint their proxies to attend, speak and vote on their behalf. A proxy does not need to be a shareholder of the Company. Shareholders shall have the right to speak and vote at general meetings, unless individual shareholders are required by the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) to abstain from voting on specific matters.

Individual shareholders attending the meeting in person shall present his/her identification card or other valid documents or proof of his/her identification and certificate of shareholding. In the case of attendance by proxies, they shall present his/her valid identification documents and the proxy forms from the shareholders.

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Legal person shareholders or other institutional shareholders shall be represented at the meeting by their legal representatives/executive partners or proxies appointed by the legal representatives/executive partners. In the case of attendance by legal representatives/executive partners, they shall present their identity cards, valid proof of their capacities as legal representatives/executive partners; in the case of attendance by proxies, they shall present their identity cards and written authorization letters issued by such legal representatives/executive partners of the legal person shareholders or institutional shareholders, unless the shareholder is a recognized clearing house (or its proxy) as defined in the relevant ordinances enacted in Hong Kong from time to time.

If the shareholder is a recognized clearing house (or its proxy) as defined in the relevant ordinances promulgated in Hong Kong from time to time, the shareholder may authorize one or more persons as he/she thinks fit to act as his/her proxy or representative(s) at any general meeting (and/or any meeting of creditors). However, if more than one person is authorized, the power of attorney shall state the number and class of shares in respect of which each such person is authorized and shall be signed by the authorized officer of a recognized clearing house. A person so authorized is entitled to attend meetings and exercise the rights (including the right to speak and vote) on behalf of the recognized clearing house (or its proxy) (without the need to produce a certificate of shareholding, notarized power of attorney and/or further evidence of formal authorization), as if they were the individual shareholders of the Company. Such authorized person shall be entitled with the same statutory rights as other shareholders, including the right to speak and vote.

It shall be stated clearly in the power of attorney if the shareholder proxy can vote at his/her discretion when the shareholder does not give any specific instructions.

Voting and Resolutions at General Meetings

The resolutions of general meetings shall be divided into ordinary resolutions and special resolutions. Ordinary resolutions of a general meeting shall be approved by more than one half of the voting rights held by the shareholders (including proxies thereof) present at the general meeting. special resolutions of a general meeting shall be approved by more than two-thirds of the voting rights held by the shareholders (including proxies thereof) present at the general meeting.

The following matters shall be approved by ordinary resolutions at the general meeting:

- (I) work reports of the Board and the supervisory committee;
- (II) profit distribution plans and loss recovery plans drafted by the Board;
- (III) appointment or dismissal of the members of the Board and the supervisory committee, and determination of the remuneration of the Board and the supervisory committee;

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- (IV) issuance of corporate bonds;
- (V) annual reports of the Company;
- (VI) engagement or dismissal of the accounting firm, and determination of the remuneration of the accounting firm;
- (VII) connected transactions between the Company and connected persons that meet the requirements of the Hong Kong Listing Rules to be submitted to a general meeting for approval; and
- (VIII) matters other than those approved by special resolution as stipulated by the laws, administrative regulations, the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) or the Articles of Association.

The following matters shall be approved by special resolutions at the general meeting:

- (I) the increase or decrease of the registered capital of the Company;
- (II) division, spin-off, merger, termination, dissolution, liquidation and change in the form of the Company;
- (III) amendments to the Articles of Association;
- (IV) purchase and disposal of substantial assets by the Company within one year, or a guaranteed amount exceeding 30% of the latest audited total assets of the Company;
- (V) other matters as required by the laws, administrative regulations, the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) or the Articles of Association, and confirmed by an ordinary resolution at a general meeting that it may have a material impact on the Company and accordingly shall be approved by special resolutions.

In accordance with the applicable laws, administrative regulations, departmental rules, normative documents and the securities regulatory rules of the place where the Company’s shares are [REDACTED], where any shareholder shall abstain from voting for any particular resolution, or is restricted to vote only for or against such resolution, any votes in violation of such requirement or restriction by the shareholders (or their proxies) shall not be counted in the voting results.

The shares of the Company held by it have no voting rights, and such portion of shares shall not be counted in the total number of voting shares present at the general meeting.

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Where matters relating to connected transactions (as defined under the Hong Kong Listing Rules) are considered at the general meeting, the connected shareholders and their associates (as defined under the Hong Kong Listing Rules) shall not be involved in voting, and the voting shares they represent shall not be counted in the total number of valid voting rights. The voting particulars of the non-connected persons shall be fully disclosed in the announcement on the resolution of the general meeting.

In order to be valid, the resolution of the general meeting on matters relating to connected transactions shall be approved by more than one half of the voting rights held by the non-connected persons attending the general meeting. However, in the event of such connected transaction involving matters that are required to be approved by special resolution stipulated in the Articles of Association, in order to be valid, the resolution of the general meeting must be approved by more than two-thirds of the voting rights held by the non-connected persons attending the general meeting.

DIRECTORS AND THE BOARD

Directors

Directors of the Company shall be natural persons. The following person may not serve as a director of the Company:

- (I) a person without capacity or with limited capacity for civil conduct;
- (II) a person who has been sentenced to criminal punishment for corruption, bribery, infringement of property, misappropriation of property or for damaging the order of the socialist market economy, where less than five years have elapsed since the sentence was served, or who has been deprived of his/her political rights due to criminal offense, where less than 5 years have elapsed since the sentence was served, or where less than 2 years have elapsed since the date of expiration of the probationary period if such person is sentenced to probation;
- (III) a person who served as a director, or factory director or manager, and who assumed personal liability for the bankruptcy liquidation of a company or enterprise, where less than 3 years have elapsed since the date of completion of the bankruptcy liquidation of such company or enterprise;
- (IV) a person who served as a legal representative of a company or enterprise which had its business license revoked and was ordered to close down due to violation of law, and who assumed personal liability for such violation, where less than 3 years have elapsed since the date of the revocation of business license of such company or enterprise;

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- (V) a person who has a relatively large amount of debts which have fallen due but have not been settled and was listed as a dishonest person subject to enforcement by the People’s Court;
- (VI) a person who is banned by the CSRC from entering into the securities market for a period which has not yet expired;
- (VII) other contents required by the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules).

