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Application Proof of

 **HIGHTIDE**
HighTide Therapeutics, Inc.
君圣泰医药
(the “Company”)
(Incorporated in the Cayman Islands with limited liability)

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 **HIGHTIDE**
HighTide Therapeutics, Inc.
君圣泰医药

(Incorporated in the Cayman Islands with limited liability)

[REDACTED]

Number of [REDACTED] under : [REDACTED] Shares (subject to the the [REDACTED] [REDACTED])
Number of [REDACTED] : [REDACTED] Shares (subject to adjustment)
Number of [REDACTED] : [REDACTED] Shares (subject to adjustment and the [REDACTED])
Maximum [REDACTED] : HK\$[REDACTED] per [REDACTED], plus brokerage of 1.0%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.00565% and AFRC transaction levy of 0.00015% (payable in full on [REDACTED] in Hong Kong Dollars and subject to refund)
Nominal Value : US\$0.0001 per Share
[REDACTED] : [REDACTED]

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



UBS 瑞銀集團



华泰国际
HUATAI INTERNATIONAL

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Our Company is incorporated in the Cayman Islands and a significant portion of our businesses are located in the PRC. Potential [REDACTED] should be aware of the differences in legal, economic and financial systems between the Cayman Islands, the PRC and Hong Kong and that there are different risk factors relating to the [REDACTED] in our Company. Potential [REDACTED] should also be aware that the regulatory frameworks in the Cayman Islands and the PRC are different from the regulatory framework in Hong Kong and should take into consideration the different market nature of our [REDACTED]. Such differences and risk factors are set out in the sections headed “Risk Factors” and “Regulatory Overview”.

The [REDACTED] is expected to be fixed by agreement between the [REDACTED] and the [REDACTED] (for themselves and on behalf of the [REDACTED]) and us on the [REDACTED]. The [REDACTED] is expected to be on or around [REDACTED] and, in any event, not later than [REDACTED]. The [REDACTED] will be not more than HK\$[REDACTED] per [REDACTED] and is currently expected to be not less than HK\$[REDACTED] per [REDACTED]. If, for any reason, the [REDACTED] is not agreed by [REDACTED] between the [REDACTED] and the [REDACTED] (for themselves and on behalf of the [REDACTED]) and us, the [REDACTED] will not proceed and will lapse.

Applicants for [REDACTED] are required to pay, on application, the maximum [REDACTED] of HK\$[REDACTED] for each [REDACTED] together with brokerage fee of 1%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.00565% and AFRC transaction levy of 0.00015%, subject to refund if the [REDACTED] as finally determined is less than HK\$[REDACTED].

The [REDACTED] (for themselves and on behalf of the [REDACTED]), and with our consent, may, where considered appropriate, reduce the number of [REDACTED] and/or the indicative [REDACTED] range below that is stated in this document (which is HK\$[REDACTED] to HK\$[REDACTED]) at any time prior to the morning of the last day for lodging applications under the [REDACTED]. In such case, notices of the reduction in the number of [REDACTED] and/or the indicative [REDACTED] range will be published on the website of our Company at www.hightidetx.com and on the website of the Stock Exchange at www.hkexnews.hk as soon as practicable following the decision to make such reduction, and in any event not later than the morning of the day which is the last day for lodging applications under the [REDACTED]. Further details are set forth in “Structure of the [REDACTED]” and “How to Apply for [REDACTED]” in this document.

The obligations of the Hong Kong [REDACTED] under the [REDACTED] to subscribe for, and to procure applicants for the subscription for, the [REDACTED], are subject to termination by the [REDACTED] (for themselves and on behalf of the Hong Kong [REDACTED]) if certain grounds arise prior to 8:00 a.m. on the day that [REDACTED] in the [REDACTED] commences on the Hong Kong Stock Exchange. Such grounds are set out in the section headed “[REDACTED]—[REDACTED] Arrangements and Expenses—[REDACTED]—Grounds for termination” in this document.

The [REDACTED] have not been and will not be registered under the Securities Act or any state securities law in the United States and may not be [REDACTED], [REDACTED], pledged or transferred within the United States or to, or for the account or benefit of United States persons, except in transactions exempt from, or not subject to, the registration requirements of the Securities Act. The [REDACTED] are being [REDACTED] and [REDACTED] (i) in the United States solely to QIBs as defined in Rule 144A pursuant to an exemption from registration under the Securities Act and (ii) outside the United States in offshore transactions in reliance on Regulation S under the Securities Act.

[REDACTED]

[REDACTED]

IMPORTANT

[REDACTED]

IMPORTANT

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

CONTENTS

IMPORTANT NOTICE TO [REDACTED]

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	<i>Page</i>
EXPECTED TIMETABLE	i
CONTENTS	v
SUMMARY	1
DEFINITIONS	26
GLOSSARY OF TECHNICAL TERMS	39
FORWARD-LOOKING STATEMENTS	49
RISK FACTORS	51
WAIVERS AND EXEMPTIONS	109
INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]	114

CONTENTS

	<i>Page</i>
DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]	118
CORPORATE INFORMATION	123
INDUSTRY OVERVIEW	126
REGULATORY OVERVIEW	160
HISTORY, REORGANIZATION AND CORPORATE STRUCTURE	199
BUSINESS	238
DIRECTORS AND SENIOR MANAGEMENT	356
SHARE CAPITAL	376
SUBSTANTIAL SHAREHOLDERS	379
CONNECTED TRANSACTION	382
FINANCIAL INFORMATION	391
FUTURE PLANS AND USE OF [REDACTED]	425
[REDACTED]	430
STRUCTURE OF THE [REDACTED]	441
HOW TO APPLY FOR [REDACTED]	452
APPENDIX I – ACCOUNTANTS’ REPORT	I-1
APPENDIX II – [REDACTED]	II-1
APPENDIX III – SUMMARY OF THE CONSTITUTION OF THE COMPANY AND CAYMAN ISLANDS COMPANY LAW	III-1
APPENDIX IV – STATUTORY AND GENERAL INFORMATION	IV-1
APPENDIX V – DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND ON DISPLAY	V-1

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. Your [REDACTED] decision should be made in light of these considerations.

OVERVIEW





















Established in 2011, we are a biopharmaceutical company specializing in the discovery, development and commercialization of multifunctional, multi-targeted therapies for the treatment of metabolic and digestive diseases. We have developed a product pipeline of one Core Product and other four product candidates in-house. Our Core Product, HTD1801 (berberine ursodeoxycholate), a new molecular entity, is a gut-liver anti-inflammatory metabolic modulator which targets multiple pathways pivotal to metabolic regulation, including those associated with metabolic and digestive diseases.


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

Our Pipeline

As of the Latest Practicable Date, we have researched and developed in-house a pipeline with five proprietary drug candidates covering nine indications, including five indications that are at clinical stage. The following chart summarizes the development status of our drug candidates as of the Latest Practicable Date.

SUMMARY

Candidate	Mechanism/Target	Indication	Right	Designations	Pre-Clinical	Phase I	Phase II	Phase III	Competent or regulatory authorities	Upcoming Milestone
HTD1801 	Berberine ursodeoxycholate (BUDC)	MASH	 Global ^(b)	FTD	Ph I is completed in US; Ph I is initiated in US and Hong Kong and to be initiated in Mexico and Mainland China				FDA, NMPA, The Federal Commission for Protection against Sanitary Risks, Department of Health	Ph I in Mexico and Mainland China initiated in late 2023 and studies in all clinical sites expected to be completed in 2025
		T2DM	 Global		Ph II completed in Mainland China, Ph III initiated in Mainland China ^(c)				NMPA	Ph III to be completed in 2025
		SHTG	 Global		Ph II to be initiated in US ^(e)				FDA	Ph II to be initiated in 1H 2024
		PSC	 Global ^(b)	FTD, ODD	Ph II completed in US and Canada; IND approval obtained in China ^(d)				FDA, Health Canada, NMPA	Joint collaboration strategy
		PBC	 Global		Ph II completed in US				FDA	Joint collaborations strategy
HTD4010	Polypeptide drug	AH	 Global		Ph I completed in Australia				TGA	Ph II to be initiated in late 2024 or beyond
HTD1804	Undisclosed	Obesity	 Global						N/A	IND-enabling
HTD1805	Undisclosed	Metabolic disease	 Global						N/A	IND-enabling
HTD2802	Undisclosed	IBD	 Global						N/A	IND-enabling

 **Core Product**

Abbreviations: MASH: metabolic dysfunction-associated steatohepatitis, formerly known as nonalcoholic steatohepatitis or NASH; T2DM: type 2 diabetes mellitus; SHTG: severe hyperriglyceridemia; PSC: primary sclerosing cholangitis; PBC: primary biliary cholangitis; AH: alcoholic hepatitis; IBD: inflammatory bowel disease; FTD: Fast Track Designation; ODD: Orphan Drug Designation; Ph: Phase.

Notes:

1. Researched and developed in-house. We have granted Hepalink an exclusive, sublicensable (solely to Hepalink's designated wholly-owned subsidiaries), non-transferable license for the commercialization of HTD1801 for MASH and PSC in Europe. The Company reserved the rights to (i) research, develop and manufacturing HTD1801 globally; (ii) commercialize HTD1801 for any indications outside Europe; (iii) commercialize HTD1801 in Europe for any indications other than MASH and PSC; and (iv) import and export HTD1801. For details, see "Business — Collaboration Agreement — HTD1801 License-Out Agreement" and "Connected Transaction".
2. In November 2023, we initiated the two Phase III clinical trials (i.e. one with HTD1801 as a standalone treatment and one with HTD1801 as an add-on therapy with metformin) for the T2DM indication of our self-developed HTD1801 in China. We expect to complete those two Phase III studies in 2025. For details, see "Business — Clinical Stage Candidate — Core Product HTD1801 — Summary of Clinical Trials of HTD1801".
3. We have completed a Phase Ib/Ia trial for hypercholesterolemia in Australia and a Phase IIa trial for MASH in the United States. Based on FDA's written responses to the pre-IND meeting, the FDA concluded that the available preclinical and clinical data of the above trials was adequate to support the initiation of Phase II trial for SHTG.
4. We have obtained the IND approval from the NMPA to conduct the China part in the Phase II MRCT of PSC. However, due to COVID-19 pandemic, we did not initiate the China part of the Phase II clinical trial. After the completion of Phase II trials in the United States and Canada, the China part of the Phase II trial is not required because the Phase II trials had met the endpoints in the United States and Canada.
5. Competent authority in respective jurisdictions: US — FDA; Mainland China — NMPA; Canada — Health Canada; Australia — TGA; Hong Kong — The Department of Health; Mexico — The Federal Commission for Protection against Sanitary Risks.

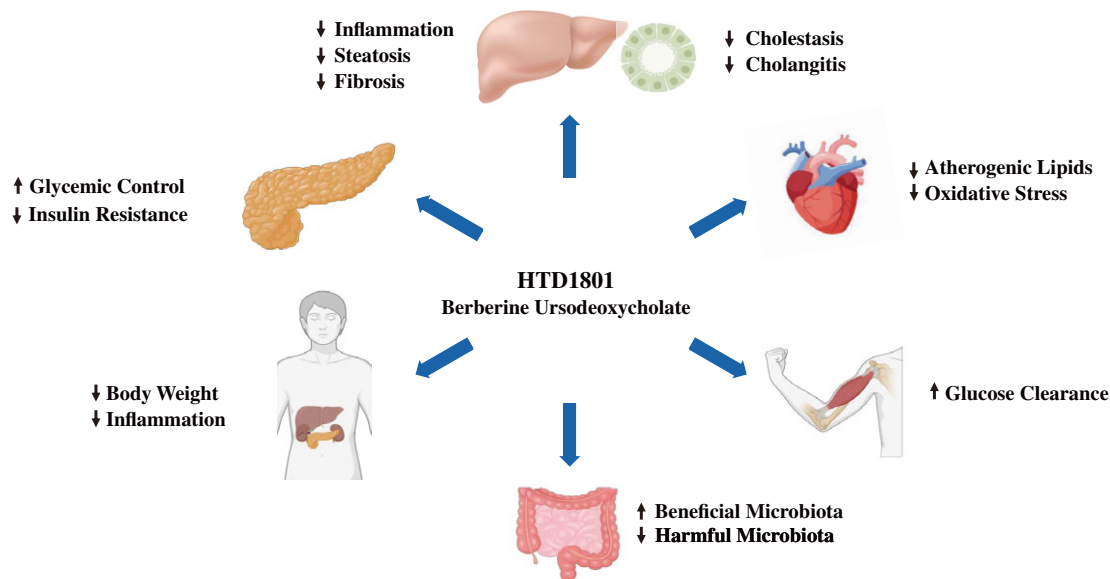
SUMMARY

Core Product

HTD1801 is a salt with an ionic bond formed between two active moieties (the molecule or ion responsible for the physiological or pharmacological action of the drug substance), berberine ("BBR") and ursodeoxycholic acid ("UDCA"). The two active moieties BBR and UDCA have a long history of medicinal applications as treatments for gut and liver diseases in traditional Chinese medicine. In HTD1801, BBR and UDCA work in tandem in the salt form with unique microstructure to produce distinct and improved properties as demonstrated in our studies. The improved properties are not observed with either of the individual active moieties or their physical mixture. Our clinical results show that HTD1801 delivers a therapeutic effect for patients including metabolic improvement, liver protection, anti-inflammation and antioxidative stress. However, therapeutic effect of the Core Product is based on preliminary clinical data only which is yet to be validated in later clinical trials, and the Core Product may fail to meet the primary and secondary endpoints at the late-stage clinical trials due to higher clinical development risks. For details, see "Risk Factors — Risks relating to development, clinical trials and regulatory approval of our drug candidates — the Core Product may fail to meet the primary and secondary endpoints at the late-stage clinical trials due to higher clinical development risks resulted from HTD1801 being a new molecular entity and potential rejection from competent authorities" in this Document. HTD1801 is currently being developed by us for indications across metabolic dysfunction-associated steatohepatitis ("MASH", formerly known as nonalcoholic steatohepatitis or NASH), type 2 diabetes mellitus ("T2DM"), severe hypertriglyceridemia ("SHTG"), primary sclerosing cholangitis ("PSC") and primary biliary cholangitis ("PBC") globally, with a focus on comorbidities and a potential for indication expansion. 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 development, clinical trials and regulatory approval of our drug candidates — Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may be unable to commercialize our drug candidates at all."

The following diagram illustrates mechanism of action of HTD1801:

HTD1801: A Gut-Liver Anti-inflammatory Metabolic Modulator ("GLAM")



Source: Company Data

SUMMARY

In the United States, we have received fast track designation (“**FTD**”) from the Food and Drug Administration (“**FDA**”) for MASH and PSC indications, as well as orphan drug designation (“**ODD**”) for the PSC indication. Under the Orphan Drug Act, the FDA granted the ODD to HTD1801 for PSC on the condition that HTD1801 is intended to treat a rare disease of PSC affecting fewer than 200,000 individuals in the United States. For more details, please see “Regulatory Overview — Laws and Regulations in the United States and EU — Orphan Drugs.” According to CIC, HTD1801 is the first PSC drug candidate to receive FTD from the FDA. The FTD is based on available preclinical and clinical data that demonstrate the potential to address an unmet medical need and is intended to facilitate an expedited regulatory review process. In China, we received government support from “Major National Science and Technology Projects for New Drug Development” under the “National 13th Five-Year Plan”, which may further accelerate the domestic market approval for HTD1801. According to the current development progress and timeline, we expect to submit the first New Drug Application (“**NDA**”) for HTD1801 for T2DM in 2025 in China.

As of the Latest Practicable Date, we held 58 patents and patent applications in relation to our Core Product, representing four types of patents that have been applied in different jurisdictions, including a new molecular entity (a “composition-of-matter” patent), the process used to manufacture the drug, the way the drug is used and new formulations of the drug to protect our assets. The reasons for applying these patents in various jurisdictions are to provide extensive patent protections and maintain our Core Product’s exclusivity in these jurisdictions. We have successfully obtained composition of matter patent for HTD1801 in many countries and regions, including the United States, China, the European Union and Japan, as well as crystalline form patent in United States and China.

Considering the market size and addressable patient population of MASH and T2DM, we have and will continue to prioritize our resources for the clinical development of the MASH and T2DM indications of HTD1801. We are currently conducting the Phase IIB clinical trial for the MASH indication of our self-developed HTD1801, and may seek joint development opportunities for its Phase III clinical trials. For T2DM, we completed two Phase I clinical trials, one Phase Ib clinical trial, and one Phase II clinical trial in China, which are all required by the NMPA. In November 2023, we initiated the two Phase III clinical trials (i.e. one with HTD1801 as a standalone treatment and one with HTD1801 as an add-on therapy with metformin) for the T2DM indication of our self-developed HTD1801 in China. We expect to complete those two Phase III studies in 2025. In addition, we have no immediate plans to conduct clinical trials for and commercialise T2DM outside of China. Since the completion of Phase II clinical trials for PSC in August 2020 and for PBC in May 2022, no clinical development progress has been made for the PSC and PBC indications of HTD1801. We have no immediate development plans and will not allocate any net [REDACTED] of the [REDACTED] to these two indications, and we are seeking collaboration opportunities with global partners for future clinical development and commercialisation of HTD1801 for PSC and PBC indications. Despite the rebound in liver biochemistry during the follow-up period in the Phase II trial for PBC and a long period of clinical development suspension for the PBC and PSC indications, we have not encountered any difficulties in identifying collaboration opportunities with global partners for future clinical development and commercialisation of HTD1801 for PBC and PSC. In addition to Hepalink obtaining a license to commercialize HTD1801 in Europe for the MASH and PSC indications, we are in negotiations with global partners for the future development of HTD1801 for such orphan diseases of cholestasis (the category of diseases which PSC and PBC fall within); however, due to

SUMMARY

the time required to negotiate the commercial terms, as of the Latest Practicable Date, no collaboration agreements had been entered into. The follow-up periods in the Phase II clinical trial for PBC, during which HTD1801 treatment was withdrawn, showed a worsening in liver biochemistry compared with baseline, also suggesting the efficacy of HTD1801. Therefore, we believe that it has no impact on our clinical development.

We designed the MRCTs for HTD1801 for MASH and PSC indications. The use of MRCT for MASH and PSC was determined in 2017. The Phase IIb clinical trial for MASH and Phase II clinical trial for PSC were conducted in the form of MRCT, and MRCT would also be the approach for the clinical trials going forward for MASH and PSC. We believe MRCTs can expedite global clinical development and facilitate registration in multiple regions across the globe. We use the same study protocol for IND approval of clinical trials and conducting clinical trials in different phases after obtaining IND approvals in each of MRCT’s jurisdictions. The clinical results of the MRCT in various jurisdictions can be used to support registration approval by the competent authorities in those jurisdictions. There are no differences in primary endpoints, extent or type of clinical trials to be conducted across various jurisdictions but might be slight differences in materials to be submitted among the different regulatory bodies.

For Phase IIb MRCT of HTD1801 for MASH indication in the United States, Hong Kong, Mexico and Mainland China, the details of communications with competent authorities have been set forth in the section “Business — Clinical-Stage Candidates — Core Product HTD1801 — Material Communications with Competent Authorities”. In April 2023, we submitted the Phase IIb study protocol to the FDA and we did not receive any comments or rejections from the FDA within the 30-day clearance period. We also obtained the IND approvals in Hong Kong and Mainland China in August and September 2023, respectively, and filed an IND application in Mexico in July 2023.

For Phase II MRCT of HTD1801 for PSC in the United States, Mainland China and Canada, the details of communications with competent authorities have been set forth in the section “Business — Clinical-Stage Candidates — Core Product HTD1801 — Material Communications with Competent Authorities”. We obtained IND approvals from the FDA in 2017, and from the NMPA and the Health Canada in 2019.

Other Product Candidates

Building on our expertise in the development of HTD1801, we have also invested in and developed our pipeline to cover alcoholic hepatitis (“**AH**”), obesity, inflammatory bowel disease (“**IBD**”) and other metabolic diseases to address large unmet medical needs. For AH, we are advancing the early clinical development of HTD4010. AH is one of the manifestations from alcohol-associated liver disease (“**ALD**”) characterized by acute liver inflammation. There are currently no approved drug treatments specifically targeting AH. The current standard of care, corticosteroids, often used in patients with severe AH, has not shown a meaningful long-term survival benefit and usually carries serious side effects. HTD4010 is a Toll-like receptor 4 (“**TLR4**”) inhibitor potentially capable of modulating the innate immune response and the resulting liver inflammation, a major contributor to AH pathogenesis. In animal studies, HTD4010 demonstrated potent beneficial effects for AH, alleviating signs of severe liver injury and reducing systemic inflammation. Our completed Phase I clinical trial demonstrated its favorable safety profile in healthy humans.

SUMMARY

We are also evaluating HTD1804 for the treatment of obesity, which is a growing global health risk associated with a wide range of comorbidities, most notably cardiovascular diseases (“CVDs”) and T2DM. Preclinical studies show that HTD1804 may be an important modulator of energy metabolism as well as cardiovascular protection. HTD1805, another drug candidate in our pipeline, is a multifunctional small molecule drug for the treatment of metabolic diseases. HTD2802 is a preclinical-stage, multifunctional drug for the treatment of IBD. In preclinical studies, HTD2802 has shown positive effects on stool formation and the occurrence of fecal occult blood, as well as reducing inflammatory cytokine levels and preventing pathological injury.

Business Model

Self-Development

We adopt a self-development business model. All our product candidates are self-developed. In addition, we have granted Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司) (“**Hepalink**”) an exclusive, sublicensable (solely to Hepalink’s wholly-owned subsidiaries), non-transferable license of HTD1801 for all aspects of commercialization for the indications of MASH and PSC in Europe. We retain the rights to (i) research and develop HTD1801 worldwide; (ii) manufacture HTD1801 worldwide; (iii) commercialize HTD1801 for any indications outside Europe; (iv) commercialize HTD1801 in any region in Europe for indications other than for MASH and PSC; and (v) import and export HTD1801 for the purposes described above. Please see the paragraphs headed “— HTD1801 License-Out Agreement” in this section for more details.