Directors shall be elected or replaced at a general meeting and he/she may be dismissed at a general meeting before the expiry of his/her term of office. Directors serve a term of office of 3 years for each session. A director may be re-elected and reappointed upon the expiry of his/her term of office, unless otherwise stipulated by the relevant laws, regulations and the securities regulatory rules of the place where the Company’s shares are [REDACTED].

The term of office of a director shall commence from the date on which the said director assumes office to the expiry of the current term of the Board. If the term of office of a director expires but re-election is not carried out in a timely manner, the said director shall continue to perform the duties as director pursuant to the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) and the Articles of Association until the elected director assumes his/her office. Any person appointed by the Board to fill a temporary vacancy on or as an addition to the Board shall hold office only until the first annual general meeting immediately following his/her appointment, and shall then be eligible for re-election, provided that the securities regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules), applicable laws, regulations and regulatory rules are not violated. Subject to the relevant laws and administrative regulations, the shareholders have the right to dismiss a director whose term of office has not expired by an ordinary resolution at a general meeting, but such dismissal shall not affect the director’s claim for damages under any contract.

There are no employee representative directors in the Company. The general manager or other senior management may concurrently serve as directors.

Duties of Directors

Directors shall comply with the laws, administrative regulations, the securities regulatory rules of the place where the Company’s shares are [REDACTED] and the Articles of Association, and bear the following duties of loyalty to the Company:

- (I) not to exploit their positions to accept bribes or obtain other illegal income;
- (II) not to expropriate the property of the Company, not to misappropriate the funds of the Company;

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- (III) not to open any account in their own name or in any other name for the deposit of the assets or funds of the Company;
- (IV) not to take as their own any commission for any transaction with the Company;
- (V) not to disclose any secret of the Company without authorization;
- (VI) not to use their connected relationships to harm the interests of the Company;
- (VII) other duties of loyalty as stipulated by the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company’s shares are [REDACTED] and the Articles of Association.

Directors shall comply with the laws, administrative regulations, departmental rules, normative documents, the Hong Kong Listing Rules and the Articles of Association, and fulfill the obligations of diligence to the Company, and exercise the reasonable care normally expected of a manager in the best interests of the Company in the performance of their duties.

Where a director directly or indirectly enters into a contract or transaction with the Company, he/she shall report the matters relating to the entering of the contract or transaction to the Board or the general meeting, and the contract or transaction shall be subject to the approval of the Board or the general meeting in accordance with the laws, regulations and the securities regulatory rules of the place where the Company’s shares are [REDACTED].

The provisions above shall be applicable to the close family members of the directors, the enterprises directly or indirectly controlled by the directors or their close family members, and the related persons who have other related relationships with the directors when they enter into contracts or conduct transactions with the Company.

Directors shall not use their position to seek business opportunities that belong to the Company for themselves or others, except in any of the following circumstances:

- (I) reporting to the Board or the general meeting and being approved by a resolution of the Board or the general meeting in accordance with the laws, regulations and the securities regulatory rules of the place where the Company’s shares are [REDACTED];
- (II) where the Company is not permitted to make use of the business opportunity in accordance with the laws, administrative regulations or the Articles of Association.

Directors, without reporting to the Board or the general meeting and being approved by a resolution of the Board or the general meeting in accordance with the laws, regulations and the securities regulatory rules of the place where the Company’s shares are [REDACTED], shall not engage in or operate a business similar to that of the Company either on their own account or for others.

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The Board

The Company shall set up a board of directors, which shall be accountable to the general meeting. Directors of the Company are classified as executive directors, non-executive directors and independent non-executive directors, and the number of independent non-executive directors shall comprise at least one-third of the members of the Board and shall not be less than 3 members.

The Board exercises the following functions and powers:

- (I) to convene general meetings and report on work to the general meeting;
- (II) to implement the resolutions of the general meeting;
- (III) to determine the business plans and investment plans of the Company;
- (IV) to formulate the profit distribution plans and loss recovery plans of the Company;
- (V) to formulate plans for increasing or decreasing the registered capital of the Company, the issuance of bonds or other securities, as well as the [REDACTED] plan of the Company;
- (VI) to formulate plans for merger, division, dissolution or change of form of the Company;
- (VII) to decide on the setup of the internal management organization of the Company;
- (VIII) to appoint or dismiss the general manager of the Company, and determine their remunerations; based on the nomination of the general manager, to appoint or dismiss other senior management of the Company, and determine their remunerations;
- (IX) to set the basic management systems of the Company;
- (X) other functions and powers authorized by the laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company's shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) or the Articles of Association.

The Board of the Company shall establish the special committees, namely, an audit committee, a nomination committee and a remuneration committee. The special committees shall be accountable to the Board and perform their duties in accordance with the Articles of Association and the authorization from the Board. Their proposals shall be submitted to the Board for consideration and decision making. The members of each special committee shall all be directors, with reference to the laws, administrative regulations, departmental rules, and the

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regulatory rules of the place where the Company’s shares are [REDACTED] (including but not limited to the Hong Kong Listing Rules) for specific composition and qualification requirements. The Board of Directors is responsible for formulating the working rules of the special committees and regulating the operation of the special committees.

The chairman of the Board exercises the following functions and powers:

- (I) to preside over general meetings, and to convene and preside over the Board meetings;
- (II) to supervise and inspect the implementation of the resolutions of the Board;
- (III) other functions and powers granted by the Board.

Board meetings shall be classified into regular meetings and extraordinary meetings. The Board shall convene regular meetings at least 4 times a year, which shall be held approximately once each quarter and convened by the chairman of the Board. The written notice of the regular meeting shall be delivered 14 days before the date of the meeting. The chairman of the Board shall hold at least one meeting with the independent non-executive directors without the presence of other directors each year.

An extraordinary meeting of the Board shall be convened and presided over by the chairman of the Board within 10 days after the receipt of such proposal under any of the following circumstances:

- (I) when it is proposed by more than 1/10 of the shareholders with voting rights;
- (II) when it is jointly proposed by more than 1/3 of directors;
- (III) when it is proposed by the supervisory committee;
- (IV) when the chairman of the Board deems it necessary;
- (V) at the request of the relevant securities regulatory authorities;
- (VI) other circumstances as stipulated by the Articles of Association.

A Board meeting may be held only when a majority of the directors are present at the meeting. A resolution of the Board meeting must be approved with affirmative votes of a majority of all directors.

Directors shall attend Board meetings in person, or actively participate through electronic means. If a director cannot attend the meeting for any reason, he/she may authorize in writing another director to act on his/her behalf. The power of attorney shall set out the name of the proxy, the matters represented, scope of authorization and validity period, and shall be signed

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or sealed by the appointing director. The appointed director who attends the meeting shall exercise the director's duties within the scope of authorization. If a director does not attend a Board meeting in person and does not appoint a proxy to attend the meeting, he/she shall be deemed to have waived the voting rights at the meeting.

SENIOR MANAGEMENT

The Company shall have one general manager, one chief financial officer and one secretary to the Board of whom shall be appointed or dismissed by the Board. In the future, the Company may decide to appoint other senior management according to the actual operational development needs.

Each term of office of the general manager is 3 years and is renewable upon re-election of the Board.

The general manager is accountable to the Board and exercises the following functions and powers:

- (I) to be in charge of the production and operational management of the Company, organize the enforcement of resolutions of the Board and report to the Board on work;
- (II) to organize the implementation of the annual operation plans and investment schemes of the Company;
- (III) to formulate the structure scheme of the internal management department of the Company;
- (IV) to formulate the specific rules and regulations of the Company;
- (V) to propose to the Board the appointment or dismissal of the chief financial officer of the Company and other senior management;
- (VI) to decide on the appointment or dismissal of responsible management personnel except those whose appointment or dismissal shall be determined by the Board;
- (VII) other functions and powers authorized by the Articles of Association or the Board.

SUPERVISORS AND SUPERVISORY COMMITTEE

The Company shall have a supervisory committee, which shall be composed of 3 supervisors, with 1 chairman. The chairman of the supervisory committee shall be elected by a majority of all directors. Meetings of the supervisory committee shall be convened and

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presided over by the chairman of the supervisory committee; if the chairman of the supervisory committee is unable or fails to perform his/her duties, a supervisor who has been elected by more than one half of the supervisors shall convene and preside over the meeting of the supervisory committee.

The supervisory committee exercises the following functions and powers:

- (I) to examine the financial operations of the Company;
- (II) to supervise the performance of duties to the Company by the directors and senior management, and propose dismissal of any director or senior management who violates any laws, administrative regulations, the Articles of Association or resolutions of the general meeting;
- (III) to require directors and senior management to make corrections if their conduct has damaged the interests of the Company;
- (IV) to propose the convening of an extraordinary general meeting, and to convene and preside over the general meeting when the Board fails to perform such duties as specified in the Company Law;
- (V) to submit proposals to the general meeting;
- (VI) to institute legal proceedings against the directors and senior management according to the Company Law;
- (VII) in the event that the supervisory committee discovers any unusual operation of the Company, it may conduct an investigation and, when necessary, professionals, such as accounting firms and law firms, may be engaged to assist in its work; any expenses incurred thereby shall be borne by the Company;
- (VIII) other functions and powers authorized by the general meeting.

The supervisory committee shall hold at least one meeting every six months. The written notice (including by post, email, fax or personal delivery) shall be delivered 10 days before the date of the meeting. A meeting of the supervisory committee may be held only when a majority of the supervisors are present at the meeting.

A supervisor may propose to convene an extraordinary meeting of the supervisory committee. The written notice of the extraordinary meeting of the supervisory committee shall be delivered 5 days before the date of the meeting. With the unanimous consent of all supervisors of the Company, the time limit for notification stipulated in the preceding paragraph may be waived.

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FINANCIAL AND ACCOUNTING SYSTEM, PROFIT DISTRIBUTION AND AUDIT

Financial and Accounting System

The Company shall establish its financial and accounting system in accordance with the laws, administrative regulations and the requirements of the relevant authorities of China. If the securities regulatory authorities of the place where the Company’s shares are [REDACTED] have any other provisions, such provisions shall prevail.

The Company shall not establish any other accounting books except for the statutory ones. No assets of the Company shall be deposited in any account opened in the name of any individual.

Profit Distribution

In distributing the after-tax profit of the current year, the Company shall withdraw 10% of the profit as its statutory reserve funds. When the aggregate amount of the statutory reserve funds of the Company is more than 50% of its registered capital, further appropriations are not required.