Our Capabilities

Our R&D team has profound expertise, deep understanding, and broad development experience in metabolic and digestive diseases. Our R&D team pioneered the identification of compounds designed to modulate multiple pathways underlying chronic diseases, providing a unique advantage in addressing the unmet clinical needs across complex pathologies. Our CMC team is specialized in preclinical and clinical support throughout the drug development process. The CMC function 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 not established our in-house sales team. We will pursue the commercialization strategy of external cooperation for future assets to maximize the value of our drug candidates globally.

ADDRESSABLE MARKETS AND COMPETITIVE LANDSCAPE OF CORE PRODUCT

There has been an increasing industry focus on metabolic and digestive diseases in recent years, which has driven our continued investment in the development of new and more effective treatments. According to CIC, there are significant commercial opportunities across multiple metabolic and digestive diseases including MASH, T2DM, SHTG, PSC and PBC, together representing a large global market size of US\$330 billion in 2022.

SUMMARY

MASH is a growing health issue, particularly in developed countries, due to the rising rates of obesity and metabolic syndrome. As of the end of 2022, the prevalence of MASH reached 40.4 million, 20.7 million and 35.0 million in China, the United States and Europe, respectively, according to CIC. There are currently no approved therapies for the treatment of MASH. While lifestyle modifications and management of underlying conditions can help slow or stop the progression of MASH, there are currently no approved pharmacologic therapies that comprehensively improve the full spectrum of MASH, from inflammation and liver cell damage to fibrosis and cirrhosis. Therefore, there is a significant need for safe and effective pharmacologic therapies to treat MASH, specifically therapies that comprehensively improve the pathologic spectrum of MASH. Effects on cardiometabolic parameters such as lipid metabolism, glycemic control, and body weight are also important considerations given the prevalence of such comorbidities in patients with MASH. Lastly, given the pathogenetic complexity and heterogeneity of the disease, there is growing interest in developing therapies that target multiple pathways involved in the development and progression of MASH.

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, and performance of CROs and other parties involved in clinical trial development and others. For example, Intercept’s ocaliva, one of the most advanced MASH drugs in the pipeline, filed the second application for MASH but it was rejected by the FDA in June 2023. The FDA reviewers flagged increased risk of diabetes and liver injury from using the oral tablets, called obeticholic acid (“**OCA**”), for the treatment of MASH. The FDA concluded that benefits of ocaliva did not outweigh the risks in MASH patients with fibrosis based on current data. Intercept expressed that continuing a long-term outcomes study as requested by the FDA may not be economically feasible and has decided to discontinue all MASH-related investment, which has a negative impact on MASH market. Therefore, favorable safety profiles matter in new drug development for chronic diseases. We believe that such risk is low in our HTD1801 development given its good preliminary clinical results.

We may fail to develop the HTD1801 MASH indication, which is one of the major indications of HTD1801, in particular the high probability of failure to achieve the primary and second efficacy endpoints in late-stage clinical trials because HTD1801 is based on a new molecular entity, which is yet to be tested in large-scale clinical studies, thus facing higher clinical risks. Despite that HTD1801 is different from ocaliva in many aspects, such as mechanism of actions, PK profiles and others as applicable, our development of HTD1801 may still be subject to development risks, including those faced by ocaliva in their development.

T2DM is one of the most common metabolic disorders worldwide, which is characterized by chronic hyperglycemia resulting from insulin deficiency due to pancreatic β -cell dysfunction and insulin resistance. According to CIC, China has the largest number of T2DM patients globally, with approximately 123.2 million patients in 2022, this number is expected to increase to 141.8 million by 2032. Despite low diagnosis rate at 50% in 2022 and relatively low penetration rate, the market size in T2DM treatment reached US\$7.9 billion in 2022 in China. T2DM and metabolic dysfunction-associated steatotic liver disease (“**MASLD**”, formerly known as nonalcoholic fatty liver disease or NAFLD) are closely interrelated metabolic diseases. A key function of the liver is the storage and management of energy (e.g., sugars and lipids) in the body, as such a dysregulation in energy management or sensitivity (e.g., insulin resistance in T2DM) may have a substantial impact in that function. T2DM aggravates MASLD and results in a higher risk of disease

SUMMARY

progression and outcomes including MASH, cirrhosis and hepatocellular carcinoma. Similarly, MASLD compounds the severity of T2DM and with an increase in comorbidities such as cardiovascular disease and liver-related outcomes. The worldwide prevalence of MASLD among people with T2DM is 55.5%; in China the prevalence of T2DM with MASLD was 64.1 million as of the end of 2022. According to CIC, there are currently no approved drugs which can provide sufficient and comprehensive therapeutic benefits for both T2DM and MASLD. And most drugs under development are designed for targeting a single target. The goal in treating these patients is to halt or reverse the progression of T2DM and MASLD, thereby reducing the risk of clinical outcomes associated with advanced disease. Therefore, an ideal therapy for patients with T2DM and MASLD should provide comprehensive benefits across a wide variety of parameters which encapsulate the spectrum of these diseases.

SHTG is the presence of high levels of triglycerides. The diagnosis of hypertriglyceridemia (**HTG**) is defined by the presence of serum triglycerides (**TGs**) greater than 150 mg/dL with SHTG being defined by TGs greater than or equal to 500 mg/dL. As of the end of 2022, the prevalence of SHTG reached 1,586.4 thousand, 339.8 thousand and 813.0 thousand in China, the United States and Europe, respectively, according to CIC. Dietary modification is one of the current standard of cares (**SoC**) in treating patients with SHTG. In addition to dietary modification, fibrates, prescription omega-3 fatty acids or statins are also considered as SoC of SHTG to reduce risk of pancreatitis. Unfortunately, while each of these classes of therapeutics offer benefit in the treatment of SHTG, each of them still leaves a large fraction of patients with an incomplete response to treatment or presents additional risks or adverse reactions. Furthermore, while the existing therapies for SHTG offer a benefit in treating high TGs, they offer limited benefit in the treatment of the constellation of metabolic issues in orbit around or underlying the TG levels (e.g., T2DM, MASLD/MASH, obesity).

PSC is a rare, chronic cholestatic liver disease characterized by intrahepatic or extrahepatic bile duct injury, or both. Inflammation and fibrosis of the bile ducts leads to stricturing, impaired bile flow (i.e. cholestasis), and progressive liver dysfunction. As of the end of 2022, the prevalence of PSC reached 171.9 thousand, 48.4 thousand and 60.7 thousand in China, the United States and Europe, respectively, according to CIC. PSC has a high incidence of liver related morbidity and mortality, cholangiocarcinoma, and an increased risk for colorectal cancer. There is also a strong association of PSC and inflammatory bowel disease. Prior to the liver transplant era, death from liver failure was the leading outcome in PSC; but now, death due to cholangiocarcinoma (**CCA**) has been reported to be more common. The exact pathogenesis of PSC is not fully understood, but it is believed to be a complex interplay of genetic, environmental, and immune factors. Despite the seriousness of the disease, there is no available therapy for patients with PSC, and standard of care consists of supportive therapies to manage symptoms and prevent complications. Given the pathogenesis of PSC is complex and multifactorial, an effective treatment should target multiple underlying mechanisms that contribute to the development and progression of PSC.

PBC is a chronic, slowly progressive autoimmune, cholestatic liver disease characterized by female predominance. PBC 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. As of the end of 2022, the prevalence of PBC reached 789.8 thousand, 135.4 thousand and 175.6 thousand in China, the United States and Europe, respectively, according to CIC. There are only two approved treatments for PBC to date, each with their own limitations. While UDCA is prescribed for patients with PBC as the current first-line therapy, up to 40% of

SUMMARY

PBC patients do not achieve an adequate response to UDCA as a monotherapy. In the United States and Europe, obeticholic acid (“OCA”) is approved as second-line therapy for the treatment of patients with PBC patients who have had an inadequate response to or are intolerant of UDCA. Approximately 40% of patients with PBC who are incomplete responders to UDCA alone also do not achieve a complete response with the addition of OCA. Further, OCA is contraindicated for patients with PBC who have compensated cirrhosis with evidence of portal hypertension or patients with decompensated cirrhosis. Tolerability concerns related to the use of OCA include an exacerbation of pruritus, a common symptom of PBC. Hence, there remains a significant unmet medical need for patients with PBC.

We face fierce competition from approved products and product candidates under clinical development in the MASH, T2DM, SHTG, PSC and PBC markets. We may also face potential competition from off-label treatment paradigms for MASH and PSC. The indications of such approved products may also be expanded and potentially compete with HTD1801. As there are multiple product candidates currently in Phase III clinical trials for each of the targeted indications of HTD1801, our development and commercialization of HTD1801 may be adversely affected if some or all of such product candidates receive NDA approval prior to HTD1801. For example, the FDA may request head-to-head studies for HTD1801 before granting the approval, which may impose higher risk of clinical failure and also delay the original development plan. For details, see “Risk Factors — Risks relating to development, clinical trial and regulatory approvals of our drug candidates — We may face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates” in this Document.

STRENGTHS

We believe the following strengths differentiate us from our competitors:

- Develop novel multifunctional, multi-target therapies for metabolic and digestive diseases to treat patients as a whole
- HTD1801, a “pipeline-in-a-product” new molecular entity with the potential to become a therapy for MASH, T2DM, and other metabolic and digestive diseases
- Pipeline of new molecular entities with a therapeutic profile to address unmet needs in metabolic and digestive diseases
- Commercial opportunity in metabolic and digestive diseases for HTD1801 and our pipeline of other highly differentiated therapeutic candidates
- R&D capabilities bolstered by visionary management team and world-renowned key opinion leaders with deep expertise in metabolic and digestive diseases

SUMMARY

STRATEGIES

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

- Rapidly advance our current pipeline of drug candidates through clinical development, and continue to expand indication coverage to maximize the therapeutic and economic value of our assets
- Leverage our drug discovery capabilities and team expertise to build a pipeline based on the multi-mechanism approach
- Expand our R&D team and capabilities
- Pursue strategic collaboration in drug development and commercialization in the global market
- Strategically seek partnerships to drive long-term growth
- Continue to protect our global IP by employing various life-cycle management patent strategies including a new molecular entity (a “composition-of-matter” patent), the process used to manufacture the drug, how the drug is used, and new formulations of the drug to protect our assets and maintain the market exclusivity

RESEARCH AND DEVELOPMENT

As of the Latest Practicable Date, our drug discovery members have average 11 years’ experience. We have worked on our product candidates’ advancement for more than 10 years and developed product candidates in-house. Our drug discovery team members have expertise in biology, medicinal chemistry, drug metabolism and pharmacokinetics (“DMPK”), chemistry and early clinical areas, which support our product development, and all of them have obtained post-graduate degrees.

Our drug discovery comprises (i) identifying unmet medical needs and integrating real-world data, network pharmacology, known and established molecules with desired therapeutic benefits to design novel, multifunctional drug candidates; (ii) performing in vitro and in vivo assays of drug candidates including but not limited to pharmacological activities, pharmacokinetics and toxicities; and (iii) developing formulations, and analytical assays for quality control and assurance. During the drug discovery stage, our R&D chemistry team carries out synthesis and optimization of the target molecules for potential drug candidates. During the drug evaluation stage, our drug discovery team coordinates and accomplishes preclinical R&D activities in relation to the product candidates’ pharmacology, pharmacokinetics and toxicology.

SUMMARY

As of the Latest Practicable Date, the clinical development team consisted of 30 members, including scientists and physicians with strong drug development experience, who participate in clinical development strategy development, clinical trial protocol design, clinical trial operation organization, drug safety monitoring, and clinical trial quality control. Our clinical development team members have average 11 years’ experience. Among our clinical development team members, over 60% have obtained post-graduate degrees. Our clinical development staff represent a highly skilled and experienced team of professionals who work collaboratively to design and execute complex clinical trials and drug development programs. Our core capabilities in the area of development include clinical trial design, regulatory and quality compliance, project management, clinical operations, medical writing, safety monitoring and drug development strategy. Our team has the expertise to design clinical trials that are rigorous and compliant with regulatory requirements. This involves collaborating internally, with experts and regulatory authorities to determine the appropriate patient population, defining endpoints, and selecting appropriate control groups. Our regulatory team has a thorough understanding of regulatory requirements for clinical trials in the relevant countries and regions, including knowledge of Good Clinical Practice (“GCP”) guidelines. The team has proven to be able to manage complex projects, including clinical trials that involve multiple sites and stakeholders. This involves developing and managing timelines, budgets, and resources, as well as monitoring and mitigating risks. Lastly, the team has the strategic vision to guide drug development programs from early-stage research through clinical development and regulatory approval.

In line with industry practice, we collaborate with contract research organizations (“CROs”) to conduct and support our preclinical and clinical studies. We select our CROs by weighing various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. To the best of our Company’s knowledge, all of our CROs during the Track Record Period are Independent Third Parties.

In 2021 and 2022 and the six months ended June 30, 2023, we recorded R&D costs of RMB84.0 million, RMB182.7 million and RMB120.1 million, respectively, representing 62%, 81% and 70% of total operating expenses in 2021, 2022 and the six months ended June 30, 2023, respectively. In 2021 and 2022 and the six months ended June 30, 2023, we recorded R&D costs of RMB76.0 million, RMB173.7 million and RMB114.4 million, respectively, for our Core Product HTD1801, representing 90.5%, 95.1% and 95.2% of total R&D expenses in 2021, 2022 and the six months ended June 30, 2023, respectively.

SUMMARY

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we held 132 patents and patent applications, including 58 patents and patent applications in relation to our Core Product. All of our material patents and patent applications are self-owned. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our Core Product as of the Latest Practicable Date:

Product	Name of Patent ⁽¹⁾	Jurisdiction	Status	Patent Expiration ⁽²⁾	Market commercial rights of the Company
HTD1801	Berberine Salts, Ursodeoxycholic Salts and Combinations, Methods of Preparation and Application Thereof	Australia, Brazil, Mainland China, EAPO, EPO, Israel, Japan, Korea, Mexico, Singapore, United States, South Africa, Canada, India, New Zealand	Granted	2035	Ownership
		Canada, Mainland China, EAPO, Israel, Japan, Korea, Mexico, New Zealand, United States	Pending	–	Ownership
	Solid Forms of Berberine Ursodeoxycholate and Compositions and Methods Thereof	Australia, Mainland China, EAPO, United States	Granted	2038 (2037 in Mainland China)	Ownership
		Australia, Canada, EPO, Hong Kong, Israel, Japan, Korea, New Zealand, United States	Pending	–	Ownership
	Compositions of Berberine Ursodeoxycholate and Methods Thereof for Treating Fatty Liver Disease, Diabetes and/or Hyperlipidemia, and Related Diseases and Disorders	United States, EPO, Mainland China	Pending	–	Ownership
Compositions of Berberine Ursodeoxycholate and Methods for Treating Primary Sclerosing Cholangitis	United States	Pending	–	Ownership	

Abbreviations: EPO = European Patent Office; PCT = Patent Cooperation Treaty; EAPO = Eurasian Patent Organization.

Notes:

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

We conduct our business under the brand name of “HighTide” or “君圣泰.” As of the Latest Practicable Date, we held 34 trademarks and trademark applications in the United States, Mainland China, Hong Kong, Europe and United Kingdom. We are also the owner of seven domain names. During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights, in which we may be a claimant or a respondent. To our best knowledge, we are not aware of any potential or material claims or disputes in relation to the infringement of intellectual properties of our products during the Track Record Period.

SUMMARY

LICENSING ARRANGEMENTS AND CONTINUING CONNECTED TRANSACTION

We have entered into and will continue to engage in the below transaction which would constitute continuing connected transaction for our Company under the Listing Rules following completion of the [REDACTED]. [We have applied to the Stock Exchange for, and the Stock Exchange has granted us], waivers from strict compliance with certain requirements set out in Chapter 14A of the Listing Rules for such continuing connected transactions. For further details of such potential non-exempt continuing connected transaction and the waivers, please see “Connected Transaction”.

HTD1801 License-Out Agreement

On August 29, 2020, we entered into a license-out agreement (“**HTD1801 Agreement**”) with Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司) (“**Hepalink**”) to promote the commercialization of innovative drug formulations containing HTD1801 in Europe. Pursuant to the HTD1801 Agreement, we have granted Hepalink an exclusive, sublicensable (solely to Hepalink’s wholly-owned subsidiaries), non-transferable license of HTD1801 for all aspects of commercialization for the indications of MASH and PSC in Europe, including, but not limited to, distribution, dispensing, promotion, sales, branding, pricing, import, export and use of the product, use of the product name and packaging. We reserved the rights to (i) research and develop HTD1801 worldwide; (ii) manufacture HTD1801 worldwide; (iii) commercialize HTD1801 for any indications outside Europe; (iv) commercialize HTD1801 in any region in Europe for indications other than for MASH and PSC; and (v) import and export HTD1801 for the purposes described above. Hepalink is the owner of new intellectual property rights generated from the commercialization of HTD1801 by Hepalink.

In consideration of the license grant, Hepalink shall pay milestone payments for various development milestones for MASH and PSC, each ranging from RMB30.0 million to RMB50.0 million. In addition, during the royalty term of HTD1801 in Europe, Hepalink is also obligated to pay tiered royalty payments calculated as a percentage ranging from 10% to 25% of total annual net sales of HTD1801 in Europe. After expiration of the royalty term of HTD1801 in Europe, both parties shall agree in advance on a separate written agreement regarding the sales royalties if Hepalink plans to continue sales of HTD1801, or continue to accrue sales royalties on the foregoing rates.

The term of HTD1801 Agreement shall continue in full force until the date of expiration of the last applicable royalty term (the patent expiration date or the expiration date of regulatory exclusion for other administrative protections, whichever is later), or the date of earlier termination, whichever is earlier. For details, please refer to “Business — Collaboration Agreement — HTD1801 License-Out Agreement.”

SUMMARY

SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of CROs, SMOs 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. In 2021 and 2022 and the six months ended June 30, 2023, our purchases from our five largest R&D suppliers in each year/period in aggregate amounted to RMB26.9 million, RMB68.7 million and RMB36.4 million, representing 45.5%, 54.4% and 45.7% of our total corresponding purchases, respectively, and our purchases from the largest R&D supplier in each year/period accounted for 12.0%, 17.9% and 26.5% of our total corresponding purchases, respectively.

All of our five largest suppliers 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 during the Track Record Period.

MANUFACTURING

As of the Latest Practicable Date, our CMC team consisted of six 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 eight years’ experience. Among our CMC team members, over 50% have obtained post-graduate degrees.

As of the Latest Practicable Date, we had not established an internal clinical manufacturing facility. Collaborating with leading CDMOs, we currently outsource the production of product candidates to support global clinical trials. Given the highly sophisticated nature of the drug substance and drug product manufacturing process, we support our CDMOs with our extensive CMC know-hows in production, packaging, transportation, and storage of our products through technology transfer. We have a stable relationship with our major CDMOs for more than five years, in particular, the CDMO providing APIs for HTD1801. To the best of our Company’s knowledge, none of CDMOs, including their shareholders, directors and senior management, have any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates. After market launch of our drug candidates, we plan to continue to outsource our commercial-scale manufacturing to globally recognized CDMOs.

SHAREHOLDING OF AIC GROUP AND HEPALINK ENTITIES

As of the Latest Practicable Date, our single largest group of Shareholders comprised Dr. Liu, the Founder BVI, Greaty Investment, ZT Global Energy and Orient Champion (collectively, the “**AIC Group**”), each of which is a party to the Concert Party Agreement, which provided that (i) such parties had acted in concert since September 1, 2019 and would continue to act in concert and collectively for all matters relating to the operation and development of our Group that need to be approved by the Shareholders pursuant to applicable laws and the constitutional documents of our Company after the [REDACTED], and (ii) when and if they could not reach unanimous consent, the decision of Dr. Liu shall prevail. Prior to [REDACTED], the shareholdings of AIC

SUMMARY

Group and Hepalink entities in our Company are approximately 30.84% and 24.06%, respectively. Upon [REDACTED], the shareholdings of AIC Group and Hepalink entities in our Company are approximately [REDACTED]% and [REDACTED]%, respectively.

Immediately after the [REDACTED], Dr. Liu will abstain from voting on the [REDACTED] ([REDACTED]) as adjusted after the [REDACTED]) unvested Shares held in the 2020 ESOP Platform for the purpose of compliance with Rule 17.05A of the Listing Rules. As a result, the exercisable voting rights of the AIC Group and the Hepalink Entities in our Company will not be equal to their respective shareholding in our Company upon [REDACTED]. For details of the exercisable voting rights of the AIC Group and the Hepalink Entities, please refer to “History, Reorganization and Corporate Structure — Shareholding and Voting Rights of AIC Group and Hepalink Entities”.

Upon [REDACTED], the day-to-day management and operation of the Group will remain to be driven by the executive Directors and the senior management under Dr. Liu’s leadership as the founder, chief executive officer, executive Director and chairwoman of the Board. Therefore, the AIC Group will continue to have day-to-day control over the management and operation of our Group upon [REDACTED], while the designated director from Hepalink Entities remains a non-executive Director of the Company who will not involve in the day-to-day management of our Company. For further details, see “History, Reorganization and Corporate Structure — Day-to-Day Control over Management and Operation of the Group before and after the [REDACTED]”.

OUR [REDACTED] INVESTORS

We have received seven rounds of [REDACTED] investments with an aggregate amount of RMB12,000,000 and USD188,316,000 raised since our establishment. Our [REDACTED] Investors include Hepalink, Qianhai Haichuang, Goldlink, Able Holdings, Yuexiu Jinchan IV, Pingtan Rongjing and Yuthai Investment, MPCAPITAL, Greaty Investment, ZT Global Energy, Green Pine, Orient Champion, Blue Ocean and Shenzhen BioResearch, Shenzhen Taixun, Poly Platinum and Greater Bay Area Fund, HK Tigermed and Hangzhou Tigermed, Pluto and CITIC, Xinyu Cowin, Shenzhen Winzac, Sichuan Rongxin, Ningbo Borui, Hongtu Capital, BAIYI Capital and Traditional Chinese Medicine Fund. Our [REDACTED] Investors include two Sophisticated Investors, namely, Greater Bay Area Fund and Traditional Chinese Medicine Fund, which will hold approximately [REDACTED]% and [REDACTED]% respectively, of the total issued Shares of the Company upon the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised). The Shares held by each of the Sophisticated Investors will be subject to lock-up for a period of [six] months commencing from the [REDACTED]. We utilize the proceeds from the [REDACTED] Investments to finance our research and development activities and fund our daily operations. For further details of the identity and background of our [REDACTED] Investors, and the principal terms of the [REDACTED] Investments, see “History, Reorganization and Corporate Structure — [REDACTED] Investments.”

SUMMARY

SUMMARY OF KEY FINANCIAL INFORMATION

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

The following table sets forth a summary of our consolidated statements of profit or loss and other comprehensive income for the years indicated. Our historical results presented below are not necessarily indicative of the results that may be expected for any future period. During the Track Record Period and as of the Latest Practicable Date, we had not generated any revenue.

	For the year ended December 31,		For the six months ended June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Other income and gains	13,821	20,581	3,925	22,722
Fair value (losses)/gains on convertible redeemable preferred shares	(93,656)	23,242	31,247	(399,635)
Other expenses	(1)	(7,518)	(4,381)	(502)
Fair value losses on financial liabilities at				
FVTPL	(4,609)	–	–	–
Research and development costs	(84,012)	(182,651)	(76,322)	(120,088)
Administrative expenses	(48,064)	(43,433)	(28,357)	(52,014)
Finance costs	(4,528)	(426)	(217)	(201)
Loss before tax	(221,049)	(190,205)	(74,105)	(549,718)
Total comprehensive loss for the year/period .	(217,410)	(223,888)	(92,387)	(586,343)

We have incurred operating losses during the Track Record Period. Our loss before tax was RMB221.0 million, RMB190.2 million and RMB549.7 million for 2021, 2022 and the six months ended June 30, 2023, respectively. Substantially all of our loss resulted from fair value losses on convertible redeemable preferred shares, research and development costs and administrative expenses, as a result of the expansion of our business operations.

Our research and development costs increased by 57.3% from RMB76.3 million in the six months ended June 30, 2022 to RMB120.1 million in the six months ended June 30, 2023. Our research and development costs increased by 117.4% from RMB84.0 million in 2021 to RMB182.7 million in 2022. The increase was primarily attributable to an increase in expenditures for our clinical and preclinical development activities, including increase in third-party contracting expenses, staff costs and ESOP expenses.

SUMMARY

We recorded fair value gains on convertible redeemable preferred shares of RMB31.2 million in the six months ended June 30, 2022 and fair value losses on convertible redeemable preferred shares of RMB399.6 million in the six months ended June 30, 2023, mainly due to the increase in fair value of our convertible redeemable preferred shares as of June 30, 2023. We recorded fair value losses on convertible redeemable preferred shares of RMB93.7 million in 2021 mainly because of the increase in fair value of Series B+ convertible redeemable preferred shares as of December 31, 2021 compared with December 31, 2020. We recorded fair value gains on convertible redeemable preferred shares of RMB23.2 million in 2022 mainly because of the decrease in fair value of Series B+ and C convertible redeemable preferred shares as of December 31, 2022 compared with December 31, 2021, resulting from the issuance of Series C+ convertible redeemable preferred shares in 2022, which retained with more preferential rights.

For more details, see “Financial Information — Description of Certain Key Items of the Consolidated Statements of Profit or Loss and Other Comprehensive Income.”

Summary of Consolidated Statements of Financial Position

The following table sets forth a summary of our consolidated statements of financial position for the years indicated.

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		
Total non-current assets	3,450	4,806	5,263
Total current assets	775,182	851,018	753,319
Total assets	778,632	855,824	758,582
Total current liabilities	28,534	1,319,720	310,888
Total non-current liabilities	1,022,360	6,632	1,476,120
Total liabilities	1,050,894	1,326,352	1,787,008
Net liabilities	(272,262)	(470,528)	(1,028,426)
Net current assets/(liabilities)	746,648	(468,702)	442,431

SUMMARY

As of June 30, 2023, we maintained a net liabilities position, primarily due to the recognition of convertible redeemable preferred shares issued to investors as our non-current liabilities. We had net liabilities of RMB272.3 million, RMB470.5 million and RMB1,028.4 million as of December 31, 2021 and 2022, and June 30, 2023, respectively. The increase in our net liabilities was primarily due to the increase in total comprehensive loss. Our total comprehensive loss increased from RMB217.4 million in 2021 to RMB223.9 million in 2022 and our total comprehensive loss increased from RMB92.4 million for the six months ended June 30, 2022 to RMB586.3 million for the six months ended June 30, 2023. The increase in total comprehensive loss was driven by the expanded research and development activities, fair value changes on convertible redeemable preferred shares issued to investors, as well as administrative expenses. The majority of our convertible redeemable preferred shares was reclassified from current liabilities as of December 31, 2022, to non-current liabilities as of June 30, 2023, as we entered into the supplementary deferred redemption agreement with majority of our investors of series B+, series C and series C+ convertible redeemable preferred shares. All preferred shares will be reclassified from financial liabilities to equity as a result of the automatic conversion into our Shares upon [REDACTED], which will reverse our net liability position to a net asset position. See the Accountants’ Report set out in Appendix I to this document for a detailed description of our statements of changes in equity.

We had net current liabilities of RMB468.7 million as of December 31, 2022, as compared to net current assets of RMB442.4 million as of June 30, 2023. This was mainly attributable to our convertible redeemable preferred share reclassification from short-term to long-term liabilities as of June 30, 2023. We had net current assets of RMB746.6 million as of December 31, 2021, as compared to net current liabilities of RMB468.7 million as of December 31, 2022. This was mainly attributable to an RMB1,260 million increase in convertible redeemable preferred shares which is primarily due to reclassification of our convertible redeemable preferred shares from long-term to short-term liabilities. The convertible redeemable preferred shares will be re-classified as equity as the convertible redeemable preferred shares will automatically convert into Shares upon [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares. See the Accountants’ Report set out in Appendix I to this document for a detailed description of our statements of changes equity.

For more details, see “Financial Information — Description of Certain Selected Items from the Consolidated Statements of Financial Position.”

SUMMARY

Summary of Consolidated Statements of Cash Flows

The following table sets forth the components of our consolidated statements of cash flows for the years indicated.

	For the year ended December 31,		For the six months ended June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Net cash flows used in				
operating activities	(90,546)	(172,379)	(74,419)	(143,908)
Net cash flows from/(used in)				
investing activities	1,588	(415,661)	2,749	271,034
Net cash flows from financing				
activities	493,982	46,034	845	(1,946)
Net increase/(decrease) in				
cash and cash equivalents	405,024	(542,006)	(70,825)	125,180
Cash and cash equivalents at				
beginning of year	367,252	765,290	765,290	273,047
Effects of foreign exchange rate				
changes, net	(6,986)	49,763	29,290	19,671
Cash and cash equivalents at				
end of year	765,290	273,047	723,755	417,898

In the six months ended June 30, 2023, our net cash used in operating activities was RMB143.9 million. This net outflow from operating activities primarily reflected loss before tax of RMB549.7 million, positively adjusted primarily by (i) fair value losses on convertible redeemable preferred shares of RMB399.6 million, (ii) equity-settled share option arrangements of RMB28.4 million and (iii) an increase in trade payables of RMB8.1 million, partially offset by (i) an increase in prepayments, other receivable and other assets of RMB8.4 million and (ii) a decrease in other payables and accruals of RMB6.3 million.

In 2022, our net cash used in operating activities was RMB172.4 million. This net outflow from operating activities primarily reflected loss before tax of RMB190.2 million, positively adjusted primarily by (i) equity-settled share option arrangements of RMB25.6 million and (ii) foreign exchange differences, net of RMB7.5 million. The amount was further adjusted by changes in working capital, primarily including (i) an increase in trade payables of RMB15.6 million and (ii) an increase in other payables and accruals of RMB13.5 million, partially offset by a decrease in deferred income of RMB3.9 million.

SUMMARY

In 2021, our net cash used in operating activities was RMB90.5 million. This net outflow from operating activities primarily reflected loss before tax of RMB221.0 million, positively adjusted primarily by (i) fair value losses on convertible redeemable preferred shares of RMB93.7 million and (ii) transaction costs for preferred shares of RMB16.2 million. This amount was further adjusted by changes in working capital, primarily including (i) an increase in other payables and accruals of RMB14.4 million and (ii) an increase in deferred income of RMB3.4 million, partially offset by an increase in prepayments, other receivables and other assets of RMB3.6 million.

In 2022, our net cash used in investing activities was RMB415.7 million, which was primarily attributable to purchase of financial assets at FVTPL of RMB717.8 million and purchase of short-term time deposits of RMB621.4 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB717.8 million, proceeds from disposal of short-term time deposits of RMB197.5 million, receipts of investment income from short-term time deposits of RMB3.9 million and bank interest received of RMB3.5 million.

Our cash burn rate refers to our average monthly (i) net cash used in operating activities, (ii) capital expenditures and (iii) lease payments. Assuming an average cash burn rate going forward of 2.1 times the level in 2022, we estimate that our total cash balance as of June 30, 2023, will be able to maintain our financial viability for approximately 25 months or, if taking into account the estimated net [REDACTED] (based on the mid-point of the indicative [REDACTED] and assuming the [REDACTED] is not exercised) from the [REDACTED], for at least [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.

Key Financial Ratios

	As of December 31,		As of six months ended June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
Gearing Ratio ⁽¹⁾	(3%)	(2%)	(2%)	(1%)
Current Ratio ⁽²⁾	27.2	0.6	0.7	2.4

Notes:

- (1) Equals bank loans and other borrowings divided by total equity as of the same date.
- (2) Equals current assets divided by current liabilities as of the same date.

SUMMARY

[REDACTED]

DIVIDEND

We have never declared or paid regular cash dividends on our Shares. Any declaration and payment as well as the amount of dividends will be subject to our Memorandum and Articles and the Cayman Companies Act. Our Board of Directors has the discretion to pay interim dividends and to recommend to Shareholders to pay final dividends, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. In addition, our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman counsel, under the Cayman Companies Act, a Cayman Islands company may pay a dividend out of either profits and/or share premium account, provided that in no circumstances may a dividend be paid out of share premium if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

SUMMARY

If we pay dividends in the future, in order for us to distribute dividends to our Shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries. Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, 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. See “Risk Factors — Risks Relating to Doing Business in the PRC” in this document.

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 exercise of the [REDACTED] and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the midpoint of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] in this document. We intend to use the net [REDACTED] from the [REDACTED] for the following purposes:

- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the continuing clinical development activities as well as registration filings, post-approval studies and costs and expenses of R&D staff and activities of our Core Product HTD1801;
- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the ongoing research and development as well as R&D personnel costs, drug production for the clinical studies and contracting costs with third parties of our product candidate HTD1804 for obesity. We are currently conducting the preclinical study of HTD1804 in China;
- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used for the early drug discovery and development of other drug candidates and the enhancement of FUSIONTX™ development approach;
- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used for working capital and other general corporate purposes.

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

RISK FACTORS

We believe that there are certain 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:

- The Core Product may fail to meet the primary and secondary endpoints at the late-stage clinical trials due to higher clinical development risks resulted from HTD1801 being a new molecular entity and potential rejection from competent authorities.

SUMMARY

- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may be unable to commercialize our drug candidates at all.
- If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.
- If we lose the Fast Track Designation or the Orphan Drug Designation by the FDA for our drug candidates, the time and cost we incur to obtain regulatory approvals may increase.
- The regulatory approval processes of the NMPA, FDA, EMA and other comparable regulatory authorities are time-consuming and may evolve over time, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.
- We work with third parties to manufacture a portion of our drug candidates for clinical development and commercial sales. Our business could be harmed if those third parties fail to deliver sufficient quantities of products or fail to do so at acceptable quality levels or prices.
- We have incurred significant net losses since inception and we may continue to incur net 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 if our business fails.
- We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.
- The market size of our drug candidates might be smaller than we expected.

[REDACTED]

Our [REDACTED] represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. Assuming an [REDACTED] of HK\$[REDACTED] per Share at the mid-point of the indicative [REDACTED] range stated in this document and no [REDACTED] is exercised, we estimated that the total [REDACTED] for the [REDACTED] are approximately HK\$[REDACTED], accounting for approximately [REDACTED]% of the gross [REDACTED] from the [REDACTED], including HK\$[REDACTED] that we have incurred for the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, of which HK\$[REDACTED] was charged to our consolidated statements of profit or loss, while the remaining amount of HK\$[REDACTED] was directly attributable to the issue of Shares as of June 30, 2023 and will be subsequently deducted from equity upon completion of the [REDACTED], and HK\$[REDACTED] that we expect to further incur after June 30, 2023, of which HK\$[REDACTED] will be charged to our consolidated income statements, and

SUMMARY

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]-related expenses, including [REDACTED] and other expenses, of HK\$[REDACTED]; and (ii) non-[REDACTED]-related 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]. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS

Impact of the COVID-19 Outbreak

The outbreak of the COVID-19 and its recurrence had caused temporary disruption to our operations to the extent that certain on-site meetings, deployment and technical support had to be delayed or cancelled. As of the Latest Practicable Date, however, COVID-19 had not had any material adverse impact on our R&D activities, clinical development, daily operation, supply chain and regulatory affairs. Given that the PRC government has substantially lifted its COVID-19 prevention and control policies since December 2022, our Directors are of the view that it is unlikely that the COVID-19 will have a material adverse impact on our business going forward.

Recent Developments in Clinical Development

For MASH, we initiated our Phase IIb study (HTD1801.PCT014) in the United States in December 2022 and in Hong Kong in October 2023, and we are actively enrolling patients in this study in the United States and Hong Kong. We obtained the IND approval from the NMPA in Mainland China in September 2023. In July 2023, we submitted an IND application to initiate Phase IIb study (HTD1801.PCT014) for MASH with T2DM or prediabetes in Mexico. We expect to initiate the same study in Mexico and Mainland China in December 2023.

For T2DM, we initiated Phase II study (HTD1801.PCT103) in China in March 2022 and completed in January 2023 with 113 patients enrolled. The Phase II clinical trial has demonstrated a strong therapeutic effect in improving glucose metabolism, including statistically significant decreases in HbA1c and fasting glucose levels, which may be the result of decreased insulin resistance. In the clinical trial, improvements in other disease-relevant parameters were also observed. With HTD1801 treatment, liver biomarkers (ALT, AST, GGT) were reduced. HTD1801 also led to improvement of lipid profiles, such as reduction of low-density lipoprotein cholesterol (“LDL-c”) and non-high-density lipoprotein cholesterol (“non-HDL-c”) levels. In November 2023, we initiated the two Phase III clinical trials (i.e. one with HTD1801 as a standalone treatment and one with HTD1801 as an add-on therapy with metformin) for the T2DM indication of our self-developed HTD1801 in China. We expect to complete those two Phase III studies in 2025.

For SHTG, in April 2023, the FDA concluded that the available clinical results from Phase Ib/IIa study for hypercholesterolemia (HTD1801.PCT004) in Australia and completed Phase IIa MASH study in the United States (HTD1801.PCT012) were sufficient to support a Phase II study in subjects with SHTG. We plan to file IND with the FDA to initiate the Phase II of HTD1801 for SHTG in the United States in the first half of 2024.

SUMMARY

Recent Regulatory Developments

On February 17, 2023, the CSRC promulgated 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》) (the “**Overseas Listing Trial Measures**”) and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities.

Pursuant to the Overseas Listing Trial Measures, where a PRC domestic company submits an application for initial public offering to competent overseas regulators or overseas stock exchanges, such issuer must file with the CSRC within three business days after such application is submitted. As advised by our PRC Legal Advisor, we are required to complete the filing with the CSRC pursuant to the Overseas Listing Trial Measures. We submitted required filing documents to the CSRC on June 1, 2023. On October 19, 2023, the CSRC issued a notification on our Company’s completion of the PRC filing procedures for the [REDACTED] of our Shares on the Stock Exchange.

Expected Increase in Net Loss

We expect to incur a significant increase in net loss for 2023 due to (i) increase in fair value losses on convertible redeemable preferred shares, (ii) the anticipated costs associated with increased research and development activities and (iii) expenses in connection with the [REDACTED] incurred in 2023.

No Material Adverse Change

Our Directors confirm that up to the date of this document, save as disclosed above, there has been no material adverse change in our financial, operational or trading positions or prospects since June 30, 2023, 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.

“2020 ESOP Platform”	Wisdom Spring Group Limited
“2020 Share Incentive Plan”	the employee long term incentive plan originally adopted by our Company on January 22, 2020, amended and restated on October 18, 2021 and further amended and restated in its entirety on March 4, 2022, the principal terms of which are set out in “Appendix IV — Statutory and General Information — D. Incentive Plans — 1. 2020 Share Incentive Plan” to this document
“2023 ESOP Platform”	Wisdom Summer Group Limited
“2023 Share Incentive Plan”	the employee long term incentive plan adopted by our Company on May 24, 2023, the principal terms of which are set out in “Appendix IV — Statutory and General Information — D. Incentive Plans — 2. 2023 Share Incentive Plan” to this document
“AFRC”	the Accounting and Financial Reporting Council
“AIC Group”	refers to Dr. Liu, the Founder BVI, Greaty Investment, ZT Global Energy and Orient Champion
“Articles of Association” or “Articles”	the amended and restated articles of association of our Company conditionally adopted on [●], 2023, and with effect from the [REDACTED], a summary of which is set out in Appendix III to this document, as amended from time to time
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Audit Committee”	the audit committee of the Board
“Australia HighTide”	HIGHTIDE BIOPHARMA PTY. LTD., a proprietary company limited by shares registered in Australia on July 15, 2015, and a subsidiary of our Company
“Board” or “Board of Directors”	the board of directors of our Company
“Business Day”	a day on which banks in Hong Kong are generally open for normal banking business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong

DEFINITIONS

“BVI HighTide” HighTide Therapeutics, Ltd., a limited company incorporated in the BVI on March 26, 2018, a wholly-owned subsidiary of our Company

[REDACTED]

“CCASS” the Central Clearing and Settlement System established and operated by HKSCC

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

“China”, “Mainland China” or “PRC” People’s Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires otherwise, references in this document to “China” and the “PRC” do not apply to Hong Kong, Macau and Taiwan

“CIC” China Insights Industry Consultancy Limited, a global market research and consulting company, which is an Independent Third Party

“close associate(s)” has the meaning ascribed thereto under the Listing Rules

“Company” or “our Company” HighTide Therapeutics, Inc., a company incorporated under the laws of the Cayman Islands with limited liability on February 28, 2018

“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 Act” or “Cayman Companies Act” the Companies Act, Cap. 22 (As Revised) of the Cayman Islands

DEFINITIONS

“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) as amended, supplemented or otherwise modified from time to time
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“connected transaction(s)”	has the meaning ascribed thereto under the Listing Rules
“core connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Core Product”	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for the purpose of this document, our Core Product refers to HTD1801
“COVID-19”	disease caused by a new strain of coronavirus where ‘CO’ stands for corona, ‘VI’ for virus, and ‘D’ for disease
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會)
“Director(s)” or “our Director(s)”	the directors of our Company, including all executive, non-executive and independent non-executive Directors
“Dr. Liu”	Dr. LIU Liping (劉利平), the founder, executive Director and chief executive officer of our Company
“EIT Law”	the PRC Enterprise Income Tax Law (中華人民共和國企業所得稅法), as enacted by the NPC on March 16, 2007 and effective on January 1, 2008, as amended, supplemented or otherwise modified from time to time
“EMA”	the European Medicines Agency
“ESOP Platforms”	the 2020 ESOP Platform and the 2023 ESOP Platform
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the Government of Hong Kong
“Family Trust”	an irrevocable discretionary trust settled by Dr. Liu as the settlor pursuant to a trust deed dated December 31, 2020 under the laws of the State of Delaware for her succession planning, and pursuant to the aforesaid trust deed, the beneficiary is any one or more of Dr. Liu’s children and more remote issue
“FDA”	the United States Food and Drug Administration

DEFINITIONS

[REDACTED]

“Founder BVI” GREAT Mantra Group Limited, a limited company incorporated in the BVI on November 24, 2017, one of the members of the AIC Group and wholly-owned by the Family Trust

[REDACTED]

“Group” or “our Group” our Company and all of our subsidiaries or, where the context so requires, in respect of the period before our Company became the holding company of its present subsidiaries, the businesses operated by such subsidiaries or their predecessors (as the case may be)

“Hebei Puhui” Hebei Puhui Pharmaceutical Co., Ltd. (河北普惠醫藥有限公司), a limited liability company established in the PRC on September 27, 2023, a wholly-owned subsidiary of our Company

“Hepalink” Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司), a joint stock limited company incorporated under the laws of the PRC, whose A shares are listed on the Shenzhen Stock Exchange (stock code: 002399) and H Shares are listed on the Stock Exchange (stock code: 9989)

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

“HK HighTide” HighTide Therapeutics (Hong Kong) Limited, a limited company incorporated in Hong Kong on April 9, 2018, a wholly-owned subsidiary of our Company

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

DEFINITIONS

[REDACTED]

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

“Hong Kong” 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

“Hong Kong Takeovers Code” or “Takeover 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]

DEFINITIONS

[REDACTED]

“Incentive Plans”	the 2020 Share Incentive Plan and the 2023 Share Incentive Plan
“Independent Third Party(ies)”	party or parties that, to the best of our Directors’ knowledge, information and belief, having made all reasonable enquiries, is or are not a connected person or connected persons of the Company within the meaning of the Listing Rules

[REDACTED]

DEFINITIONS

[REDACTED]

- “Joint Sponsors” UBS Securities Hong Kong Limited and Huatai Financial Holdings (Hong Kong) Limited
- “JSK Healthcare” JSK Consumer Healthcare, Ltd. (深圳君聖康生物技術有限公司), a limited liability company established in the PRC on July 21, 2015, a wholly-owned subsidiary of our Company
- “Latest Practicable Date” [November 27], 2023, 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 or supplemented from time to time
- “M&A Rules” Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (關於外國投資者併購境內企業的規定), which were jointly promulgated by MOFCOM, the State Assets Supervision and Administration Commission, the SAT, the SAIC, the CSRC, and the SAFE on August 8, 2006, and came into effect on September 8, 2006 and subsequently amended on June 22, 2009, as amended, supplemented or otherwise modified from time to time
- “Main Board” the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the GEM of the Stock Exchange.