Where the statutory reserve funds of the Company are insufficient to make up for the losses of the previous year, the profits of the current year shall be used to make up for such losses before making allocation to its statutory reserve funds in accordance with the preceding paragraph.

After withdrawing the statutory reserve funds from after-tax profit, the Company may, subject to a resolution of the general meeting, withdraw the discretionary reserve funds from after-tax profit.

After making up for the losses and making allocations to the reserve funds, any remaining after-tax profit shall be distributed by the Company to the shareholders in proportion to their respective shareholdings.

The shares of the Company held by it are not entitled to any profit distribution.

Reserve funds of the Company shall be used for making up for the losses, business expansion for operation or registered capital replenishment of the Company. When using the reserve funds to make up for the losses of the Company, the discretionary reserve funds and the statutory reserve funds shall be used first; if the losses still cannot be made up, the capital reserve funds can be used in accordance with the requirements.

When the statutory reserve funds are converted into the capital, the remaining amount of such reserve funds shall not be less than 25% of the registered capital of the Company before the conversion.

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Engagement of Accounting Firms

The Company shall engage an accounting firm which complies with the laws and regulations to conduct accounting statements audit, net assets verification and other relevant consultancy services, which is subject to renewal.

The appointment of any accounting firm of the Company shall be subject to the approval of the general meeting, prior to which the Board shall not appoint any accounting firm.

When the Company intends to dismiss or not to reappoint an accounting firm, it shall give 15 days prior notice to the accounting firm. When a general meeting of the Company votes on the dismissal of the accounting firm, the firm shall be allowed to represent its opinions.

NOTICES

The notices of the Company may be served as follows:

- (I) by personal delivery;
- (II) by fax, email or post;
- (III) by telephone;
- (IV) by announcement (including on the designated website and the website of the Company in accordance with the securities regulatory rules of the place where the Company's shares are [REDACTED]);
- (V) by other means as specified by the securities regulatory authorities of the place where the Company's shares are [REDACTED] or the Articles of Association.

MERGER, DIVISION, CAPITAL INCREASE AND CAPITAL REDUCTION

In the event of a merger, the parties to the merger shall enter into a merger agreement, and prepare balance sheets and inventories of assets. The Company shall notify the creditors within 10 days from the date of the resolution to merge and publish an announcement within 30 days in accordance with the requirements. The creditors may require the Company to settle the debts or provide appropriate guarantees within 30 days after the receipt of the notice or within 45 days after the date of the announcement if the creditors have not received the notice.

In the event of a division, balance sheets and inventories of assets shall be prepared. The Company shall notify the creditors within 10 days from the date of the resolution to divide and publish an announcement within 30 days in accordance with the requirements.

The Company shall prepare balance sheets and inventories of assets when it needs to reduce its registered capital.

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The Company shall notify the creditors within 10 days from the date of the resolution to reduce its registered capital and publish an announcement within 30 days in accordance with the requirements. The creditors may require the Company to settle the debts or provide appropriate guarantees within 30 days after the receipt of the notice or within 45 days after the date of the announcement if the creditors have not received the notice.

Where a merger or division of the Company involves any changes to any registration, an application for modification of registration shall be made to the Company’s registration authority pursuant to the laws; where the Company is dissolved, the Company shall apply for cancellation of its registration in accordance with the laws; where a new company is established, the Company shall apply for registration thereof in accordance with the laws.

Where the Company increases or reduces its registered capital, an application for modification of registration shall be made to the Company’s registration authority pursuant to the laws.

Dissolution and Liquidation

In any of the following circumstances, the Company shall be dissolved:

- (I) the term of business operation set out in the Articles of Association has expired or other events of dissolution specified in the Articles of Association have occurred;
- (II) a resolution for dissolution is passed at a general meeting;
- (III) dissolution is necessary due to a merger or division of the Company;
- (IV) the business license is revoked, the Company is ordered to close or is eliminated according to the laws;
- (V) the Company has experienced material difficulties in operation and management, and the continuous operation would lead to substantial losses to the interests of its shareholders and there are no other solutions to resolve the matters. Shareholders holding 10% or more of the total voting rights of the Company may appeal to the People’s Court for dissolution of the Company.

The Company shall, within ten days of the occurrence of the reasons for dissolution as stipulated in the preceding paragraph, disclose the reasons for dissolution on the National Enterprise Credit Information Publicity System.

In the circumstances set forth in (I) and (II) above, and where no property has been distributed to shareholders, the Company may carry on its existence by amending the Articles of Association or by resolution of the general meeting.

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The amendments to the Articles of Association pursuant to the preceding paragraph or by resolution of the general meeting shall require approval of more than 2/3 of voting rights of shareholders attending a general meeting.

Where the Company is dissolved pursuant to (I), (II), (IV) and (V) above, a liquidation committee shall be formed within 15 days from the date of occurrence of such grounds for dissolution to start the liquidation process. The composition of the liquidation committee shall be determined by directors or the general meeting. In case no such committee is established to timely proceed with liquidation, the creditors may make an application to the People's Court for appointing relevant persons to form the liquidation committee for liquidation.

The liquidation committee exercises the following functions and powers during the liquidation period:

- (I) to sort out the assets of the Company and prepare balance sheets and inventories of assets respectively;
- (II) to notify creditors by notice or public announcements;
- (III) to deal with and settle any outstanding businesses of the Company;
- (IV) to pay outstanding taxes as well as taxes arising in the course of liquidation;
- (V) to settle claims and debts;
- (VI) to allocate the remaining assets of the Company after the repayment of debts;
- (VII) to represent the Company in any civil proceedings.