DEFINITIONS

“Memorandum” or “Memorandum of Association”	the amended and restated memorandum of association of our Company conditionally adopted on [●] 2023 with effect from the [REDACTED], a summary of which is set out in Appendix III to this document, as amended from time to time
“MOFCOM” or “Ministry of Commerce”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“Nanchang Fusion”	Nanchang Fusion Therapeutics, Ltd. (南昌福藥生物技術有限公司), a limited liability company established in the PRC on November 29, 2021, a wholly-owned subsidiary of our Company
“National Bureau of Statistics”	the National Bureau of Statistics of China (中華人民共和國國家統計局)
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“NHFPC”	National Health and Family Planning Commission (國家衛生和計劃生育委員會)
“NMPA”	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局) from 2013 to 2018 and the State Food and Drug Administration (國家食品藥品監督管理局) from 2003 to 2013
“Nomination Committee”	the nomination committee of the Board
“Non-PRC Resident Enterprise”	as defined under the EIT Law, means companies established pursuant to a non-PRC law with their de facto management conducted outside the PRC, but which have established organizations or premises in the PRC, or which have generated income within the PRC without having established organizations or premises in the PRC
“NPC”	the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)

DEFINITIONS

[REDACTED]

“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
“PRC Legal Advisor”	Han Kun Law Offices
“Preferred Shares”	the Series A Preferred Shares, the Series B-1 Preferred Shares, the Series B-2 Preferred Shares, the Series B+ Preferred Shares, the Series C Preferred Shares and the Series C+ Preferred Shares
“[REDACTED] Investments”	certain rounds of financing carried out by the Group before the [REDACTED], details of which are set out in the section headed “History, Reorganization and Corporate Structure — [REDACTED] Investments” in this document
“[REDACTED] Investors”	The investors of the [REDACTED] Investments

[REDACTED]

DEFINITIONS

[REDACTED]

“QIB”	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
“Reorganization”	the reorganization conducted by our Group in preparation for the [REDACTED] as described in the section headed “History, Reorganization and Corporate Structure — Reorganization” in this document
“Rule 144A”	Rule 144A under the United States 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)
“SAIC”	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 Administration of Taxation of the PRC (中華人民共和國國家稅務總局)
“Series A Preferred Shares”	the series A preferred shares of our Company with a par value of US\$0.0001 each
“Series B-1 Preferred Shares”	the series B-1 preferred shares of our Company with a par value of US\$0.0001 each
“Series B-2 Preferred Shares”	the series B-2 preferred shares of our Company with a par value of US\$0.0001 each
“Series B+ Preferred Shares”	the series B+ preferred shares of our Company with a par value of US\$0.0001 each
“Series C Preferred Shares”	the series C preferred shares of our Company with a par value of US\$0.0001 each

DEFINITIONS

“Series C+ Preferred Shares”	the series C+ preferred shares of our Company with a par value of US\$0.0001 each
“SFC”	the Securities and Futures Commission of Hong Kong
“SFO”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong, as amended, supplemented or otherwise modified from time to time
“Shanghai Fusion”	Shanghai Fusion Therapeutics, Ltd. (上海福藥生物技術有限公司), a limited liability company established in the PRC on May 20, 2021, a wholly-owned subsidiary of our Company
“Shanghai HighTide”	Shanghai HighTide Biopharmaceutical Ltd. (上海君聖泰生物技術有限公司), a limited liability company established in the PRC on March 14, 2014, a wholly-owned subsidiary of our Company
“Share(s)” or “Ordinary Share(s)”	ordinary shares in the share capital of our Company with a par value of US\$0.0001 each
“Shareholder(s)”	holder(s) of our Share(s)
“Shenzhen HighTide”	Shenzhen HighTide Biopharmaceutical Ltd. (深圳君聖泰生物技術有限公司), a limited liability company established in the PRC on November 15, 2011, a wholly-owned subsidiary of our Company
“Sophisticated Investor(s)”	has the meaning ascribed to it under Guidance Letter HKEX-GL92-18 issued by the Stock Exchange and for the purpose of this document refers to Greater Bay Area Homeland Development Fund LP and Guangdong Chinese Medicine Comprehensive Health Equity Investment Fund Partnership (Limited Partnership), both of which have made meaningful investment in our Company at least six months before the [REDACTED] [REDACTED]
“State Council”	the State Council of the PRC (中華人民共和國國務院) [REDACTED]

DEFINITIONS

“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
“Track Record Period”	the two years ended December 31, 2021 and 2022 and the six months ended June 30, 2023

[REDACTED]

“U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. dollars” or “US\$” or “USD”	United States dollars, the lawful currency of the United States
“U.S. HighTide”	HighTide Therapeutics USA, LLC (formerly known as HighTide Biopharma USA, LLC), a stock corporation incorporated in the State of Maryland, United States on January 24, 2018, and a wholly-owned subsidiary of our Company
“U.S. persons”	United States 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
“VAT”	value-added tax; all amounts are exclusive of VAT in this document except where indicated otherwise
“we”, “us” or “our”	the Company or the Group, as the context requires

“

[REDACTED]

“WHO”	the World Health Organization
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DEFINITIONS

Certain amounts and percentage figures included in this 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 certain of our subsidiaries) have been included in the 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.

For the purpose of this document, references to “provinces” of China include provinces, municipalities under direct administration of the central government and provincial-level autonomous regions.

GLOSSARY OF TECHNICAL TERMS

Unless the context otherwise requires, explanations and definitions of certain terms used in this document in connection with our Group and our business shall have the meanings set out below. The terms and their meanings may not correspond to standard industry meaning or usage of these terms.

“active moiety”	the active component which is responsible for a drug’s physiological or pharmacological action
“AEs”	adverse effects
“AH”	alcoholic hepatitis, a type of alcohol-associated liver disease characterized by acute liver inflammation
“ALD”	alcohol-associated liver disease, characterized by liver damage caused by heavy alcohol intake
“ALP”	alkaline phosphatase, an enzyme primarily found in the liver, bones, intestine, and kidneys, and a key biomarker indicating the presence of cholestatic liver diseases including primary sclerosing cholangitis and primary biliary cholangitis
“ALS”	amyotrophic lateral sclerosis, a paralyzing progressive disease with a short life expectancy typically of only two to five years from diagnosis
“ALT”	alanine transaminase, an enzyme found in the liver that helps convert proteins into energy for the liver cells; the level of ALT increases when the liver is damaged, making it a biomarker commonly associated with injury or apoptosis of liver cells
“AMPK”	AMP-activated protein kinase
“AP”	acute pancreatitis, a condition where the pancreas becomes inflamed over a short period of time
“API”	active pharmaceutical ingredients, any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product in order to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body
“apoptosis”	a type of programmed cell death

GLOSSARY OF TECHNICAL TERMS

“APRI”	aspartate aminotransferase to platelet ratio index, a noninvasive and readily available tool for the assessment of liver fibrosis
“AST”	aspartate aminotransferase, an enzyme found mostly in the liver, heart, muscles and kidneys; high levels of which in the blood may indicate hepatitis, cirrhosis, or other liver diseases
“BBR”	berberine, an isoquinoline alkaloid with a long history of use for its wide-ranging biological effects, particularly antimicrobial effects, in Chinese, Indian and Middle-Eastern medicine, and is an approved drug for the treatment of intestinal infection in mainland China, Japan and Taiwan
“BID”	two times a day
“bioavailability”	the fraction of an administered drug that reaches the systemic circulation
“biomarker”	a measurable indicator of a biological state or condition
“BSH”	bile salt hydrolase, an enzyme produced in the intestinal microbiota that catalyzes the hydrolysis of amide bonds in conjugated bile acids, resulting in the release of free amino acids
“BUDC”	berberine ursodeoxycholate, the molecular entity of our Core Product HTD1801
“CAGR”	compound annual growth rate
“CCA”	cholangiocarcinoma, a type of cancer that forms in the bile ducts
“CD”	Crohn’s disease, a type of inflammatory bowel disease which can affect any part of the gastrointestinal tract
“CDMO”	contract development and manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“cholestatic liver disease”	a disease characterized by a decrease or blockage in the flow of bile, including primary sclerosing cholangitis and primary biliary cholangitis

GLOSSARY OF TECHNICAL TERMS

“cirrhosis”	the impaired liver function caused by the formation of scar tissue due to damage caused by liver disease
“clinical trial/study”	a research study 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
“ClinicalTrials”	ClinicalTrials.gov, a registry of clinical trials run by the United States National Library of Medicine at the National Institutes of Health
“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 for drug manufacturing
“CNS”	central nervous system, the part of the nervous system consisting primarily of the brain and spinal cord
“cohort”	a group of patients as part of a clinical trial 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
“comorbidity”	the simultaneous presence of two or more diseases or medical conditions in a patient
“complex disease”	also known as multifactorial disease, caused by a combination of genetic, lifestyle and environmental factors
“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
“cT1”	corrected T1 value, a novel MRI-based quantitative metric for assessing a composite of liver inflammation and fibrosis
“CVDs”	cardiovascular diseases, conditions affecting the heart or blood vessels

GLOSSARY OF TECHNICAL TERMS

“diabetes”	a complex, chronic metabolic disease characterized by elevated levels of blood glucose, which leads over time to serious damage to the heart, blood vessels, eyes, kidneys, nerves and other organs, comprised of two categories including type 1 diabetes mellitus and type 2 diabetes mellitus
“digestive diseases”	health conditions associated with the digestive system
“DN”	diabetic neuropathy, nerve damages caused by diabetes
“DPP-4I”	dipeptidyl peptidase 4 inhibitors, a class of oral hypoglycemics that block the enzyme dipeptidyl peptidase-4 (DPP-4) for the treatment of T2DM
“EOP meeting”	end-of-phase meeting; a meeting held when the clinical trial has reached the end of a particular phase and is ready to move to the next
“ESG”	environmental, social and governance; a collection of corporate performance evaluation criteria that assess the robustness of a company’s governance mechanisms and its ability to effectively manage its environmental and social impacts
“FGF21”	fibroblast growth factor 21, a liver-secreted peptide hormone to regulation of lipid, glucose, and energy metabolism
“FIB-4”	a non-invasive scoring system based on several laboratory tests that help to estimate the amount of scarring in the liver
“FTD”	fast track designation, a designation granted by the FDA of a drug for expedited review to facilitate the development of drugs which treat serious or life-threatening condition or fill an unmet medical need
“FXR”	farnesoid X receptor, a nuclear receptor that is encoded by the NR1H4 gene in humans
“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans

GLOSSARY OF TECHNICAL TERMS

“GGT”	gamma-glutamyl transferase, an enzyme found primarily in the liver; the level of GGT increases when the liver is damaged, making it a biomarker commonly associated with injury or apoptosis of liver cells
“GLP-1”	glucagon-like peptide-1, a gastrointestinal peptide to encourage the release of insulin from the pancreas
“GLP-1R”	glucagon-like peptide-1 receptor
“GLP-1RA”	glucagon-like peptide-1 receptor agonist
“glycemic control”	the management of blood sugar levels
“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
“gut microbiota”	the microorganism including bacteria, archaea and fungi that live in the digestive tracts of humans and other animals
“HbA1c”	glycated haemoglobin, formed when haemoglobin joins with glucose in the blood and becomes glycated
“HCC”	hepatocellular carcinoma
“HDL-C”	high-density lipoprotein cholesterol, often referred to as “good” cholesterol as it is known to remove other forms of cholesterol from the bloodstream
“HSCs”	hepatic stellate cells, also known as perisinusoidal cells or Ito cells, that are pericytes found in the perisinusoidal space of the liver
“HTG”	hypertriglyceridemia, the presence of high amounts of triglyceridemia in the blood
“hypercholesterolaemia”	elevated amounts of cholesterol in the blood
“hyperlipidemia”	abnormally elevated levels of any or all lipids or lipoproteins in the blood
“IBD”	inflammatory bowel disease, a group of inflammatory conditions of the colon and small intestine, comprised of two major categories including CD and ulcerative colitis

GLOSSARY OF TECHNICAL TERMS

“IFN γ ”	interferon gamma
“in vitro”	Latin for “within the glass”, referring to studies that are performed with microorganisms, cells, or biological molecules outside their normal biological context
“in vivo”	Latin for “within the living”, referring to 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, an application in the drug review process required by a regulatory authority to decide whether a new drug is permitted to initiate clinical trials; also known as clinical trial application, or CTA, in China
“ITT”	intention-to-treat
“ITT population”	the set of all randomised subjects in a randomised trial
“KOL”	key opinion leader, a trusted, well-respected influencer with proven experience and expertise in a particular field
“LDL-C”	low-density lipoprotein cholesterol, often referred to as “bad” cholesterol as it may build up in the walls of blood vessels and cause atherosclerotic diseases
“LFC”	liver fat content, fat accumulated in the liver
“LPS”	lipopolysaccharides, an agent commonly used to induce inflammatory responses in animal studies
“MASLD”	metabolic dysfunction-associated steatotic liver disease (formerly known as nonalcoholic fatty liver disease or NAFLD), characterized by the excessive fat accumulation in the liver. At EASL Congress 2023, the multinational liver societies leaders from La Asociación Latinoamericana para el Estudio del Hígado (ALEH), American Association for the Study of Liver Diseases (AASLD), and European Association for the Study of the Liver (EASL) as well as the co-chairs of the MASLD Nomenclature Initiative announced that steatotic liver disease (SLD) was chosen as an overarching term to encompass the various aetiologies of steatosis

GLOSSARY OF TECHNICAL TERMS

“MASH”	metabolic dysfunction-associated steatohepatitis (formerly known as nonalcoholic steatohepatitis or NASH), an advanced form of MASLD
“mechanism of action”	the specific biochemical interaction through which a drug substance produces its pharmacological effect
“MRCT”	multi-regional clinical trials
“MRI”	magnetic resonance imaging, a non-invasive imaging technology that uses strong magnetic fields and radio waves to produce three dimensional detailed anatomical images
“MRI-PDFF”	magnetic resonance imaging-derived proton density fat fraction, a noninvasive, quantitative, and accurate measure of liver fat content
“NAS”	NAFLD activity score, a sum of numerical score system applying to steatosis, hepatocellular ballooning, and lobular inflammation
“NDA”	new drug application, a process required by an regulatory authority to approve a new drug for sale and marketing
“obesity”	abnormal or excessive fat accumulation in the body; defined as an individual having a body mass index over 30 kg/m ² or more
“OCA”	obeticholic acid, an FDA-approved second line treatment in combination with ursodeoxycholic acid for primary biliary cholangitis
“ODD”	orphan drug designation, a designation granted by the FDA to a drug or biological product which prevents, diagnoses or treats a rare disease or condition, qualifying the sponsors for certain incentives
“off-label”	related to the use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, dosage or route of administration
“OTC”	over-the-counter, ordinary retail purchase of drugs, with no need for medical prescription or license
“pan PPAR”	pan agonists acting on all three isoforms of PPAR

GLOSSARY OF TECHNICAL TERMS

“PBC”	primary biliary cholangitis, an autoimmune liver disease resulting from a slow, progressive destruction of the intra-hepatic small bile ducts
“PCSK9”	proprotein convertase subtilisin/kexin type 9, an enzyme binding to and degrading the receptor for low-density lipoprotein particles
“PD”	pharmacodynamics; the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug
“Phase I clinical trial”	a 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 efficacy
“Phase II clinical trial”	a study in which a drug is administered to a limited patient population to preliminarily evaluate the efficacy of the product for specific targeted diseases, to identify possible adverse effects and safety risks, and to determine optimal dosage
“Phase III clinical trial”	a 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
“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
“placebo”	a medical treatment or preparation with no specific pharmacological activity
“PPAR”	peroxisome proliferator-activated receptors with three main classes, namely α , γ and δ ; a family of nuclear receptors to regulate metabolism, inflammation and fibrosis

GLOSSARY OF TECHNICAL TERMS

“preclinical study”	a study 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
“pre-diabetes”	a condition characterized by elevated blood sugar levels that fall below the threshold to diagnose diabetes
“pre-T2DM”	a condition characterized by elevated blood sugar levels that fall below the threshold to diagnose type 2 diabetes mellitus
“primary endpoint”	the specific key measurement upon which a clinical study is designed to assess the effect of the drugs being investigated
“PSC”	primary sclerosing cholangitis, a life-threatening, multifactorial and rare liver disease characterized by hepatic inflammation, scarring and abnormal liver damage
“Reg3 α ”	regenerating islet derived protein 3 alpha; a prognostic biomarker for gastrointestinal chronic graft-versus-host disease
“registrational clinical trial”	a clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
“ROS”	reactive oxygen species; a type of unstable molecule that contains oxygen and that easily reacts with other molecules in a cell
“SAEs”	serious adverse events, an event or reaction that, in the view of either the investigator or sponsor, results in severe outcomes such as death, life-threatening adverse events, in-patient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect
“SHTG”	severe hypertriglyceridemia, SHTG is the presence of high levels of triglycerides, a type of fat, in the blood. SHTG is well known to be associated with other complex and serious disorders such as acute pancreatitis and CVDs
“SGLT-2I”	sodium-glucose cotransporter-2 inhibitors, a class of prescription medicines that are FDA-approved for use with diet and exercise to lower blood sugar in adults with T2DM

GLOSSARY OF TECHNICAL TERMS

“SMO”	site management organization, an organization that has adequate infrastructure and staff to meet the requirements of the clinical trial protocol and provides clinical trial related services to a CRO, a pharmaceutical company, a biotechnology company, or a clinical site
“SOD”	superoxide dismutase; an antioxidant enzyme which converts reactive oxygen species into less aggressive forms, and reduce serum malondialdehyde
“T2DM”	type 2 diabetes mellitus, a form of diabetes characterized by high blood sugar, insulin resistance and relative lack of insulin
“TEAEs”	treatment-emergent adverse events, undesirable events not present prior to medical treatment or already present events that worsen in either intensity or frequency following the treatment
“TG”	triglycerides, the main constituents of body fat in humans
“TGA”	Therapeutic Goods Administration; Australia’s regulatory authority for therapeutic goods such as medicines, medical devices, and diagnostic tests
“THR- β ”	thyroid hormone receptor β , one receptor for thyroid hormone to mediate the biological activities of thyroid hormone
“TLR4”	Toll - like receptor 4, a transmembrane protein in humans encoded by the TLR4 gene which plays a pivotal role in the regulation of immune responses to infection
“TNF- α ”	tumor necrosis factor alpha
“TZD”	thiazolidinediones, a family of drugs used in the treatment of T2DM
“UC”	ulcerative colitis, a type of IBD which primarily affects the colon
“UDCA”	ursodeoxycholic acid, a secondary bile acid approved by the FDA as first-line treatment for PBC, and widely used off-label to treat PSC
“ULN”	upper limit of normal, the 95th percentile of the target population

FORWARD-LOOKING STATEMENTS

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

This document contains certain 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", "believe", "could", "expect", "going forward", "intend", "may", "might", "ought to", "plan", "potential", "predict", "project", "seek", "should", "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 other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing our company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- general political and economic conditions, including those related to the PRC;
- our ability to successfully implement our business plans and strategies;
- future developments, trends and conditions in the industry and markets in which we operate or into which we intend to expand;
- our business operations and prospects;
- our capital expenditure plans;
- the actions and developments of our competitors;
- our financial condition and performance;
- capital market developments;
- our dividend policy;
- any changes in the laws, rules and regulations of the central and local governments in the PRC and other relevant jurisdictions and the rules, regulations and policies of the relevant governmental authorities relating to all aspects of our business and our business plans;
- various business opportunities that we may pursue; and
- changes or volatility in interest rates, foreign exchange rates, equity prices or other rates or prices, including those pertaining to the mainland China and Hong Kong and the industry and markets in which we operate.

FORWARD-LOOKING STATEMENTS

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. Moreover, the inclusion of forward-looking statements should not be regarded as representations by us that our plans and objectives will be achieved or realized. All forward-looking statements in this document are qualified by reference to the cautionary statements in this section.

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

[REDACTED] in our Shares involves significant risks. You should carefully consider all of the information set out in this document, including the risks and uncertainties described below, before making an [REDACTED] in our 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 Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The trading price of our Shares could decline due to any of these risks, 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, which 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.

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 development, clinical trials and regulatory approval of our drug candidates; (ii) risks relating to manufacturing and commercialization of our drug candidates; (iii) risks relating to our financial prospects; (iv) risks relating to our intellectual property rights; (v) risks relating to our business and industry; (vi) risks relating to doing business in the PRC; and (vii) 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 and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

RISKS RELATING TO DEVELOPMENT, CLINICAL TRIALS AND REGULATORY APPROVAL OF OUR DRUG CANDIDATES

The Core Product may fail to meet the primary and secondary endpoints at the late-stage clinical trials due to higher clinical development risks resulted from HTD1801 being a new molecular entity and potential rejection from competent authorities.

We may fail to develop the HTD1801 for certain indications as they progress to the late-stage clinical trials. There is a high probability of failure to achieve the primary and second efficacy endpoints in late-stage clinical trials because HTD1801 is based on a new molecular entity, which is yet to be tested in large-scale clinical studies, thus facing higher clinical risks. Taking the MASH indication as an example, despite that HTD1801 is different from ocaliva in many aspects, such as mechanism of actions, PK profiles and others as applicable, our development of HTD1801 may still be subject to development risks, including those faced by ocaliva in their development.

RISK FACTORS

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may be unable to commercialize our drug candidates at all.

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. For example, Intercept's ocaliva, one of the most advanced MASH drugs in the pipeline, filed the second application for MASH but it was rejected by the FDA in June 2023. The FDA reviewers flagged increased risk of diabetes and liver injury from using the oral tablets, called obeticholic acid ("OCA"), for the treatment of MASH. The FDA concluded that benefits of Ocaliva did not outweigh the risks in MASH patients with fibrosis based on current data. Intercept expressed that continuing a long-term outcomes study as requested by the FDA may not be economically feasible and has decided to discontinue all MASH-related investment, which has a negative impact on MASH market.