The liquidation committee shall notify the creditors within 10 days from the date of its establishment and publish an announcement within 60 days in accordance with the requirements. The creditors shall declare their claims to the liquidation committee within 30 days after the receipt of the notice or within 45 days after the date of the announcement if the creditors have not received the notice.

When declaring the claims, the creditors shall specify the relevant matters about the claims and provide corresponding evidence. The liquidation committee shall register such claims.

During the period of declaration of claims, the liquidation committee shall not repay any debts to the creditors.

After sorting out the assets of the Company and preparing balance sheets and inventories of assets, the liquidation committee shall formulate a liquidation plan and present it to the general meeting or to the People's Court for confirmation.

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The remaining assets of the Company after repayment of liquidation expenses, staff wages and social insurance expenses and statutory compensation, payment of outstanding taxes, and payment of the debts of the Company shall be distributed by the Company to the shareholders in proportion to their respective shareholdings.

During the liquidation, the Company shall continue to exist but shall not commence any business activities unrelated to the liquidation. The assets of the Company shall not be distributed to the shareholders before repayment of its debts in full in accordance with the preceding paragraph.

If, after sorting out the assets of the Company and preparing balance sheets and inventories of assets, the liquidation committee discovers that the assets of the Company are insufficient to repay its debts in full, it shall apply to the People’s Court for bankruptcy in accordance with the laws.

After the People’s Court has ruled that the Company is declared bankrupt, the liquidation committee shall hand over the liquidation matters to the bankruptcy administrator designated by the People’s Court.

Upon completion of the liquidation of the Company, the liquidation committee shall prepare a liquidation report and submit to the general meeting or the People’s Court for confirmation. The liquidation committee shall submit the foregoing documents to the Company’s registration authority and apply for deregistration of the Company.

AMENDMENTS TO THE ARTICLES OF ASSOCIATION

The Company shall amend the Articles of Association in any of the following circumstances:

- (I) after amendment has been made to the Company Law or relevant laws, administrative regulations and the securities regulatory rules of the place where the Company’s shares are [REDACTED], the contents of the Articles of Association are in conflict with the amended laws, administrative regulations or securities regulatory rules of the place where the Company’s shares are [REDACTED];
- (II) the changes that the Company have undergone are inconsistent with the records made in the Articles of Association;
- (III) the general meeting has resolved to amend the Articles of Association.

Where the amendments to the Articles of Association approved by the general meetings are subject to the examination and approval by the competent authorities, such amendments shall be submitted to the competent authorities for approval. Where the amendments involve registration of the Company, the Company shall register relevant changes according to the laws.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

FURTHER INFORMATION ABOUT OUR COMPANY

Establishment of our Company

Our Company was established as a limited liability company in the PRC on August 23, 2017 and was converted into a joint stock company with limited liability on September 29, 2024 under the laws of the PRC. As of the Latest Practicable Date, the registered share capital of our Company is RMB26,774,063.

Our Company has established a place of business in Hong Kong at 46/F., Hopewell Centre, 183 Queen’s Road East, Wan Chai, Hong Kong and has been registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on December 18, 2024. Mr. NG Tung Ching Raphael, one of our joint company secretaries, has been appointed as the authorized representative in Hong Kong and our agent for the acceptance of service of process in Hong Kong whose correspondence address is the same as our place of business in Hong Kong.

As we are established in the PRC, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. A summary of the relevant provisions of our Articles of Association is set out in “Summary of Articles of Association” in Appendix III.

Changes in Share Capital of Our Company

The changes in the share capital of our Company during the two years immediately preceding the date of this Document is set out as follows:

On January 6, 2024, the registered capital of our Company increased from RMB25,100,255.68 to RMB26,774,062.58.

Save as aforesaid, as of the Latest Practicable Date, there had been no alterations of our share capital within the two years preceding the date of publication of this Document.

Changes in Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in the Accountants’ Report in Appendix I. Details of the changes in the share capital of the Company’s subsidiaries within the two years immediately preceding the date of this Document are set out below:

On September 1, 2023, the registered of GenFleet Zhejiang increased from RMB10,000,000 to RMB60,000,000.

Save as disclosed above, there had been no other alterations of share capital of our subsidiaries within the two years preceding the date of this Document.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Resolutions of our Shareholders

Pursuant to a general meeting held on December 3, 2024, among other things, our Shareholders resolved that:

- (a) the issuance by our Company of the H Shares of nominal value of RMB[REDACTED] each and such H Shares being [REDACTED] on the Hong Kong Stock Exchange;
- (b) the [REDACTED] with nominal value of RMB1.0 each on the basis of [REDACTED], effective immediately prior to the [REDACTED], and taking into account the [REDACTED], the issue of H Shares of nominal value of RMB[REDACTED] each and such H Shares be [REDACTED] on the Stock Exchange;
- (c) 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] (or their representatives) of the [REDACTED] of not more than [REDACTED] of the number of H Shares issued pursuant to the [REDACTED];
- (d) authorization of the Board to handle matters relating to, among other things, the [REDACTED], the issue and [REDACTED] of the H Shares; and
- (e) subject to the completion of the [REDACTED], the conditional adoption of the Articles of Association, which shall become effective on the [REDACTED] and the authorization of the Board to amend the Articles of Association in accordance with relevant laws and regulations and upon the request from the Stock Exchange and relevant PRC regulatory authorities.

FURTHER INFORMATION ABOUT OUR BUSINESS

Summary of Material Contract

We have entered into the following contract (not being contract entered into in the ordinary course of business) within the two years immediately preceding the date of this Document that is or may be material:

- (a) the [REDACTED].