We may experience numerous 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 may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- 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;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our CROs 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 a finding that participants are being exposed to unacceptable health risks;
- regulators may require that we or our investigators suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate; or
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

RISK FACTORS

If we do not achieve one or more of these factors in a timely manner, we may be unable to commercialize our drug candidates at all which would materially harm our business, and we may fail to generate sufficient revenues or cash flows to continue our operations. These factors present uncertainty and material risks to our commercial success and may cause potential [REDACTED] to lose a substantial amount, or substantially all, of their [REDACTED] in our business.

We may face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

We are developing our drug candidates in competition with a number of biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the same indications. Our competitors may develop generic or biosimilar drugs if the patent protection of our drug candidates were to expire. Many of our competitors have significantly greater financial, development, manufacturing, marketing, sales and supply resources or experience than we do. Our commercial opportunity and success will be reduced or eliminated, if any competing products become available that are more effective or cost-efficient than ours.

We also face fierce competition from existing products and product candidates under development in the entire MASH, T2DM, SHTG, PSC and PBC market. In addition to approved therapies, there are a large number of competing drug candidates currently under different clinical stages. We may also face potential competition from existing products used off-label for MASH and PSC. Those existing products may also be developed to expand their indications targeted by the Core Product. As multiple product candidates are currently in Phase III clinical trials for each of the targeted indications of the Core Product, our development and commercialization of Core Product may be adversely affected by some or all of such product candidates that receive NDA approval prior to the Core Product. For example, the FDA may request head-to-head studies for HTD1801 before the granting of the approval, which may impose higher risk of clinical failure and also delay the original development plan.

Our clinical development progress could be delayed or otherwise adversely affected due to our resources allocation.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to allocate sufficient resources to participate in these trials. We have historical and potential delay of clinical trials due to prioritisation of resources for the clinical development of the Core Product and other product candidates. For example, the longtime gap between the completion of the MASH Phase IIa clinical trial and the initiation of the MASH Phase IIb clinical trial for HTD1810 and no clinical development for PSC since August 2020 and for PBC since May 2022. Significant clinical trial delays may 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.

RISK FACTORS

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

Before obtaining regulatory approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. If the results of the clinical trials of our drug candidates are not positive or only modestly positive for proposed indications, or if they raise safety concerns, any or some of the following would occur:

- regulatory approvals for our drug candidates would be delayed or denied;
- we may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan;
- we may be required to add labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of the adverse effects for distribution to patients;
- we may be required to implement a risk evaluation and mitigation strategy program, including medication guides, doctor communication plans and other risk management tools with restricted distribution methods and patient registries;
- we may not be able to obtain regulatory approvals for all the proposed indications as intended;
- we may be subject to restrictions on how the drug is distributed or used;
- we may be sued or held liable for injury caused to individuals exposed to or taking our drug candidates;
- we may be unable to obtain reimbursement for use of the drug; or
- conditional regulatory approval of our drug candidates may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn.

For example, HTD1801 experienced significant rebound of ALP during the follow-up period for the PBC Phase II clinical trial. Although it is due to a withdrawal of HTD1801 treatment, if HTD1801 fails to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on HTD1801. If HTD1801 ultimately fails to receive regulatory approvals due to unsatisfactory clinical trial results, our business, financial condition, results of operations and prospects would be materially and adversely affected.

RISK FACTORS

If we lose the Fast Track Designation or the Orphan Drug Designation by the FDA for our drug candidates, the time and cost we incur to obtain regulatory approvals may increase.

HTD1801 is the first primary sclerosing cholangitis ("PSC") drug that has obtained Fast Track Designation from the FDA, followed by an Orphan Drug Designation in the United States, according to CIC. However, there is no assurance that an Orphan Drug Designation or Fast Track Designation will not be lost. Any future policies, or changes to current policies might require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our drug candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our drug candidates, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidates that we may in-license, acquire or develop in the future.

Most of our pipeline products are in preclinical development stage, thus facing higher clinical risks.

We have three product candidates that are in preclinical development stage. We may face higher clinical risk, for instance, we might have to suspend or terminate preclinical studies of certain drug candidates for various reasons, including unexpected safety concerns, severe adverse effects, undesirable side effects or other unexpected characteristics, causing us or investigators to suspend or terminate the trials. These factors present uncertainty and material clinical risks to our commercial success and may cause [REDACTED] to lose a substantial amount, or substantially all, of their investments in our business.

The regulatory approval processes of the NMPA, FDA, EMA and other comparable regulatory authorities are time-consuming and may evolve over time, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain the approval of the NMPA, FDA, EMA, TGA and other comparable regulatory authorities is uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take years to be obtained following the commencement of preclinical studies and clinical trials. In addition, 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.

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-license or acquire and seek to develop in the future. Our drug candidates could fail to receive the regulatory approval of the NMPA, FDA, EMA, TGA 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;

RISK FACTORS

- failure of our clinical trial results to meet the level of statistical significance required for approval;
- 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 our drug candidates to pass current 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, FDA, EMA, TGA 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, FDA, EMA, TGA 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. Legislative and regulatory proposals may also, from time to time, be made to expand existing requirements. For example, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, and potentially introduce more stringent product labeling and post-marketing conditions. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

We may not be able to identify or discover new drug candidates.

We may fail to identify drug candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful adverse effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. We have devoted significant resources to compound discovery efforts through our drug discovery approach, and we cannot guarantee that we will be successful in identifying potential drug candidates.

RISK FACTORS

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial and human resources. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to:

- the research methodology used may not be successful in identifying potential indications and/or drug candidates;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

If we encounter delays or difficulties enrolling subjects in our clinical trials, clinical development of our drug candidates 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 a sufficient number of patients or participants who remain in the trial until its conclusion. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients or participants to participate in these trials, or if there are delays in the enrollment of eligible patients or participants as a result of the competitive clinical enrollment environment. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including but not limited to:

- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our investigators' or clinical trial sites' efforts to screen and recruit eligible patients or participants; or
- proximity and availability of clinical trial sites for prospective patients or participants.

RISK FACTORS

In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients or participants who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors' drug candidates, which may further delay our clinical trial enrollments.

Even if we are able to enroll a sufficient number of patients or participants in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

We work with various third parties to develop our drug candidates. 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 drug candidates, 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 parties on our ongoing preclinical and clinical programs. For example, we rely on 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, FDA, EMA, TGA and other comparable regulatory authorities for all of our drugs 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, FDA, EMA, TGA 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.

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 deadlines, 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 cost increases, restrict our ability to generate revenue and have a material adverse effect on our business and prospects.

RISK FACTORS

Our ability to generate future revenue is 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. In addition, we may rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately carried out and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on us until deficiencies are remedied.

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 marketing activities. We have established extensive interaction channels with PIs, KOLs, physicians and experts to gain first-hand knowledge of unmet 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 or attend our conferences, 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.

RISK FACTORS

Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later phase clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial and early phase clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Future clinical trial results may not be favorable for these and other reasons.

In some cases, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. As drug candidates are developed through preclinical to early- to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates and/or jeopardize our ability to commence commercialization of our drug candidates.

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

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. Differences in regulatory regimes across jurisdictions may lead to a higher compliance burden.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include but are not limited to: refusal to approve pending applications; withdrawal of an approval; license revocation; clinical hold; mandatory product recalls; product seizures; total or partial suspension of production or distribution; injunctions, refusals of government contracts; injunctions, fines and other civil or criminal penalties. Failure to comply with these regulations could therefore have a material adverse effect on our business.

RISK FACTORS

We may not be able to comply with ongoing regulatory obligations and continued regulatory review even if we receive regulatory approval for our drug candidates.

Once our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, post-marketing studies, and submission of safety, efficacy, and other post-market information in different jurisdictions, such as the United States, China and Europe. For example, in order to produce drugs for sales, we may become subject to extensive laws and regulations enforced by the NMPA, FDA, EMA, TGA and other applicable regulatory authorities, including those ensuring that quality control and manufacturing procedures conform to current GMP regulations. Moreover, any new legislation addressing drug safety issues could result in increased costs to ensure compliance with ongoing regulatory requirements.

The NMPA, FDA, EMA, TGA or other applicable regulatory authorities may withdraw its approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drugs reach the market. Later discovery of previously unknown problems with our drug candidates, including but not limited to adverse events of unanticipated severity or frequency, or with our manufacturing processes, or failure to comply with regulatory requirements, may result in voluntary or mandatory product recalls; revocation of or refusal to grant permits and approvals; revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation program.

The NMPA, FDA, EMA, TGA and other applicable regulatory authorities also strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, FDA, EMA, TGA and other applicable regulatory authorities 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.

Moreover, the biopharmaceutical market is heavily regulated in China. Changes in government regulations or in practices relating to the biopharmaceutical industry, such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may cause difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects.

RISK FACTORS

RISKS RELATING TO MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

We work with third parties to manufacture a portion of our drug candidates for clinical development. Our business could be harmed if those third parties fail to deliver sufficient quantities of products.

We currently do not have in-house manufacturing facilities. Currently and in the long term future, we plan to work with qualified CDMOs (including CMOs) to manufacture product candidates for preclinical and clinical supply. We also procure technical services, including CRO and CDMO services and consulting services that support our clinical trials and preclinical studies.

Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and the NMPA, FDA, EMA, TGA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates;
- 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 are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, FDA, EMA, TGA or other comparable regulatory authorities to ensure strict compliance with GMP. We do not have control over third party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- 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;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and suppliers may be subject to inclement weather, as well as natural or man-made disasters.

RISK FACTORS

However, given the complex manufacturing nature of HTD1801, termination or change with our CDMOs can adversely affect our R&D and commercialization of HTD1801, such as delaying or preventing the completion of our clinical trials or the approval of HTD1801.

We work with third parties for the clinical development and commercialization of our drug candidates. We may fail to identify competent third parties for such purposes, fail to achieve the expected synergies with the clinical development partners, and have little or no control over the marketing and sales efforts of the commercialization partners.

We may also pursue collaborative arrangements regarding the sales and marketing of our product candidates. On August 29, 2020, we entered into a license-out agreement with Hepalink to promote the commercialization of HTD1801 for MASH and PSC in Europe. According to the agreement, Hepalink may determine at its sole discretion the commercialisation and sales plan of HTD1801 for MASH and PSC in Europe. Generation of revenue from HTD1801 after it is approved for marketing will partly depend upon the efforts of Hepalink, which may not be successful. We may have little or no control over the marketing and sales efforts of Hepalink. Therefore, our revenue generated from the commercialization collaboration model may be lower than the revenue that we would have generated if we commercialized the HTD1801 ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. We cannot assure you that we will be able to establish or maintain relationships with third-party collaborators to successfully commercialize our product candidates, and as a result, we may not be able to generate product revenue.

In addition, we may pursue collaborative arrangements regarding the future clinical development of our product candidates. For example, we are also seeking partners on the development of HTD1801 for indications of PSC and PBC. As of the Latest Practicable Date, no partners had been identified. Despite the rebound in liver biochemistry during the follow-up period in the Phase II trial for PBC and a long period of clinical development suspension for the PBC and PSC indications, we have not encountered any difficulties in identifying collaboration opportunities with global partners for future clinical development and commercialisation of HTD1801 for PBC and PSC. However, we may not achieve the revenue and cost synergies expected from the collaboration. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. Even if we achieve the expected benefits, they may not be achieved within the anticipated timeframe. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that these synergies will be achieved.

We may fail to identify competent third parties for the future clinical development and commercialization of our drug candidates, or fail to identify such partners within the anticipated timeframe, which may result in delay or termination of clinical development and/or commercialization of our drug candidates. Also, disputes may arise between us and our collaboration partners. Such disputes may cause delay or termination of the research, development or commercialization of our drug candidates, or may result in costly litigation or arbitration that diverts management attention and resources.

RISK FACTORS

Our drug candidates 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.

Even if we are able to receive the requisite regulatory approvals of our existing and future drug candidates, such drug candidates may fail to gain sufficient market acceptance by physicians, patients, third-party payers and other relevant parties in the medical community. If drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from our product portfolio and we may not become profitable. The degree of market acceptance of our drug candidates will depend on a number of factors, including but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians’ and patients’ perception of our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the NMPA, FDA, EMA, TGA or other applicable regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA, FDA, EMA, TGA or other applicable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competing drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage and reimbursement by government authorities under the National Reimbursement Drug List (“NRDL”) (《國家醫保藥品目錄》) and other government-sponsored medical insurance programs, or by third-party payers;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; or
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue. Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

RISK FACTORS

Our drugs may not be covered by reimbursement programs or may become subject to unfavorable reimbursement practices, either of which could harm our business.

Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities and/or third-party payers, such as private health insurers and health maintenance organizations. The regulations that govern reimbursement for new therapeutic drugs vary substantially from country to country.

In China, the NRDL and Provincial Reimbursement Drug Lists (“**PRDL**”) (《省級醫保藥品目錄》) include drugs under the National Medical Insurance Catalogue, which affect the amounts reimbursable to program participants for those drugs. There can be no assurance that any of our drug candidates will be included in the NRDL or the PRDL after initial approval for commercial sale. Pharmaceutical products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or the PRDL due to cost constraints. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL or PRDL, our revenue from commercial sales will be highly dependent on patient self-payment, which can make our products less competitive.

In addition, a key trend in the global healthcare industry is cost containment. Government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. As a result, even if our drug candidates are successfully approved by the NRDL or PRDL or any other reimbursement programs sponsored by government health administration authorities and third-party payers, our potential revenue from the sales of these products could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in such reimbursement programs due to price control policies. 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 assure you that reimbursement will be available for our drug candidates that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any approved drug candidate that we commercialize. Obtaining or maintaining reimbursement for approved drug candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop.

There may also be significant delays in obtaining reimbursement for approved drug candidates, and reimbursement coverage may be more limited than the approved indications of the drug candidates by the NMPA, FDA, EMA, TGA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the uses of the drugs and the clinical setting in which the drugs are 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

RISK FACTORS

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 reimbursement coverage at intended payment rates from both government funded and private payers for our drug candidates and any new drug candidates that we develop could have a material adverse effect on our business, operating results, and overall financial conditions.

The manufacture of pharmaceutical products is a highly exacting and complex process, and if we encounter problems in manufacturing our products, our business could be materially and adversely affected.

The manufacturing of our drug candidates is highly complex and we have limited experience in commercial manufacturing. Problems may arise during manufacturing for a variety of reasons, including but not limited to equipment malfunction, failure to follow specific protocols and procedures, changes in product specification, low quality or insufficient supply of raw materials, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and other environmental factors. Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

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

The market size of our drug candidates might be smaller than we expected.

Our estimates regarding our eligible patient population, pricing and available coverage and reimbursement determine our estimated market size, which may differ significantly from the actual market addressable by our drug candidates. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and analysis. These estimates have been derived from a variety of sources, including patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of our target patients may turn out to be lower than expected. For example, the Phase IIa and Phase IIb trial (HTD1801.PCT012/014) IND approval of our Core Product as well as its FTD approval were granted for the treatment of MASH in general. Although we conducted Phase IIa and Phase IIb trials for the treatment of MASH with T2DM and MASH with T2DM or prediabetes, respectively, our planned pivotal Phase III clinical trial for our Core Product and its planned NDA are intended to enroll MASH patients with or without diabetes. Unless in the case that, based on our Phase IIa and Phase IIb clinical results, we decide to

RISK FACTORS

specifically conduct our planned Phase III clinical trial for the treatment of MASH with T2DM instead of MASH in general, then our market potential may be more limited than we expected. Likewise, the potentially addressable patient population for each of our drug candidates may be limited or may not be receptive to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our drug candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

Our Core Product has been developed for the indications of MASH, T2DM, SHTG, PSC and PBC. However, given the presence of various prevention methods, such as lifestyle changes, regular exercise and weight management, as well as existing and potential alternative treatment options for our targeted indications, the market potential of the Core Product may be limited. As a result, even though the number of patients of our targeted indications may be large, the actual addressable patients of our drug candidates may be limited and smaller than we expected.

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

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' drugs and drug candidates. Currently, there are not any unfavorable guidelines, recommendations and studies published by various organizations in relation to our product candidates. However, any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to our competitive drug candidates, could result in current or potential decreased use and/or sales of, and revenue from one or more of our drug candidates. Furthermore, our success depends in part on our ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third parties' guidelines, recommendations or studies.

RISKS RELATING TO OUR FINANCIAL PROSPECTS

We have incurred significant net losses since inception and we may continue to incur net 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 if our business fails.

Investment in pharmaceutical or biotechnology companies is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We have incurred significant expenses related to the research and development of our drug candidates. For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, our research and development costs amounted to RMB84.0 million, RMB182.7 million and RMB120.1 million, respectively. In addition, we also incurred other expenses related to our operations including administrative expenses. As a result, we recorded net losses of RMB221.1 million, RMB190.2 million and RMB549.7 million for the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, respectively.

RISK FACTORS

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we 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 drug candidates;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- commercialize any of our drug candidates for which we may obtain marketing approval;
- seek to identify additional drug candidates;
- address any competing technological and marketing developments, including new drugs developed by competitors;
- maintain, protect and expand our intellectual property portfolio; and
- create additional infrastructure to support our operations as a public company and our drug development and future commercialization efforts.

We cannot guarantee that we will be able to obtain regulatory approvals for any of our drug candidates in a timely manner, or at all. In addition, none of our drug candidates has been approved for marketing in China or any other jurisdictions yet. Substantial investments may be incurred before we generate any revenue from product sales. Considering the numerous risks and uncertainties associated with regulatory approval, we are unable to accurately predict the timing or amount of additional expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the NMPA, FDA, EMA, TGA or other applicable authorities to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we expect to continue incurring significant costs associated with the manufacturing and the commercial launch of the drug candidates.

We had net operating cash outflows, net liabilities and net current liabilities during the Track Record Period.

Since our inception, our operations have consumed substantial amounts of cash. We had operating cash outflows of RMB90.5 million, RMB172.4 million and RMB143.9 million in 2021 and 2022 and the six months ended June 30, 2023, respectively. We had net liabilities of RMB272.3 million, RMB470.5 million and RMB1,028.4 million as of December 31, 2021 and 2022 and June 30, 2023, respectively. We had net current assets of RMB746.6 million, net current liabilities of RMB468.7 million and net current assets of RMB442.4 million as of December 31, 2021, December 31, 2022 and June 30, 2023, respectively.

We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage drug candidates, continue the research and development of our preclinical stage drug candidates, initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates.

RISK FACTORS

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.

Uncertainty over the fair value changes in our Preferred Shares and related valuation may materially affect our financial condition and results of operations.

Our convertible redeemable preferred shares in relation to our Preferred Shares are classified as financial liabilities measured at FVTPL. The estimated changes in fair value 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 financial liabilities valuation has been, and will continue to be, subject to uncertainties in accounting estimation, which may not reflect the actual fair value of these derivative financial liabilities and result in significant fluctuations in profit or loss from year to year. Our Preferred Shares will be converted into Shares upon the [REDACTED], but we may still retain accumulated losses due to the loss on the fair value change of our Preferred Shares after the [REDACTED].

We may incur impairment losses for prepayments, other receivable and other assets.

Our prepayments, other receivables and other assets primarily consist of short-term time deposits, prepayments to suppliers, input value-added tax and other receivables and other current assets. During the Track Record Period, we did not record impairment loss for prepayments, other receivables and other assets. However, we may incur such impairment losses in the future. The assessment of impairment losses involves a significant degree of management judgments as well as estimates in determining the key assumptions, and unpredictable adverse changes in the future may also result in decreases in the value of our prepayments, other receivables and other assets. Therefore, we cannot assure you that these assumptions and estimates would not result in outcomes that require a material adjustment to the carrying amounts of our prepayments, other receivables and other assets in the future, which may in turn result in impairment losses. Any significant impairment losses of prepayments, other receivables and other assets in the future could have an adverse effect on our business, financial condition and results of operations.

RISK FACTORS

We have never generated any revenue from sales of drug products, and our ability to generate revenue from sales of drug products and become profitable depends significantly on our success in a number of factors.

We have no drug products approved for commercial sale, have not generated any revenue from drug product sales, and do not anticipate generating any revenue from drug product sales until sometime after we have received regulatory approval for the commercial sale of our drug candidates. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including but not limited to:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates, intellectual property and technologies;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trademarks, trade secrets, and know-how; or
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the NMPA, FDA, EMA, TGA or other regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the market for the relevant product in China or the relevant jurisdictions, the accepted price for the product to be paid with out-of-pocket expenses and the ability to get reimbursement for any amount. If the number of patients with our addressable disease is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted

RISK FACTORS

population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We benefit from certain preferential tax treatments and government grants, the expiration of or changes to which could adversely affect our profitability.

We currently benefit from certain preferential tax treatments. Shenzhen HighTide has been approved as a high technology enterprise under the relevant tax rules and regulations, and accordingly, is entitled to a preferential corporate income tax rate of 15% from 2022 to 2024. We cannot assure you that these preferential tax treatments will continue to be available to us in the future or that these preferential tax treatments will not be changed as a result of changes in government policy, administrative decisions or otherwise, in which case our financial condition and results of operations may be adversely affected.

During the Track Record Period, we recognized RMB9.8 million, RMB8.0 million and RMB8.9 million of government grants in other income and gains for the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, respectively. The timing, amount and criteria of government financial incentives are determined at the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project by project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions. If we fail to satisfy any such condition, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives may have an adverse effect on our results of operations. In addition, we may not be able to receive government grants in the future, which may have an adverse effect on our financial condition and results of operations.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our commercial success will depend, in large part, on our ability to obtain and maintain patent and other intellectual property protection with respect to our drugs and drug candidates. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our drug candidates, or otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. Patent applications we had applied may not be granted in the end. As such, we do not know the degree of future protection that we will have on our drugs and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our drug candidates could have a material adverse impact on our business.

RISK FACTORS

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws or their interpretation in the United States, the PRC, or other countries or regions may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future granted patents will provide sufficient protection from competitors.