Intellectual Property Rights

As of the Latest Practicable Date, our Group has registered, or has applied for the registration of the following intellectual property rights which were material to our Group’s business.

APPENDIX IV STATUTORY AND GENERAL INFORMATION

Trademarks

As of the Latest Practicable Date, our Company had registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Registration Number	Class	Place of registration	Effective period
1. . .	劲方	72980546	5	PRC	May 21, 2024 to May 20, 2034
2. . .	劲方	65254924	5	PRC	April 7, 2023 to April 6, 2033
3. . .	劲 方	51025814	42	PRC	August 7, 2021 to August 6, 2031
4 . . .	A. 劲方 B. 勁方	306740569	5	Hong Kong	November 28, 2024 to November 27, 2034
5 . . .	A. GENFLEET B. GenFleet C. Genfleet D. genfleet	306740587	5	Hong Kong	November 28, 2024 to November 27, 2034
6 . . .		306740578	5	Hong Kong	November 28, 2024 to November 27, 2034

Patents

For material patents and patent applications of our Group as of the Latest Practicable Date, see paragraph headed “Business — Intellectual Property” for more details.

Domain Names

As of the Latest Practicable Date, we have registered the following internet domain name which we consider to be or may be material to our business:

No.	Domain Name	Registered Owner	Registration Date	Expiry Date
1.	genfleet.com	Company	April 6, 2017	April 6, 2027

Save as the above, as of the Latest Practicable Date, there were no other intellectual property rights which were material to our business.

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FURTHER INFORMATION ABOUT OUR DIRECTORS, SUPERVISORS, SENIOR MANAGEMENT AND SUBSTANTIAL SHAREHOLDERS

Interests and short positions of our Directors, Supervisors and chief executive of our Company in the Shares, underlying Shares and debentures of our Company and our associated corporations

Save as disclosed in the section headed “Substantial Shareholders” and below, immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), so far as our Directors are aware, none of our Directors, Supervisors and chief executive has any interests and short positions in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) (i) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions in which they are taken or deemed to have under such provisions of the SFO); (ii) which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein; or (iii) which will be required to be notified to us and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers contained in the Listing Rules:

Name	Capacity/Nature of interest	Number of Shares ⁽¹⁾	Approximate percentage of shareholding in the Unlisted Shares/H Shares immediately after completion of the [REDACTED] ⁽²⁾	Approximate percentage of shareholding in the total Share capital immediately after completion of the [REDACTED] ⁽²⁾
Dr. Lu	Interest in controlled corporations	[REDACTED] [REDACTED]	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Dr. Lan	Interest in controlled corporations	[REDACTED]	[REDACTED]%	[REDACTED]%

Notes:

1. The letter “L” denotes the person’s long position in the Shares.
2. The calculation is based on the total number of [REDACTED] Unlisted Shares and [REDACTED] H Shares in issue immediately after completion of the [REDACTED] since [REDACTED] Unlisted Shares will be converted into H Shares and [REDACTED] H Shares will be issued pursuant to the [REDACTED], taking into account the [REDACTED] and assuming that the [REDACTED] and the [REDACTED] are not exercised.
3. Shanghai Kunjin is our ESOP Platform. As of the Latest Practicable Date, Shanghai Kunjin is deemed to be controlled by Dr. Lu as its sole general partner, and none of the limited partner of Shanghai Kunjin held more than one-third of the partnership interest in Shanghai Kunjin. Therefore, by virtue of the SFO, Dr. Lu is deemed to be interested in the Shares held by Shanghai Kunjin.

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4. Auspicious Delight is our ESOP Platform. As at the Latest Practicable Date, GenFleet HK was held as to 53.69% by Dr. Lu and 46.31% by Dr. Lan. GenFleet HK held 64.5% of the issued share capital of Auspicious Delight. Therefore, by virtue of the SFO, each of Dr. Lu and Dr. Lan is deemed to be interested in the Shares held by GenFleet HK and Auspicious Delight.

Interests in associated corporations

Our Directors, Supervisors and chief executive are not interested in the Shares of any associated corporation of our Company.

Interests of the substantial shareholders in the Shares

Save as disclosed in “Substantial Shareholders”, immediately following the completion of the [REDACTED] and without taking into account any Shares which may be issued pursuant to the exercise of the [REDACTED] and the [REDACTED], our Directors are not aware of any other person (not being a Director, Supervisor or chief executive of our Company) who will have an interest or short position in our Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the issued voting shares of our Company.

Interests of the substantial shareholders in other members of our Group

Our Directors are not aware of any persons (other than our Directors, Supervisors or chief executive) who will, immediately following the 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 Group.

Particulars of Directors’ and Supervisors’ Service Contracts

Each of the Directors and Supervisors [has] entered into a service contract or a letter of appointment with our Company.

Save as disclosed above, we have not entered into, and do not propose to enter into any service contracts with any of our Directors or Supervisors in their respective capacities as Directors or Supervisors (excluding agreements expiring or determinable by any member of our Group within one year without payment of compensation other than statutory compensation).

Remuneration of Directors and Supervisors

Save as disclosed in “Directors, Supervisors and Senior Management” and Notes 10 and 11 to the Accountants’ Report set out in Appendix I for the two financial years ended December 31, 2023 and 2024 and the four months ended April 30, 2025, none of our Directors or Supervisors received other remunerations or benefits in kind from us.

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Disclaimers

Save as disclosed in this Document:

- (a) none of our Directors, Supervisors or our chief executive has any interest or short position in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV 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 us and the Stock Exchange pursuant to Model Code for Securities Transactions by Directors of Listed Issuers once the H Shares are [REDACTED] on the Stock Exchange;
- (b) none of our Directors or Supervisors is aware of any person (not being a Director, Supervisor or chief executive of our Company) who will, immediately following the completion of the [REDACTED] and the conversion of Unlisted Shares into H Shares (without taking into account any H Shares which may be allotted and issued pursuant to the exercise of the [REDACTED] and the [REDACTED]), have an interest or short position in our Shares or underlying Shares which would fall to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO or who is interested, directly or indirectly, in 10% or more of the issued voting shares of any member of our Group; and
- (c) none of our Directors, Supervisors or any of the parties listed in “Qualifications of Experts” in 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 Group; or
 - ii. materially interested in any contract or arrangement subsisting at the date of this Document which is significant in relation to our business.

[REDACTED] EQUITY INCENTIVE SCHEME

We adopted the [REDACTED] Equity Incentive Scheme in 2020 as amended and restated in July 2023 and established the ESOP Platforms. All awards granted under the [REDACTED] Equity Incentive Scheme had been vested and exercised and no further awards will be granted under the [REDACTED] Equity Incentive Scheme upon [REDACTED]. The terms of the [REDACTED] Equity Incentive Scheme are not subject to the provisions of Chapter 17 of the Listing Rules as the [REDACTED] Equity Incentive Scheme do not involve the grant of new awards by our Company to subscribe for H Shares after the [REDACTED]. The [REDACTED] Equity Incentive Scheme will not cause any dilution of the shareholding of our

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Shareholders after the [REDACTED] given all underlying Shares of the awards granted under the [REDACTED] Equity Incentive Scheme have been issued to the relevant ESOP Platforms. For details of the ESOP Platforms, see “History, Development and Corporate Structure — Our ESOP Platforms”.

The following is a summary of the principal terms of the [REDACTED] Equity Incentive Scheme:

(a) Objectives

The objectives of the [REDACTED] Equity Incentive Scheme are to build incentive mechanisms for employees, to attract and retain outstanding talents, and to enhance the Company’s market competitiveness and sustainable development capabilities.

(b) Eligibility

Participants of the [REDACTED] Equity Incentive Scheme include directors, supervisors, senior management and core employees of the Group. Core employees include key business, technical and management personnel who hold positions in the Group and have a significant impact on the Group’s overall performance and sustainable development.

(c) Grant of Awards

Each Participant will be granted restricted shares in the form of economic interest in the relevant ESOP Platforms either as a limited partner or shareholder (the “Awards”). Upon becoming the limited partner or shareholder of the relevant ESOP Platforms, the Participant indirectly receives economic interest in the number of Shares underlying the Awards granted to the Participant held by the relevant ESOP Platforms.

(d) Payment of the Price of the Awards

The Participants must subscribe for the Awards with personal funds or self-financed funds, and should ensure that their source of funds is lawful. The subscription period of the Awards shall be determined by the Administrator. The Participants shall make the corresponding payment for Awards fully and timely.

(e) Administration

The Board highest authority in respect of the implementation, amendment, interpretation, termination, and execution of the [REDACTED] Equity Incentive Scheme. The Chairman and General Manager are authorized to determine, among others, list of the grantees, number of awards to be granted to the grantees and ESOP Platforms for the vesting of the awards. The Chairman and his authorized person shall be responsible for the daily management and implementation of the [REDACTED] Equity Incentive Scheme.

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(f) Restriction on transfer

Prior to the [REDACTED], the grantees may not transfer any or all of his or her interest in the relevant ESOP Platforms unless specified in the scheme rules. After the [REDACTED], in addition to the restrictions under the [REDACTED] Equity Incentive Scheme, the transfer or sale by the grantees shall be subject to the [REDACTED] requirements under the relevant laws and regulations and the stock exchange rules, or the respective agreements entered into between the Company and the relevant grantees pursuant to the terms of the [REDACTED] Equity Incentive Scheme (if applicable).

(g) Lapse of awards

A share award shall be repurchased in the event of, among others:

- (i) the employment of the grantee was dismissed by the Group for legal grounds or violation of the Group’s internal policies;
- (ii) the loss of ability to work of the grantees (except for work-relating injuries);
- (iii) the grantee is held liable for criminal offence;
- (iv) the grantee is directly responsible for any significant losses or decline in the Group’s operating performance as determined by the Company; or
- (v) the grantee committed material violation of the Group’s internal rules and regulations.

(h) *Rights of the grantees*

Grantees shall be entitled to register their interests underlying the awards granted as a limited partner or shareholder of the relevant ESOP Platforms in accordance with the [REDACTED] Equity Incentive Scheme. The grantees shall have the rights to any dividends or distributions as a limited partner or shareholder of the relevant ESOP Platforms based on the partnership agreement, shareholders agreement or articles of the relevant ESOP Platforms.

(i) Duration

The [REDACTED] Equity Incentive Scheme shall be valid and effective commencing on the effective date until the ESOP Platforms no longer hold any Shares, and in any event shall not be longer than the period of ten (10) years.

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OTHER INFORMATION

Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries under the laws of the PRC.

Litigation

As of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance was known to our Directors to be pending or threatened by or against any member of our Group, that would have a material and adverse effect on our Group’s results of operations or financial conditions, taken as a whole.

Preliminary Expenses

As of the Latest Practicable Date, our Company has not incurred any material preliminary expenses.

Promoter

The promoters of the Company are all of the 49 then Shareholders immediately before our conversion into a joint stock limited liability company. Within the two years immediately 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 the promoters in connection with the [REDACTED] and the related transactions described in this Document.