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 issue as patents, they may not issue 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 position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been a common subject of litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration ("CNIPA"), the United States Patent and Trademark Office ("USPTO") and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, the USPTO and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We work with our counsel and professionals to help us comply with these requirements with respect to our intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority 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 the failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

We focus on protecting our intellectual property rights in our target markets, primarily the United States, China and Europe. Filing, prosecuting, maintaining and defending patents on drug candidates in all other countries throughout the world could be prohibitively expensive for us. Our intellectual property rights in other jurisdictions, if obtained, can have a different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do

RISK FACTORS

not protect intellectual property rights to the same extent as the laws of our target markets. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in markets such as the United States. Consequently, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions into our target markets or other jurisdictions. 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.

We may from time to time be involved in lawsuits to protect or enforce our patents and other intellectual property, which could be expensive, time-consuming and unsuccessful and may delay us from developing or commercializing our drug candidates. Our patent rights relating to our drug candidates could be found invalid or unenforceable if being challenged.

Litigation relating to patents and other intellectual property rights is common in the pharmaceutical industries, and is inherently uncertain. Even if successful, litigation may result in substantial costs and reputational harm, and distraction of our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be inevitably compromised by disclosure during discovery.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In any infringement proceeding, the defendant may be able to counterclaim that our patent is invalid and/or unenforceable, and a court may uphold such claims, or otherwise refuse to stop the opposing party from using the technology at issue, on the potential grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent application at risk of not being issued.

On the other hand, if a third party were to assert claims of patent infringement, misappropriation of trade secrets, or violation of other intellectual property rights against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents and rights are valid, enforceable and infringed, and the holders of any such patents and rights may be able to block our ability to commercialize the applicable product unless we obtained a license from them, or until such patents or rights expire or are finally determined to be invalid or unenforceable. 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.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or [REDACTED] perceive these announcements as negative, the perceived value of our drug candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our Shares may decline. Such announcements could also harm our reputation or the commercialization of our drug candidates, which could have a

RISK FACTORS

material adverse effect on our business. 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 and continue our in-house research programs.

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize our drug candidates.

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology, or barred from developing and commercializing our drug candidates. Prohibitions against using certain technologies, or prohibitions against commercializing our drug candidates, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed.

We may face intellectual property disputes with our business partners.

We may be subject to claims that former employees, collaborators, contractors or other third parties have an interest in our patents or other intellectual property, for example as an inventor or co-inventor. When enforcing our rights in our patents or other intellectual property, we may be subject to counterclaims that we do not own or possess clean title to one or more patents or patent applications that cover development, manufacture, and commercialization of one or more of our drug candidates. If we are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents, or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we are unsuccessful in any inventorship or ownership disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our patents.

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

We own registered trademarks. We may not always be able to obtain and ensure trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need in order to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

RISK FACTORS

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

As it is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents and trademarks of our trade names. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The illustrative examples include but are not limited to:

- others may be able to make products that are similar to our drug candidates but that are not covered by the claims of the patents that we own;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we receive NDA approval for drugs containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for commercialization in our major markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications; or
- our competitors might develop biosimilar drugs if the patent protection of our drug candidates will be expired.

RISK FACTORS

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

The life of patent protection is limited, and third parties could be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, or develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

The life of a patent and the protection it affords is limited. For example, in China, if all maintenance fees are timely paid, the invention patents, design patents and utility model patents are valid for 20 years, 15 years and 10 years from its filing date, respectively, with potential patent term extension or adjustment for invention patents under the current Patent Law of the PRC. Even if we successfully obtain patent protection for an approved product candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would materially adversely affect any potential sales of that product.

Patent terms may not be adequate to protect our competitive position on our product candidates in the absence of patent linkage, patent term extensions and other exclusivities. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable 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 request. The pending patent applications, if issued, for our product candidates are expected to expire on various dates as described in "Business — Intellectual Property". Upon the expiration of our patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

According to Article 42 of the Patent Law of the PRC issued on October 17, 2020 and implemented on June 1, 2021, for the purpose of compensating for the time taken to evaluate and approve a new drug to be put on market, CNIPA shall grant compensation for duration of patent right for invention of a new drug approved to be put on market in China upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent right for a new drug approved to be put on market shall not exceed 14 years.

RISK FACTORS

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

In addition to our patents, we rely on trade secrets and confidential information, including but not limited to unpatented know-how, technology and other proprietary information to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets and confidential information, in part, by entering into confidentiality agreements with parties that have access to them, such as our employees, outside collaborators, CROs, consultants and other third parties. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Substantiating and winning 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 may have no means to prevent them from using that technology or information to compete with us, and our competitive position would be harmed.

Furthermore, many of our employees including our senior management, were previously employed at other pharmaceutical or biotechnology companies, which may include 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, consultants and advisors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any of the former employers of such employees, consultants and advisors. We are not aware of any such claims threatened or pending as of the Latest Practicable Date, but there is no assurance that we will not be subject to such claims or involved in litigations to defend against such claims in the future. 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 reputational harm, and be a distraction to our management.

In addition, while we typically require our employees, consultants 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 every party who is actually involved in developing intellectual property that we regard as our own. Further, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel and could have a material adverse effect on our business, financial condition, results of operations and prospects.

RISK FACTORS

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

Depending on decisions by the National People's Congress and the CNIPA, 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. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. The United States has enacted and is currently implementing 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 recently. 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.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our drug candidates through clinical trials, 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 drug candidates 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 manufacturing, sales, marketing and managerial teams to meet our growth targets. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

We may be subject to product liability lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical testing and any future commercialization of our drug candidates, subject to limited immunity that we may seek in connection with some of our product candidates. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, improper, insufficient or improper labelling of products, insufficient or misleading disclosures of side effects or dangers inherent in the product, negligence, strict liability and a breach of warranties. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates or any resulting products;

RISK FACTORS

- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our drug candidates; and
- a decline in our Share price.

If we are unable to defend ourselves against such claims, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management.

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

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. Any claims, disputes or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, claims, disputes or legal proceedings against us may be due to our counterparties, such as our suppliers, CROs and other service providers. Even if we are able to seek indemnity from them, they may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

RISK FACTORS

We are subject to the risks of doing business in multiple jurisdictions.

As we operate in multiple jurisdictions, our business is subject to risks associated with doing business in multiple jurisdictions. Our business and financial results in the future could be adversely affected due to a variety of factors, including but not limited:

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

For example, in the event that the countries from which we import raw materials impose import tariffs, trade restrictions or other trade barriers affecting the importation of such components or raw materials, we may not be able to obtain a stable supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. We may also sell our products to certain foreign countries in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. It is notable that the United States government has made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs,

RISK FACTORS

which have led to other countries, including the PRC and members of the EU, imposing tariffs against the United States in response. These trade disputes may further escalate and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the political relationships. International or regional tensions and political concerns may therefore adversely affect our business, financial condition, results of operations and prospects.

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

The AIC Group has substantial influence over our Company and its interests may not be aligned with the interests of our other Shareholders.

Immediately after completion of the [REDACTED] and assuming the [REDACTED] is not exercised, the AIC Group will collectively control approximately [REDACTED]% voting power at general meetings of our Company. The AIC Group will have significant influence over our business, including matters relating to our management, policies and decisions regarding acquisitions, mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of Directors and other significant corporate actions. This concentration of voting power 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 Shares as part of a sale of our Company and might reduce the [REDACTED] of our Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of the AIC Group may differ from the interests of our other Shareholders. We cannot assure you that the AIC Group 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.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other key employees.

Competition for qualified employees in the biopharmaceutical industry is intense and the pool of qualified candidates is limited. In recent years, the average labor cost in the global biopharmaceutical market, particularly for highly skilled and experienced personnel, has been rising steadily. We cannot assure you that there will be no significant increase in our labor cost, especially as we continue to expand our business and operations. Despite an increase in labor cost, we may still not be able to retain the services of experienced senior management or key clinical and scientific personnel in the future. The departure of one or more of our senior management or key clinical and scientific personnel, whether or not they join a competitor or form a competing company, may subject us to risks relating to finding replacements in a timely manner or at all,

RISK FACTORS

which may disrupt our drug development progress and have a material and adverse effect on our business and results of operations. We will also need to hire additional employees as we expand our commercialization and manufacturing teams.

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, financial condition and results of operations.

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 research institution 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 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 drug candidates. As we rely on third 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. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

RISK FACTORS

If we or our business partners fail to protect data and privacy of subjects in our clinical trials, or the medical institutions that we conduct clinical trials at or provide services to, our reputation will be damaged and we might be subject to fines or other regulatory punishments.

We need to collect and store subjects' personal data and information in clinical trials, which require us and our business partners such as clinical trial institutions and medical institutions to maintain an effective control system to protect such personal data and information. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every major target market in which we operate or intend to operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

Whilst we have adopted security policies and measures to protect our proprietary data and subjects' privacy, misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of personal data might not be avoided due to human error, employee misconduct or system breakdown. We also cooperate with third parties including principal investigators, hospitals and other third parties for our clinical trials. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims. Although we have made efforts to ensure our compliance with the applicable privacy regulations in the relevant jurisdictions, we may not be capable of adjusting our internal policies in a timely manner and any failure to comply with applicable regulations could also result in regulatory enforcement actions against us.

Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

RISK FACTORS

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

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

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

On May 6, 2023, our PRC Legal Advisor conducted a telephonic consultation with the China Cybersecurity Review Technology and Certification Center (the “**Center**”). The Center is authorized by the Cybersecurity Review Office of the CAC to accept public consultation and cybersecurity review submissions and is the competent authority to provide views and interpretation relating to the MCR. Our PRC Legal Advisor is of the view that the staff who responded our inquires during such consultation is the duly designated person in the Center to respond to public inquiries. According to the Center, (i) the listing in Hong Kong does not fall within the scope of “listing abroad”; (ii) critical information infrastructure operators are identified by the governmental authorities of corresponding industry; (iii) Draft Cyber Data Security Regulation had not come into force as of the Latest Practicable Date, the applicability of various requirements under the Draft Cyber Data Security Regulation is still subject to applicable implementation rules.

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

RISK FACTORS

Data Security Regulation. Therefore, as advised by our PRC Legal Advisor, our Directors believe that as long as there is no material change to our current business and if no further rules are introduced and no significant changes to the enforcement of the MCR by governmental authorities, cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us.

Furthermore, based on the fact that (i) the MCR came into effect recently and the Draft Cyber Data Security Regulation has not been formally adopted, and their implementation and interpretation are subject to uncertainties and (ii) we have not been involved in any investigations on cybersecurity review initiated by the CAC on such basis and nor have we received any inquiry, notice, warning, or sanctions in such respect, with the support of our PRC Legal Advisor, we are of the view that we comply with such regulations in all material aspects and we believe such regulations would not have a material adverse impact on our business operations or our [REDACTED]. Considering that (a) we have not been involved in any cybersecurity review or investigation by the CAC or other authorities with respect to the MCR; (b) we have not been informed that we are recognized as a crucial information infrastructure operator by any relevant authority; (c) the data processed by us has not been included in the effective core data and important data catalogs by any authority; and (d) we have taken reasonable and adequate technical and management measures to ensure data security, we are of the view that the likelihood that our business operation or the [REDACTED] might give rise to national security risks is remote.

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

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

RISK FACTORS

On February 22, 2023, the CAC issued the Measures for the Standard Contract for Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》), (the “**Standard Contract Measures**”), along with the formal version of the standard contractual clauses for cross-border transfer of personal information stipulated under the Personal Information Protection Law. The Standard Contract Measures will come into effect on June 1, 2023, and provide a six-month grace period. Any violation of the Standard Contract Measures shall be punished in accordance with the Personal Information Protection Law and other laws and regulations. We intend to comply with such measures within the six-month grace period in 2023. However, if we fail to comply with such measures by November 30, 2023, we may face legal liability under the Personal Information Protection Law, including being ordered to make corrections, given a warning, confiscation of illegally obtained gains, etc.

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, results of operations, financial condition 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 May 2019 and the PRC Biosecurity Law (《生物安全法》) promulgated in October 2020, 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.

Our investments or acquisitions may have a material adverse effect on our business, reputation, financial condition and results of operations.

We may in the future evaluate and consider a wide array of investments and acquisitions that we believe can augment our overall business strategy. We may be engaged in discussions or negotiations with respect to one or more of these types of transactions. These transactions involve significant challenges and risks, including but not limited to:

- difficulties integrating into our operations the personnel, operations, products and services;

RISK FACTORS

- technology, internal controls and financial reporting of companies we acquire;
- disrupting our ongoing business, distracting our management and employees and increasing our expenses;
- losing skilled professionals as well as established client relationships of the businesses we invest in or acquire;
- for investments over which we do not obtain management and operational control, we may lack influence over the controlling partner or shareholder, which may prevent us from achieving our strategic goals in such investment;
- new regulatory requirements and compliance risks that we become subject to as a result of acquisitions in new industries or otherwise;
- actual or alleged misconduct or non-compliance by any company we acquire or invest in (or by its affiliates) that occurred prior to our acquisition or investment, which may lead to negative publicity, government inquiry or investigations against such company or against us;
- unforeseen or hidden liabilities or costs that may adversely affect us following our acquisition of such targets;
- regulatory hurdles including the anti-monopoly and competition laws, rules and regulations in connection with any proposed investments and acquisitions;
- the risk that any of our pending or other future proposed acquisitions does not close;
- the costs of identifying and consummating investments and acquisitions;
- the use of substantial amounts of cash and potentially dilutive issuances of equity securities;
- the occurrence of significant goodwill impairment charges and amortization expenses for other intangible assets; or
- challenges in achieving the expected benefits of synergies and growth opportunities in connection with these acquisitions and investments.

Any such negative developments described above could disrupt our existing business and have a material adverse effect on our business, reputation, financial condition and results of operations.

RISK FACTORS

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

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including but not limited to:

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

As a result, we may not be able to realize the benefit of or choose to exercise any options under current or future collaborations, strategic partnerships or the license of our third-party drugs if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay our research and development program or one or more of our other research and development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

RISK FACTORS

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

If we, or our CROs, CDMOs or other contractors and business partners fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of 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. 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 contractors and 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 impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Healthcare providers, including physicians and others, play a primary role in the recommendation and prescription of products for which we may seek regulatory approval. If we obtain approval from the NMPA, FDA, EMA, TGA or other regulatory authorities for any of our drug candidates and if we then begin to market those drugs in the United States or in the PRC, our operations may be subject to federal and state fraud and abuse laws in the United States, PRC and other countries, including the federal Anti-Kickback Statute and the False Claims Act, as well as physician payment transparency laws and regulations, including the Federal Physician Payment Act. Our current and future operations also may be subject to regulation by U.S. federal, state and local authorities including, among others, the Centers for Medicare and Medicaid Services and other divisions within the U.S. Department of Health and Human Services such as the Office of the Inspector General and the Office for Civil Rights. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirements, we could be subject to applicable penalties.

RISK FACTORS

Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. 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 and results of operations.

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

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations. We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees or other third parties.

We are subject to anti-bribery laws in China 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 primary business operations are in China, we are subject to the Foreign Corrupt Practices Act 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. Although we have policies and procedures designed to ensure that we, our employees, agents and intermediaries comply with anti-bribery laws, there is no assurance that such policies or procedures will always effectively prevent our employees, agents and intermediaries from engaging in bribery activities. 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. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could significantly affect our business, financial condition, and results of operations. We could also be adversely affected by any allegation that we violated such laws.

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

A number of governmental agencies or industry regulatory bodies in the PRC and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our business partners' failure to comply with such regulations could result in the termination of ongoing

RISK FACTORS

research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects and results of operations.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. 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 and results of operations. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we will be able to meet new criteria that may be imposed. If the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot 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 Company and our results of operations will be adversely affected.

If we become a party or are subject to litigation, legal or contractual disputes, governmental investigations or administrative proceedings, our management's attention may be diverted and we may incur substantial costs and liabilities.

We may also from time to time become a party to various litigation, legal disputes, claims, administrative proceedings or other administrative measures arising in the ordinary course of our business. On-going litigation, legal disputes, claims, administrative proceedings or other administrative measures may divert our management's attention and consume their time and our other resources. Furthermore, any litigation, legal disputes, claims, administrative proceedings or other administrative measures which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. Negative publicity arising from litigation, legal disputes, claims, administrative proceedings or other administrative measures 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 or we are imposed any fines or penalties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business ventures or projects. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

RISK FACTORS

Failure to make social insurance and housing provident fund contributions for some of our employees timely as required by PRC laws and regulations may subject us to late payments and fines imposed by relevant governmental authorities.

During the Track Record Period, we had not made full contributions to the social insurance premium and housing provident fund based on the actual salary level of some of our employees as prescribed by relevant laws and regulations. As of the Latest Practicable Date, we had not received any notice from the local authorities or any claim or request from the relevant employees that require us to make payments or impose upon us administrative penalties for insufficient contributions. Pursuant to relevant PRC laws and regulations, the under-contribution of social insurance within a prescribed period may subject us to a daily overdue charge of 0.05% of the delayed payment amount. Although we had made timely payments for the full amount of social insurance and housing provident fund contribution since May 2022, we cannot assure you that the relevant government authorities will not require us to pay the outstanding amount within a prescribed time and impose late charges or fines on us, which may affect our business, financial condition and results of operations.

During the Track Record Period, Shenzhen HighTide engaged a third-party human resource agency to pay social insurance premium and housing provident funds for three of our employees. These three employees have accepted this arrangement and will not pursue any claims against us with the competent authorities. However, if the local governments determine the use of third-parties to pay social insurance and housing provident funds to be non-compliant in the future or such human resource agency fail to pay the social insurance premium or housing provident funds for and on behalf of our employees as required by applicable PRC laws and regulations, we may be subject to additional contribution, late payment fee or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance and housing provident funds as an employer or be ordered to rectify. This in turn may affect our financial condition and results of operations.

Our business significantly depends on our reputation, and any negative publicity on us or failure to maintain and enhance our recognition and reputation may materially and adversely affect our business, financial condition and results of operations.

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, results of operations and prospects.

RISK FACTORS

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 and results of operations, 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 wrong doing 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 drug candidates, 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.

Our information technology systems, or those of our CROs, CDMOs or other contractors and business partners, may fail or suffer security breaches.

Despite the implementation of security measures, our information technology systems and those of our CROs, CDMOs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud, and our business, financial condition, results of operations and reputation could be materially and adversely affected.

We will become a public company upon completion of the [REDACTED], and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. In order to address our internal controls issues and to

RISK FACTORS

generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program for data storage and transmission, adopting new policies, and providing training on our controls, procedures and policies to our employees. In addition, in preparation for the [REDACTED], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

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 PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. Our principal insurance policies cover employee benefits liability and adverse events in clinical trials. We currently do not maintain insurance for environmental liability or property loss. According to CIC, our insurance policy is in line with the industry practice. Our insurance coverage may be insufficient to cover any claims that we may have. 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 and may negatively impact our product development and overall operations.

We are subject to risks relating to leased properties.

As of the Latest Practicable Date, the actual usage of one leased property was inconsistent with the usage set out in its title certificate. Our PRC Legal Advisor believes that there is a likelihood that we will be asked to vacate the non-compliant leased property. In the event that we are required to relocate, there is no assurance that we will be able to identify comparable locations in a timely manner or at all, and that we will secure a lease in the vicinity on comparable terms.

Moreover, ten of our lease agreements for properties in China have not been registered with relevant authorities in China. As advised by our PRC Legal Advisor, according to the PRC Civil Code, failure to complete the registration and filing of lease agreements will not affect the validity of the lease agreements. However, the relevant PRC authorities may impose a fine on us ranging from RMB1,000 to RMB10,000 for each unregistered lease. We have used our commercially reasonable efforts to register the relevant leases. However, the registration of these relevant lease agreements requires additional steps to be taken by the lessors which are beyond our control. We cannot assure you that the lessors will be cooperative and that we can complete the registration of these lease agreements.

RISK FACTORS

Difficult conditions and turbulence in the global economic, political and financial environment may adversely affect our business.

Geopolitical, economic and market conditions, including factors such as the liquidity of the global financial markets, the level and volatility of debt and equity prices, interest rates, currency and commodities prices, investor sentiment, inflation and the availability and cost of capital and credit have been and will continue to affect the countries where we operate. The stress experienced by the global financial markets in 2020 due to the COVID-19 pandemic, the series of measures taken by major economies in response and the consequences of such measures continue to impact the global economy in varying degrees in different regions over the years. The financial markets continue to be impacted by general uncertainty, and growth rates have declined recently. In addition, tighter monetary policy in the United States could further undermine financial stability in emerging market economies. Central banks around the world, including in the United States and several large emerging markets, have tightened monetary policy and have indicated that they would continue to do so in the near future. The financial conditions of banking institutions have come under severe pressure and deterioration, as exemplified by the proposed restructuring of Credit Suisse Group AG and the failures of Silicon Valley Bank and Signature Bank in the first quarter of 2023, driven by bank runs or simultaneous withdrawals by depositors due to various reasons, including lack of confidence in the banking system. The slow economic recoveries around the world and the high inflation, high interest environment have contributed to higher global volatility. These developments may adversely impact global liquidity, heighten market volatility and increase U.S. dollar funding costs resulting in tightened global financial conditions and fears of a recession. A prolonged period of extremely volatile and unstable market conditions would likely increase our funding costs and could also adversely affect the countries where we operate, which could in turn affect our business.

RISKS RELATING TO DOING BUSINESS IN THE PRC

Changes in economic, social conditions, policies and geopolitical relationships may impact our business, financial condition, results of operations and prospects.

Substantially all of our assets and operations are located in the PRC. Accordingly, our business, financial condition, results of operations and prospects may be influenced to a significant degree by economic, political and social conditions in the PRC generally. The PRC government conducts management on the resource allocation, foreign exchange supervision and management, industry support and other aspects through relevant laws and regulations as well as the functions and powers of the government, playing an important role in China's economic growth. In addition, the PRC government plays a significant role in regulating industry development by imposing relevant industrial policies.