Taxation of Holders of H Shares

The sale, purchase and transfer of H Shares registered with our Hong Kong branch register of members will be subject to Hong Kong stamp duty. The current rate charged on each of the purchaser and seller is 0.1% of the consideration of or, if higher, of the fair value of our Shares being sold or transferred.

No Material Adverse Change

Our Directors confirm that there has been no material adverse change in the financial or trading position or prospects of the Group since June 30, 2024 (being the date to which the latest consolidated financial statements of our Group were prepared).

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STATUTORY AND GENERAL INFORMATION

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 their opinion and/or advice in this Document are as follows:

Name	Qualification
CITIC Securities (Hong Kong) Limited	A licensed corporation to conduct Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities under the SFO
Jia Yuan Law Offices	PRC legal advisor
JunHe LLP	PRC intellectual property law legal advisor
Jun He Law Offices P.C.	U.S. intellectual property law legal advisor
2K Patent- und Rechtsanwälte — München	Legal advisor as to the laws of European Patent Convention and the national patent laws of EPC contracting countries
Ernst & Young	Certified Public Accountants under Professional Accountants Ordinance (Cap. 50 of the Laws of Hong Kong) and Registered Public Interest Entity Auditor under Accounting and Financial Reporting Council Ordinance (Cap. 588 of the Laws of Hong Kong)
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Independent industry consultant

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

Consents of Experts

Each of the experts as referred to “Qualifications of Experts” in this Appendix has given and has not withdrawn their respective written consents to the issue of this Document with the inclusion of their reports and/or letters (as the case may be) and the references to their names included in the form and context in which they are respective included.

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Sole Sponsor’s Independence

The Sole Sponsor satisfies the independence criteria applicable to the sponsor set out in Rule 3A.07 of the Listing Rules.

Pursuant to the engagement letter entered into between the Company and the Sole Sponsor, the Sole Sponsor’s fees payable by us to the Sole Sponsor in respect of its service as the sponsor in connection with the [REDACTED] on the Stock Exchange is US\$500,000.

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.

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).

Miscellaneous

Save as otherwise disclosed in this Document:

- (a) within the two years preceding the date of this Document: (i) we have 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 commissions, discounts, brokerage fee or other special terms have been granted in connection with the issue or sale of any shares of our Company;
- (b) no share or loan capital of our Company is under option or is agreed conditionally or unconditionally to be put under option;
- (c) we have not issued nor agreed to issue any founder shares, management shares or deferred shares;
- (d) there are no arrangements under which future dividends are waived or agreed to be waived;
- (e) there are no procedures for the exercise of any right of pre-emption or transferability of subscription rights;

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- (f) there are no contracts for hire or hire purchase of plant to or by us for a period of over one year which are substantial in relation to our business;
- (g) there have been no interruptions in our business which may have or have had a significant effect on our financial position in the last 12 months;
- (h) there are no restrictions affecting the remittance of profits or repatriation of capital by us into Hong Kong from outside Hong Kong;
- (i) no part of the equity or debt securities of our Company, if any, is currently [REDACTED] on or [REDACTED] on any stock exchange or [REDACTED] system, and no such [REDACTED] or permission to [REDACTED] on any stock exchange other than the Hong Kong Stock Exchange is currently being or agreed to be sought;
- (j) our Company has no outstanding convertible debt securities or debentures;
- (k) our Company is a joint stock limited company and is subject to the PRC Company Law; and
- (l) our Company has adopted a code of conduct regarding Directors’ and Supervisors’ securities transactions on terms as required under the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Hong Kong Listing Rules.

APPENDIX V

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG AND AVAILABLE ON DISPLAY

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to a copy of this Document delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) a copy of the material contract referred to in “Statutory and General Information — Further Information about our Business — Summary of Material Contract” in Appendix IV; and
- (b) the written consents referred to in “Statutory and General Information — Other Information — Consents of Experts” in Appendix IV.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be published on the Stock Exchange’s website at www.hkexnews.hk and the Company’s website at www.genfleet.com during a period of 14 days from the date of this Document:

- (a) the Articles of Association;
- (b) the audited consolidated financial statements of our Group for the two years ended December 31, 2023 and 2024 and the four months ended April 30, 2025;
- (c) the Accountants’ Report from Ernst & Young, the text of which is set out in Appendix I;
- (d) the report from Ernst & Young on the unaudited [REDACTED] financial information of our Group, the text of which is set out in Appendix II;
- (e) the material contract referred to in “Statutory and General Information — Further Information about our Business — Summary of Material Contract” in Appendix IV;
- (f) the written consents referred to in “Statutory and General Information — Other Information — Consents of Experts” in Appendix IV;
- (g) the service contracts and letters of appointment referred to in “Statutory and General Information — Further Information about our Directors, Supervisors, Senior Management and Substantial Shareholders — Particulars of Directors’ and Supervisors’ Service Contracts” in Appendix IV;
- (h) the legal opinions issued by Jia Yuan Law Offices, our PRC Legal Advisor, in respect of, among other things, the general corporate matters of our Group under the PRC law;

APPENDIX V

**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES IN HONG KONG AND AVAILABLE ON DISPLAY**

- (i) the legal opinion issued by 2K Patent- und Rechtsanwälte — München, our IP counsel as to the laws of European Patent Convention and the national patent laws of EPC contracting countries;
- (j) the legal opinions issued by, JunHe LLP and Jun He Law Offices P.C., our IP counsels as to the PRC and U.S. intellectual property laws, respectively;
- (k) the industry report issued by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co. referred to in “Industry Overview”; and
- (l) a copy of the following PRC laws, together with unofficial English translations:
 - (i) the PRC Company Law;
 - (ii) the PRC Securities Law; and
 - (iii) the Overseas Listing Trial Measures.