While the PRC economy has experienced significant growth over the past decades, growth varies, both geographically and among various sectors of the economy. COVID-19 adversely affected the Chinese and global economies in recent years. If material changes occur in the policies of the PRC government or in the PRC laws and regulations, the overall economic growth of China may be affected significantly. Such developments could adversely affect our business and operating results, lead to reduction in demand for our solutions and services and adversely affect our competitive position. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the

RISK FACTORS

overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations. In addition, certain measures implemented by the PRC government based on the overall economic situation, including interest rate adjustment, will affect the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations.

Furthermore, there is no assurance that the substantial growth in the PRC economy in the previous decades will continue or continue at the same pace. In recent years, the U.S.-China relations also give rise to uncertainties on the PRC economy as well as the global economy. Since 2018, the United States government imposed several rounds of tariffs on Chinese products. In retaliation, the PRC government responded with tariffs on U.S. products. The trade tensions were accompanied with escalating economic restrictions and sanctions, which created further uncertainties and volatilities to the PRC economy and global markets. Since 2019, the United States government has imposed increasing restrictions on Chinese technology companies exporting sensitive U.S. goods. In 2021, the United States government blacklisted over 40 Chinese technology companies, citing activities contrary to the national security or foreign policy interests of the United States. The future development and lasting impact of the U.S.-China relations on China’s economy and the online chronic disease management industry remain uncertain. Should the U.S.-China relations materially impact the PRC economy, the purchasing power of our customers may decrease and procurement costs of the imported drugs sold on our platforms may increase, which will have an adverse effect on our business operation and financial performance. Our compliance costs may increase and our results of operations will be adversely affected.

It may be difficult to effect service of legal process and enforce judgments against us and our management due to the lack of relevant international treaties regarding judicial service and judicial enforcement.

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 not be possible to effect service of process within certain jurisdictions outside the PRC upon us or most of our Directors and senior management. Furthermore, the PRC does not have treaties providing for the reciprocal enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in Mainland China or Hong Kong of judgments of a court obtained in the United States or any of the other jurisdictions mentioned above may not be consistent with expectations. On July 3, 2008, 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, 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 as expected in Mainland China if the parties in dispute have not agreed to enter into a choice of court agreement in writing. In addition, the Arrangement has

RISK FACTORS

expressly provided for “enforceable final judgment”, “specific legal relationship” and “written form.” 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 discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in Hong Kong. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective, a judgment rendered by a Hong Kong court may not be enforced as expected in Mainland China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

Under the New Arrangement, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the effective judgments in civil and commercial cases subject to the conditions set forth in the New Arrangement. Although the New Arrangement has been signed, the outcome and effectiveness of any action brought under the New Arrangement may still be uncertain. We cannot assure you that an effective judgment that complies with the New Arrangement can be recognized and enforced in a PRC court.

The interpretation and enforcement of some PRC laws, rules and regulations recently and newly issued are subject to further interpretation by the regulatory authorities.

A majority of our operations are conducted in China, and are hence governed by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In the late 1970s, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of economic activities in China. However, due to the rapid development and iteration of economic activities, recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to the significant interpretation discretion by PRC regulatory agencies. It requires us to understand and be familiar with the actual implementation methods of relevant laws and regulations in a timely manner, or otherwise we may violate relevant laws and regulations.

Additionally, the NMPA’s recent reform of the drug approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our drug candidates in a timely manner. Since PRC administrative and court authorities have discretion in interpreting and implementing statutory and contractual terms according to the authorisation of laws and regulations, it may be difficult to evaluate the outcome of administrative and court proceedings for laws and regulations and contractual treaties without specific interpretation. These uncertainties may impede our ability to

RISK FACTORS

enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Future adjustments in laws, regulations or enforcement policies in the PRC could adversely affect our business.

Laws, regulations or enforcement policies in China, including those regulating the healthcare and pharmaceutical industry, are evolving and subject to possible changes. The PRC pharmaceutical industry is heavily regulated and many aspects of our business depend on the receipt of the relevant government authorities' approvals and permits. Further, regulatory agencies in China may change their enforcement practices based on economic conditions and needs. Therefore, prior enforcement activities, or lack of enforcement activities, may not be a complete indication of future actions. Any enforcement actions against us could have an adverse effect on us.

Any litigation or governmental investigation or enforcement proceedings in China or any other regions in the world may be protracted and may result in substantial costs and diversion of resources and management attention, negative publicity, and damage to reputation.

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.

Certain of our cash and cash equivalents, with original maturity less than one year, trade payables and convertible redeemable preferred shares are denominated in foreign currencies, and are exposed to foreign currency risk. We recognized net foreign exchange gains of RMB0.6 million and net exchange loss of RMB7.5 million and RMB0.5 million for the year ended December 31, 2021 and 2022 and the six months ended June 30, 2023, respectively. The fair value change of convertible redeemable preferred shares take into account exchange gains or losses. As of December 31, 2021 and 2022 and June 30, 2023, RMB692.0 million, RMB328.2 million and RMB573.8 million of our cash and bank balances were denominated in U.S. dollars, respectively, primarily representing proceeds from our [REDACTED] Financing. The exchange rate of the Renminbi against the U.S. dollar and other foreign currencies fluctuates and is affected by a series of factors. It is difficult to predict how market forces or government policies may impact the exchange rate between the Renminbi and the Hong Kong dollar, the U.S. dollar or other currencies in the future.

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

RISK FACTORS

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

Required 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 Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under China’s current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from 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.

We may be deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law and our global income may be subject to PRC corporate tax under the PRC Enterprise Income Tax Law.

The PRC Enterprise Income Tax (“EIT”) Law provides that enterprises established outside of China whose “*de facto* management bodies” are located in the PRC are considered “resident enterprises” and are generally subject to the uniform 25% enterprise income tax rate on their global income. “*De facto* management body” is defined as the body that has the significant and overall management and control over the business, personnel, accounts and properties of an enterprise. In April 2009 and July 2011, the SAT issued several circulars to clarify certain criteria for determining location of the “*de facto* management bodies” of foreign enterprises controlled by PRC enterprises; however, no official implementation rules have been issued for determining the location of the “*de facto* management bodies” of foreign enterprises that are not controlled by PRC enterprises. Being regarded as a PRC resident enterprise may materially and adversely affect our profit and hence our retained profit available for distribution to our Shareholders.

Dividends paid by us to our foreign [REDACTED] and gains on the [REDACTED] of our Shares may be subject to withholding taxes under PRC tax laws.

Under the EIT law, PRC withholding tax at a rate of 10% is normally applicable to dividends from a PRC source paid to investors that are “non-resident enterprises”, which do not have an establishment or place of business in China, or which have an establishment or place of business in China but whose relevant income is not effectively connected with the establishment or place of business in China. Any gain realized by non-resident enterprise investors on the transfer of shares is generally subject to a 10% PRC income tax if such gain is regarded as income derived from sources within China.

RISK FACTORS

Under the PRC Individual Income Tax Law and its implementation rules, dividends from sources within China paid to foreign individual investors who are not PRC residents are generally subject to a PRC withholding tax at a rate of 20% and gains from PRC sources realized by such investors on the transfer of shares are generally subject to PRC income tax at a rate of 20% for individuals. Any PRC tax may be reduced or exempted under applicable tax treaties or similar arrangements.

If we are treated as a PRC resident enterprise as described under the risk factor headed “— We may be deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law and our global income may be subject to PRC corporate tax under the PRC Enterprise Income Tax Law”, dividends we pay with respect to our Shares, or the gain realized from the [REDACTED] of our Shares, may be treated as income derived from sources within China and as a result be subject to the PRC income taxes described above. However, owners of our Shares who are not PRC tax residents and seek to enjoy preferential tax rates under relevant tax treaties may apply to the PRC tax authorities to be recognized as eligible for treaty benefits in accordance with the Announcement of the State Taxation Administration on Promulgating the Administrative Measures for Tax Convention Treatment for Non-resident Taxpayers (《國家稅務總局關於發佈非居民納稅人享受稅收協定待遇管理辦法的公告》) (the “Circular 60”). If any PRC tax is imposed on distributions on, or dispositions of, our Shares, the value of your [REDACTED] in our Shares may be materially and adversely affected.

We have granted, and may continue to grant, options and other types of awards under our share incentive plan, which may result in increased share-based payments and potential dilution in shareholding.

We have adopted the Incentive Plans to, among others, attract and retain outstanding individuals to serve as directors, officers, employees, consultants, and advisors to 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. Our share-based payments were RMB7.3 million, RMB25.6 million and RMB28.4 million in 2021 and 2022 and the six months ended June 30, 2023, respectively. See Note 28 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 and would also potentially dilute the shareholding. 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 the reporting periods following the [REDACTED].

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

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (“SAFE Circular 7”), repealing the previous rules issued by SAFE in March 2007. Under SAFE Circular 7 and other relevant rules and regulations, PRC

RISK FACTORS

residents who participate in a stock incentive plan in an overseas publicly listed company are required to register with SAFE or its local branches and complete certain other procedures. Participants in a stock incentive plan who are PRC residents must retain a qualified PRC agent, which could be a PRC subsidiary of the overseas publicly listed company or another qualified institution selected by the PRC subsidiary, to conduct the SAFE registration and other procedures with respect to the stock incentive plan on behalf of its participants. The participants must also retain an overseas entrusted institution to handle matters in connection with their exercise of stock options, the purchase and sale of corresponding stocks or interests and fund transfers. In addition, the PRC agent is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan, the PRC agent or the overseas entrusted institution or other material changes. We and our PRC employees who have been granted share options will be subject to these regulations upon the completion of this [REDACTED]. Failure of our PRC share option holders to complete their SAFE registrations may subject these PRC residents to fines of up to RMB300,000 for entities and up to RMB50,000 for individuals, and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries, limit our PRC subsidiaries' ability to distribute dividends to us, or otherwise materially and adversely affect our business.

The STA has also issued relevant rules and regulations concerning employee share incentives. Under these rules and regulations, our employees working in the PRC will be subject to PRC individual income tax upon exercise of the share options. Our PRC subsidiaries have obligations to file documents with respect to the granted share options or restricted shares with relevant tax authorities and to withhold individual income taxes for their employees upon exercise of the share options or grant of the restricted shares. If our employees fail to pay or we fail to withhold their individual income taxes according to relevant rules and regulations, we may face sanctions imposed by the competent governmental authorities.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends.

RISK FACTORS

The PRC government will make adjustments to the enforcement measures on foreign exchange control in accordance with laws and regulations based on capital inflow and outflow as well as the status of economic activities. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our [REDACTED] or other obligations to our suppliers, or otherwise fund and conduct our business.

Our dividend income from our foreign-invested PRC subsidiaries may be subject to a higher rate of withholding tax than that which we currently anticipate.

Under the EIT Law, if a foreign entity is deemed to be a “non-resident enterprise”, a PRC withholding tax at the rate of 10% will be applicable to any dividends for earnings accumulated since January 1, 2008 payable to the foreign entity, unless the foreign entity is entitled to reduction or elimination of such tax, including by tax treaties or agreements. According to the Arrangement between the Mainland of China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Incomes (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), dividends paid by a PRC foreign-invested enterprise to its shareholder(s) incorporated in Hong Kong will be subject to withholding tax at a rate of 5% if the Hong Kong company directly holds a 25% or more interest in the PRC foreign-invested enterprise. The STA promulgated the Circular of the State Taxation Administration on Relevant Issues relating to Beneficial Owner under Tax Treaties (《國家稅務總局關於稅收協定中“受益所有人”有關問題的公告》) (the “**Circular 9**”) on February 3, 2018, which addresses the methods for determining the “beneficial owners” under tax treaties’ articles on dividends, interest and royalties. According to Circular 9, the PRC tax authorities must evaluate whether an applicant qualifies as a “beneficial owner” on a case-by-case basis, and a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner.

If our Hong Kong subsidiary is not considered as a “beneficial owner” under PRC tax law, dividends from our PRC subsidiaries to our Hong Kong subsidiary will be subject to PRC withholding tax at a 10% rate instead of a 5% rate. This would negatively impact us and our ability to pay dividends in the future.

The heightened scrutiny over acquisitions from the PRC tax authorities may has an adverse impact on our business, acquisitions or restructuring strategies.

On February 3, 2015, the STA promulgated the Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》) (the “**Circular 7**”), which provides comprehensive guidelines relating to, and heightened the PRC tax authorities’ scrutiny on indirect transfers, by a non-resident enterprise, of assets (including equity interests) of a PRC resident enterprise.

RISK FACTORS

The application of the Circular 7 is uncertain. Tax authorities may determine that Circular 7 applies to our offshore restructuring transactions or sale of the shares of our offshore subsidiaries, where non-resident enterprises are transferors. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with the Circular 7 or to establish that we and our non-resident enterprises should not be taxed under the Circular 7 for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial conditions and results of operations.

If any of our shareholders or beneficiaries who is a PRC resident fails to register foreign exchange pursuant to Circular 37, it may adversely affect our PRC subsidiaries' ability to distribute profits to us, or otherwise adversely affect our financial position.

The SAFE promulgated the Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by Domestic Residents in China via Special-Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the "Circular 37") on July 4, 2014. According to Circular 37, PRC residents (including PRC citizens and PRC enterprises) shall apply to the SAFE or its local bureau to register foreign exchange for overseas investments before contributing to special purpose vehicles (the "SPVs") with legitimate domestic and overseas assets or rights and interests. In the event of any alteration in the basic information of the registered SPVs, such as the change of a PRC citizen shareholder, name and operating duration; or in the event of any alternation in key information, such as increases or decreases in the share capital held by PRC citizens, or equity transfers, swaps, consolidations, or splits, the registered PRC residents shall timely submit a change in the registration of the foreign exchange for overseas investments with the foreign exchange bureaus. SAFE promulgated the Notice on Further Simplifying and Improving the Administration of the Foreign Exchange Concerning Direct Investment (《關於進一步簡化及改進直接投資外匯管理政策的通知》) (the "Simplifying and Improving Notice") in February 2015, which took effect on June 1, 2015. The Simplifying and Improving Notice amended Circular 37 requiring PRC residents or entities to register with qualified banks rather than SAFE or its local branch in connection with the establishment or control of an offshore entity established for the purpose of overseas investment.

We may not at all times be fully aware or informed of the identities of our beneficiaries who are PRC nationals, and may not be able to compel our beneficiaries to comply with the requirements of the Circular 37. As a result, we cannot assure you that all of our Shareholders or beneficiaries who are PRC nationals will at all times comply with, or in the future make or obtain any applicable registrations or approvals required by the Circular 37 or other related regulations. Under the relevant rules, failure to comply with the registration procedures set forth in the Circular 37 may result in restrictions on the foreign exchange activities of the relevant PRC enterprise and may also subject the relevant PRC resident to penalties under the PRC foreign exchange administration regulations.

RISK FACTORS

PRC regulations of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the [REDACTED] of the [REDACTED] to make loans or additional capital contributions to our PRC subsidiaries.

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of SAFE. Additionally, our capital contributions must be filed with or approved by the MOFCOM or its local counterpart and registered with the SAIC or its local branch. We cannot assure you that we will be able to obtain these government registrations or approvals or to complete filing and registration procedures on a timely basis, if at all, with respect to future loans or capital contributions by us to our subsidiaries or any of their respective subsidiaries. If we fail to obtain such approvals or registrations, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected. This may materially and adversely affect our PRC subsidiaries' liquidity, their ability to fund their working capital and expansion projects, and their ability to meet their obligations and commitments. As a result, this may have a material adverse effect on our business, financial conditions and results of operations.

RISKS RELATING TO THE [REDACTED]

No public market currently exists for our Shares, and an active trading market for our Shares may not develop and the market price for our Shares may decline or become volatile.

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED], and the [REDACTED] may differ significantly from the market price of the Shares following the [REDACTED]. As a result, a listing on the Hong Kong Stock Exchange does not guarantee that an active and liquid trading market for our Shares will develop, especially during the period when a significant portion of our Shares are subject to lock-up undertakings, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will rise following the [REDACTED].

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

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

RISK FACTORS

There will be a gap of several days between [REDACTED] and [REDACTED] of our [REDACTED], and the [REDACTED] of our [REDACTED] when [REDACTED] begins could be lower than the [REDACTED].

The initial [REDACTED] to the public of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be five Business Days after the [REDACTED]. As a result, [REDACTED] may not be able to sell or otherwise deal in the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the [REDACTED] of the Shares when [REDACTED] begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of [REDACTED] and the time [REDACTED] begins.

Future [REDACTED] or [REDACTED] of a substantial number of our Shares in the public market following the [REDACTED] could materially and adversely affect the [REDACTED] of our Shares.

Prior to the [REDACTED], there has not been a public market for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our Shares in the public market or the perception that these sales may occur could significantly decrease the prevailing [REDACTED] of our Shares and our ability to raise equity capital in the future.

In addition, our Shareholders would experience dilution in their shareholdings upon offer or sale of additional share capital or share capital-linked securities by our Company in future offerings. If additional funds are raised through our issuance of new share capital or share capital-linked securities other than on a pro rata basis to existing Shareholders, the shareholdings of such Shareholders may be reduced and such new securities may confer rights and privileges that take priority over those conferred by the [REDACTED].

Sales of substantial amounts of Shares in the public market after the completion of the [REDACTED], or the perception that these sales could occur, could adversely affect the market price of our Shares. Although the AIC Group is subject to restrictions on its sales of Shares within 6 months from the [REDACTED] as described in "[REDACTED]" in this document, future sales of a significant number of our Shares by the AIC Group in the public market after the [REDACTED], or the perception that these sales could occur, could cause the market price of our Shares to decline and could materially impair our future ability to raise capital through offerings of our Shares. We cannot assure you that the AIC Group will not dispose of Shares held by it or that we will not issue Shares pursuant to the general mandate to issue shares granted to our Directors, upon the expiration of restrictions set out above. We cannot predict the effect, if any, that any future sales of Shares by the AIC Group, or the availability of Shares for sale by the AIC Group, or the issuance of Shares by the Company may have on the market price of the Shares. Sale or issuance of a substantial amount of Shares by the AIC Group or us, or the market perception that such sale or issuance may occur, could materially and adversely affect the prevailing market price of the Shares.

RISK FACTORS

There may be difficulties in protecting your interests under the laws of the Cayman Islands.

Our corporate affairs are governed by, among other things, our Memorandum of Association and Articles of Association, the Companies Act and common law of the Cayman Islands. The rights of Shareholders to take action against our Directors, actions by minority shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority Shareholders may be located. See "Appendix III — Summary of the Constitution of the Company and Cayman Islands Company Law" in this document. As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or Substantial Shareholders, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such shareholders are located.

There may be dilution because of issuance of new Shares or equity securities.

In spite of our current cash and cash equivalents and the net [REDACTED] from the [REDACTED], we may require additional funds due to changes in business conditions or other future developments relating to, inter alia, our existing operations or any future expansions. The amount and timing of such additional financing needs will vary depending on the timing investments in and/or acquisitions of new businesses from third-parties, and the amount of cash flow from our operations. If our resources are insufficient to satisfy our cash requirements, we may seek additional financing through selling additional equity or debt securities or obtaining a credit facility.

The sale of additional equity securities could result in additional dilution to our Shareholders. If additional funds are raised by way of issuance of new Shares or equity linked securities other than on a pro rata basis to existing Shareholders, the percentage of ownership of our existing Shareholders in our Company, the earnings per Share and the net asset value per Share may be reduced.

Because the initial public [REDACTED] per Share is higher than the net tangible book value per Share, [REDACTED] of our Shares in the [REDACTED] will experience immediate dilution.

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

RISK FACTORS

We cannot assure you that we will declare and distribute any amount of dividends in the future.

Our ability to declare future dividends will depend on the availability of dividends, if any, received from our operating subsidiaries. Under applicable laws and the constitutional documents of our operating subsidiaries, the payment of dividends may be subject to certain limitations. The calculation of certain of our operating subsidiaries' profit under applicable accounting standards differs in certain respects from the calculation under HKFRSs. As a result, our operating subsidiaries may not be able to pay a dividend in a given year even if they have profit as determined under HKFRSs. Accordingly, since we derive all of our earnings and cash flows from dividends paid by our operating subsidiaries, we may not have sufficient distributable profit to pay dividends to our Shareholders.

In addition, any future dividend declaration and distribution will be at the discretion of our Directors and will depend on our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors deem relevant. Any declaration and payment as well as the amount of dividends will also be subject to our Articles of Association and PRC laws, including (where required) the approvals from our Shareholders and our Directors. Our Shareholders at a general meeting must approve any declaration of dividends, which must not exceed the amount recommended by our Board. Moreover, our Directors may from time to time pay such interim dividends as our Board considers to be justified by our profits and overall financial requirements, or special dividends of such amounts and on such dates as they think appropriate. As a result, we cannot assure you that we will make any dividend payments on our Shares in the future.

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

Under Rule 18A.10 of the Listing Rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or any series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Rule 18A.10. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

Certain statistics contained in this document are derived from a third-party report and publicly available official sources and they may not be reliable.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by CIC that we commissioned. 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 Directors and the Joint Sponsors have exercised reasonable care in selecting and identifying the named information sources, in compiling, extracting, and reproducing the information, and in ensuring that there is no material omission of the information.

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].

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

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your [REDACTED] decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] in our [REDACTED]. By applying to [REDACTED] our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and the [REDACTED].

WAIVERS AND EXEMPTIONS

In preparation for the [REDACTED], we have sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and certificates of exemption from strict compliance with the relevant provisions of the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rule 8.12 of the Listing Rules, an issuer must have sufficient management presence in Hong Kong. This normally means that at least two of its executive directors must be ordinarily resident in Hong Kong.

We do not have sufficient management presence in Hong Kong for the purposes of satisfying the requirements under Rule 8.12 of the Listing Rules. Our Group’s management, business operations and assets are primarily based outside Hong Kong. The principal management headquarters and senior management of our Group are primarily based in China. Our Directors consider that the appointment of 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 and our Shareholders as a whole. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rule 8.12 of the Listing Rules. We will ensure that there is a regular and effective communication between us and the Stock Exchange by way of the following arrangements:

- (a) pursuant to Rule 3.05 of the Listing Rules, we have appointed and will continue to maintain two authorised 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. The two authorised representatives are Dr. Liu, our executive Director, and Ms. CHU Pik Man (朱璧敏) (“**Ms. Chu**”), a joint company secretary of our Company. Each of our authorised representatives will be available to meet with the Stock Exchange within a reasonable time frame upon the request of the Stock Exchange and will be readily contactable by phone and email. Each of the authorised representatives is authorised to communicate on our behalf with the Stock Exchange;
- (b) both authorised representatives have means to contact all of our Directors (including our independent non-executive Directors) promptly at all times as and when the Stock Exchange wishes to contact our Directors for any matters. Our Directors who are not ordinarily resident in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and will be able to meet with the Stock Exchange within a reasonable period of time when required. To enhance communication between the Stock Exchange, our authorised representatives and our Directors, we have implemented a policy that (i) each Director has provided their respective contact details (including phone number and e-mail address) to the authorised representatives; (ii) in the event that a Director expects to travel or is otherwise out of office, he/she will endeavour to provide his/her phone number of the place of his/her accommodation to the authorised representatives or maintain an open line of communication via his/her mobile phone; and (iii) each of our Directors will provide their respective mobile phone numbers, office phone numbers and fax numbers (if applicable) to the Stock Exchange pursuant to the Guidance Letter HKEX-GL9-09;

WAIVERS AND EXEMPTIONS

- (c) in compliance with Rule 3A.19 of the Listing Rules, we have appointed Fosun International Capital Limited as our compliance advisor (the “**Compliance Advisor**”) which has access at all times to our authorised representatives, Directors, senior management and other officers of our Company, and will act as an additional channel of communication with the Stock Exchange. We will keep the Stock Exchange up to date in respect of any change to such details. Our authorised 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, authorised 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;
- (d) 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;
- (e) our Company has designated one of our staff members as the communication officer at our headquarters after the [REDACTED] who will be responsible for maintaining day-to-day communication with Ms. Chu and our Company’s professional advisors in Hong Kong, including our legal advisors in Hong Kong and the Compliance Advisor, to keep abreast of any correspondences and/or enquiries from the Stock Exchange and report to our executive Directors to further facilitate communication between the Stock Exchange and our Company; and
- (f) meetings between the Stock Exchange and our Directors could be arranged through our authorised 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 authorised representatives and/or the Compliance Advisor.

JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the company secretary must be an individual who, by virtue of his academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary. The Stock Exchange considers the following academic or professional qualifications to be acceptable: (i) a member of The Hong Kong Chartered Governance Institute (formerly known as The Hong Kong Institute of Chartered Secretaries); (ii) a solicitor or barrister (as defined in the Legal Practitioners Ordinance); and (iii) a certified public accountant (as defined in the Professional Accountants Ordinance).

WAIVERS AND EXEMPTIONS

In assessing “relevant experience”, the Stock Exchange will consider the individual’s: (i) length of employment with the issuer and other listed companies and the roles he/she played, (ii) familiarity with the Listing Rules and other relevant law and regulations including the Securities and Futures Ordinance, Companies Ordinance, Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code, (iii) relevant training taken and/or to be taken in addition to the minimum requirement of taking not less than fifteen hours of relevant professional training in each financial year under Rule 3.29 of the Listing Rules, and (iv) professional qualifications in other jurisdictions.

We have appointed Ms. Yu Li (于莉) (“**Ms. Yu**”) and Ms. Chu as our joint company secretaries. Ms. Yu is our vice president and her primary responsibility is the management of administration of our Group. Ms. Yu’s biographical information is set out in the section headed “Directors and Senior Management” in this document. Since Ms. Yu does not possess a qualification stipulated in Rule 3.28 of the Listing Rules, she is not able to solely fulfill the requirements as a company secretary of a listed issuer stipulated 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 in relation to the appointment of Ms. Yu as our joint company secretary. In order to provide support to Ms. Yu, we [have appointed] Ms. Chu, an associate member of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom, who meets the requirements under Rule 3.28 and 8.17, as a joint company secretary to provide assistance to Ms. Yu, for a three-year period from the [REDACTED] so as to enable her to acquire the relevant experience (as required under Rule 3.28(2) of the Listing Rules) to duly discharge her duties. In order to enable Ms. Yu to have good understanding of the Listing Rules and other applicable Hong Kong laws, Ms. Yu has also attended the training given by our Hong Kong legal counsel, Davis Polk & Wardwell. Ms. Chu will also work closely with Ms. Yu to jointly discharge the duties and responsibilities as a company secretary and assist Ms. Yu in acquiring the relevant experience as required under Rules 3.28 and 8.17 of the Listing Rules. Ms. Chu will assist Ms. Yu 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. Ms. Chu will maintain regular contact with Ms. Yu, the Directors and the senior management of our Company. The waiver will be revoked immediately if Ms. Chu ceases to provide assistance to Ms. Yu 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. Ms. Yu 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]. She will also be assisted by 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 the Guidance Letter HKEx-GL108-20, such waiver will be subject to the following conditions: (i) Ms. Yu must be assisted by a person, namely Ms. Chu, who possesses the qualifications or experience as required under Rule 3.28 of the Listing Rules and is appointed as a joint company secretary of our Company throughout the three-year waiver period; and (ii) the waiver can be revoked if there are material breaches of the Listing Rules by us. We will liaise with the Stock Exchange before the end of the three-year period to enable it to assess whether Ms. Yu, having had the benefit of Ms. Chu’s assistance for three years and will have acquired relevant experience within the meaning of Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

WAIVERS AND EXEMPTIONS

See the section headed "Directors and Senior Management" in this document for further information regarding the qualifications of Ms. Yu and Ms. Chu.

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

According to Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, this document shall include an accountants' report which contains the matters specified in the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

According to paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in this document a statement as to the gross trading income or sales turnover (as the case may be) of our Company during each of the three financial years immediately preceding the issue of this document as well as an explanation of the method used for the computation of such income or turnover and a reasonable breakdown of the more important trading activities.

According to paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in this document a report prepared by our Company's auditor with respect to profits and losses of our Company in respect of each of the three financial years immediately preceding the issue of the document and the assets and liabilities of our Company at the last date to which the financial statements were prepared.

According to Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from 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 interests of the [REDACTED] public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or is otherwise unnecessary or inappropriate.

According to Rule 4.04(1) of the Listing Rules, the Accountants' Report contained in this document must include, inter alia, the results of our Company in respect of each of the three financial years immediately preceding the issue of this document or such shorter period as may be acceptable to the Stock Exchange.

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. According to Rule 18A.03(3) of the Listing Rules, a biotech company must have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management. And according to Rule 18A.06 of the Listing Rules, an eligible biotech company shall comply with Rule 4.04 modified so that references to "three financial years" or "three years" in that rule shall instead reference to "two financial years" or "two years", as the case may be.

WAIVERS AND EXEMPTIONS

Accordingly, we have applied to the SFC for, and the SFC [has granted], a certificate of exemption from strict compliance with the requirements under Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, on the conditions that the particulars of the exemption are set forth in this document, on the following grounds.

- (a) our Company is primarily engaged in R&D, application and commercialization of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules;
- (b) the Accountants' Report for each of the two financial years ended December 31, 2021 and 2022 and the six months ended June 30, 2023 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (c) notwithstanding that the financial results set out in this document are only for the two years ended December 31, 2021 and 2022 and the six months ended June 30, 2023 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements; and
- (d) furthermore, as Chapter 18A of the Listing Rules provides track record period for biotech companies in terms of financial disclosure is two years, strict compliance with the requirements of Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome for our Company.

Our Company is of the view that the Accountants' Report covering the two years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, together with other disclosure in this document, has 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] public 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] public.

CONTINUING CONNECTED TRANSACTION

We have entered into and will continue to engage in certain transaction which would constitute continuing connected transaction for our Company under the Listing Rules following completion of the [REDACTED]. [We have applied to the Stock Exchange for, and the Stock Exchange has granted us], waivers from strict compliance with certain requirements set out in Chapter 14A of the Listing Rules for certain continuing connected transactions. For further details of such potential non-exempt continuing connected transaction and the waivers, please see "Connected Transaction".

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 AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Dr. LIU Liping (劉利平)	703, Building 4 Jiixin Garden Longcheng Street Longgang District Shenzhen, Guangdong PRC	United States
Ms. YU Meng (于萌)	6-2-506 Wendelford Garden Houhai Avenue Nanshan District Shenzhen, Guangdong PRC	Chinese
Non-executive Directors		
Mr. LI Li (李鋌)	9C, Building A Huifang Garden Nanguang Road Nanshan District Shenzhen, Guangdong PRC	Chinese
Dr. ZHU Xun (朱迅)	Room 402, Building 33 Yumingbieyuan Guangsheng Road Jiangang Hill Bao'an District Shenzhen, Guangdong PRC	Chinese
Mr. MA Lixiong (馬立雄)	Room 1608 International Chamber of Commerce Center No. 168 Fuhua 3rd Road Futian District Shenzhen, Guangdong PRC	Chinese

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Mr. JIANG Feng (江峰)	Room 701, Block C Poly Central North District No. 2 Jianshe Zhongma Road Yuexiu District Guangzhou, Guangdong PRC	Chinese
Independent non-executive Directors		
Mr. TAN Bo (譚肇)	Flat 32C, Block 6B Imperial Cullinan No. 10 Hoi Fai Road Kowloon Hong Kong	Canadian
Dr. Jin LI (李靖)	Room 701, Unit 7, Building 41 No. 2, Xierqi West Road Haidian District Beijing PRC	United States
Mr. HUNG Tak Wai (孔德偉)	Apt. 10B, Tower 4 Hillsborough Court 18 Old Peak Road Hong Kong	Chinese

Please see the section headed “Directors and Senior Management” in this document for further details of our Directors.

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

UBS Securities Hong Kong Limited
52/F, Two International Finance Centre
8 Finance Street, Central
Hong Kong

Huatai Financial Holdings (Hong Kong) Limited
62/F, The Center
99 Queen's Road Central
Hong Kong

[REDACTED]

DIRECTORS 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

Hong Kong

As to PRC laws:

Han Kun Law Offices

20/F, Kerry Plaza Tower 3

1-1 Zhongxinsi Road

Futian District

Shenzhen, Guangdong

PRC

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

As to Cayman Islands laws:

Conyers Dill & Pearman
29/F, One Exchange Square
8 Connaught Place
Central
Hong Kong

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

As to Hong Kong and United States laws:

Shearman & Sterling
21/F, Gloucester Tower
The Landmark
15 Queen's Road Central
Hong Kong

As to PRC laws:

Commerce & Finance Law Offices
12-14/F, China World Office 2
No.1 Jianguomenwai Avenue
Chaoyang District
Beijing
PRC

**Auditor and Reporting
Accountants**

Ernst & Young
Certified Public Accountants
27/F, One Taikoo Place
979 King's Road
Quarry Bay
Hong Kong

Industry Consultant

China Insights Industry Consultancy Limited
10/F, Block B
Jing'an International Center
88 Puji Road
Jing'an District
Shanghai
PRC

[REDACTED]

CORPORATE INFORMATION

Registered Office	Cricket Square Hutchins Drive P.O. Box 2681 Grand Cayman KY1-1111 Cayman Islands
Head Office and Principal Place of Business in the PRC	18B-102, Zhonghaixin Innovation Industry City Ganli Second Road Jihua Neighborhood Longgang District Shenzhen, Guangdong PRC
Principal Place of Business in Hong Kong	40/F, Dah Sing Financial Centre No. 248 Queen's Road East Wanchai Hong Kong
Company's Website	<u>www.hightidetx.com</u> <i>(information on this website does not form part of this document)</i>
Joint Company Secretaries	Ms. YU Li (于莉) Room 1618, Building 16 Zhonghaixin Innovation Industry City Ganli Second Road Jihua Neighborhood Longgang District Shenzhen, Guangdong PRC Ms. CHU Pik Man (朱璧敏) <i>Associate member of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom</i> 40/F, Dah Sing Financial Centre No. 248 Queen's Road East Wanchai Hong Kong

CORPORATE INFORMATION

Authorized Representatives

Dr. LIU Liping (劉利平)
703, Building 4
Jiixin Garden
Longcheng Street
Longgang District
Shenzhen, Guangdong
PRC

Ms. CHU Pik Man (朱璧敏)
40/F, Dah Sing Financial Centre
No. 248 Queen's Road East
Wanchai
Hong Kong

Audit Committee

Mr. TAN Bo (譚肇) (*Chairman*)
Dr. Jin LI (李靖)
Mr. HUNG Tak Wai (孔德偉)

Remuneration Committee

Dr. Jin LI (李靖) (*Chairman*)
Dr. LIU Liping (劉利平)
Mr. TAN Bo (譚肇)

Nomination Committee

Dr. LIU Liping (劉利平) (*Chairwoman*)*
Dr. Jin LI (李靖)
Mr. HUNG Tak Wai (孔德偉)

Compliance Advisor

Fosun International Capital Limited
Suite 2101-2105, 21/F, Champion Tower
3 Garden Road
Central
Hong Kong

[REDACTED]

* effective upon [REDACTED]

CORPORATE INFORMATION

Principal Banks

Citibank N.A. Hong Kong Branch

21/F, Citi Tower
One Bay East, 83 Hoi Bun Road
Kwun Tong, Kowloon
Hong Kong

Bank of China Shenzhen Branch

2nd Floor, International Finance Building
No. 2022 Jianshe Road
Shenzhen
PRC

China Merchants Bank Shenzhen Branch

14th Floor
China Merchants Bank Shenzhen Branch Building
No. 2016 Shennan Avenue
Futian District
Shenzhen
PRC

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from the report prepared by China Insights Consultancy, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged China Insights Consultancy to prepare the CIC Report, an independent industry report, in connection with the [REDACTED]. The information from official government sources has not been independently verified by us, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy, fairness and completeness.

OVERVIEW OF METABOLIC AND DIGESTIVE DISEASES

Introduction to Metabolic and Digestive Diseases

Metabolic and digestive diseases occur when a number of organs fail to function normally due to a lack of hormones or enzymes. These two types of diseases involve multiple organs and factors and the synergistic effect between them can worsen the condition. In addition, these diseases can lead to a number of complications and in some cases, the primary goal of treatment is to manage these complications.

There is a high prevalence of metabolic disorders and digestive diseases globally, primarily including MASH, T2DM, and obesity, which are usually caused by a complex interplay of genetic, environmental, and lifestyle factors, and are thus characterized by outstanding heterogeneity. It is clear that the treatment pathway of these diseases lies in polypharmacology, which can be a combination of multiple drugs to different targets or a drug with multitarget, to provide holistic care for a diverse group of patients. In addition, because patients' experiences and responses to treatment can vary widely, diversifying treatment options not only increases the chances of effectively managing the disease, but also allows patients to make choices based on their considerations. Thus, the industry is searching for multiple therapeutic procedures simultaneously to provide cares for a greater number of patients suffering from heterogeneous disorders and to address the intricate networks of disease mechanisms.

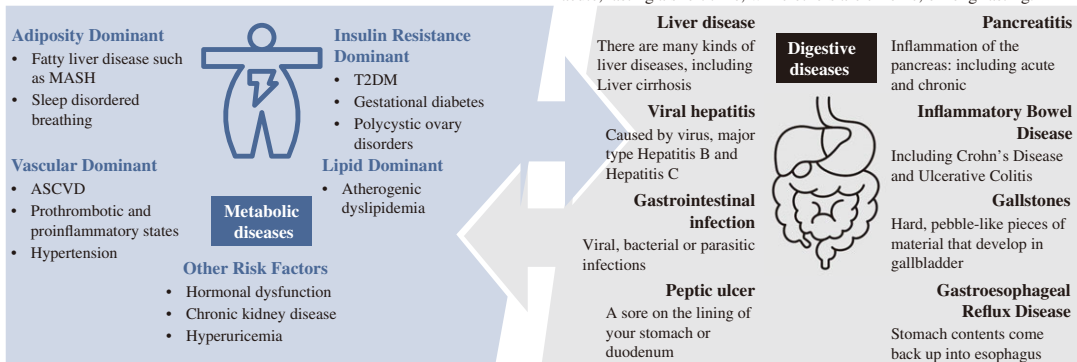
There are no current and anticipated changes in the field of targeted metabolic therapeutic areas, such as clinical guidelines, treatment paradigm, and diagnosis techniques.

INDUSTRY OVERVIEW

The following diagram illustrates the details of metabolic and digestive diseases.

Metabolic diseases

- Metabolic disorders is a complex, pathophysiological state composed of a cluster of clinically measured and typically unmeasured risk factor, is progressive in its course, and is associated with serious and extensive comorbidity, but tends to be clinically under-recognized.



Digestive diseases

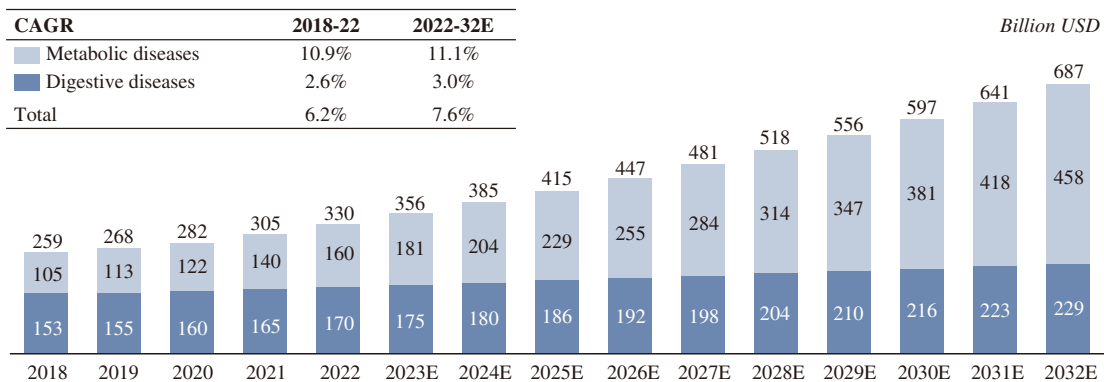
- The digestive system made up of gastrointestinal tract (GI), liver, pancreas, and gallbladder helps the body digest food.
- Digestive diseases have become prevalent in a large part of the world population. Some digestive diseases and conditions are acute, lasting a short time, while others are chronic, or long-lasting.

Source: National Institute of Diabetes and Digestive and Kidney Diseases; The CardioMetabolic Health Alliance: Working Toward a New Care Model for the Metabolic Disorders; CIC

Global Market Size of Major Metabolic and Digestive Diseases

The following chart illustrates the historical and projected expansion of global market of major metabolic and digestive diseases.

Global Market Size of Major Metabolic and Digestive Diseases, 2018-2032E



Notes:

- Major metabolic diseases include diabetes, MASLD, hypertriglyceridemia, obesity, diabetic neuropathy, etc.
- Major digestive diseases include liver cirrhosis, gallbladder and biliary diseases, inflammatory bowel disease, pancreatitis, upper digestive system diseases, etc.

Source: Annual reports published by market players, Expert interview, Literature research, CIC

INDUSTRY OVERVIEW

The following chart sets forth the top 10 metabolic disorders and digestive diseases drugs in terms of annual sales in 2022, approved by the FDA in recent years.

Top 10 Metabolic and Digestive Diseases Drugs in Terms of Sales in 2022

Rank	Drug name	Manufacturer	Indication	MoA/target	Annual sales, 2022 (USD Billions)
1	OZEMPIC	Novo Nordisk	Diabetes	GLP-1R	8.6
2	TRULICITY	Eli Lilly	Diabetes	GLP-1R	7.4
3	JARDIANCE	Eli Lilly	Diabetes	SGLT2i	6.1
4	JANUVIA	Merck	Diabetes	DPP-4i	5.7
5	ENTYVIO	Takeda	Ulcerative colitis and Crohn's disease	A4β7	5.2
6	FARXIGA	AstraZeneca	Diabetes	SGLT2i	4.4
7	LANTUS SOLOSTAR	Sanofi	Diabetes	Insulin	2.4
8	HUMALOG	Eli Lilly	Diabetes	Insulin	2.1
9	RYBELSUS	Novo Nordisk	Diabetes	GLP-1R	1.7
10	Novorapid	Novo Nordisk	Diabetes	GLP-1R	1.4

Source: Annual reports published by market players, Expert interview, Literature research, CIC

Future Trends of the Metabolic and Digestive Diseases Treatment Market

According to CIC, the global metabolic and digestive disease treatment market has demonstrated the following trends:

- Targeting multiple targets simultaneously to address complex diseases.** As complex diseases continue to challenge the healthcare industry, the innovation therapies have been developed from single-target drugs to drug combination, then to single drug with multiple targets, finally developing a multifunctional drugs approach. The following chart compares treatment options among single-target drugs, drug combination, fixed dose combination, and multifunctional drugs.

	Single-target drugs	Drug combination	Fixed Dose Combination (FDCs)	Multi-functional drugs	
Efficacy					<ul style="list-style-type: none"> Traditional treatments are symptom-by-symptom, organ-by-organ basis, which did not consider the multi-organ physiological effects of this complex disease, while multi-functional drug tackles through multiple pathways, which would have much improved potency.
Synergistic effect					<ul style="list-style-type: none"> Though drug combination therapies tend to have better efficacy comparing to single-target drugs, its synergistic effect is limited. Multi-functional drugs could work synergistically in distinct disease pathways.
Safety					<ul style="list-style-type: none"> Single-target drug usually have multiple side effects such as increased blood sugar, kidneys affection. Drug combination and FDCs on the other hand have a higher risk of drug-drug interactions. Yet great synergistic effect of multi-functional drugs results in a lower side effect and lower toxicity.
Patient compliance					<ul style="list-style-type: none"> With multi-functional drugs, patients trade a handful of pills for a single pill, which improve patients' compliance.

Source: Multitarget Drugs: Strategies and Challenges for Medicinal Chemists; CIC

INDUSTRY OVERVIEW

- *Benefit of multiple pathways.* Diseases are often the result of a breakdown of a powerful physiological system due to multiple genetic and/or environmental factors. Complex diseases are therefore more likely to be cured or alleviated by the simultaneous modulation of multiple targets or pathways. Multifunctional agents that can simultaneously target multiple pathways and modulate multiple biological targets show significant advantages in terms of higher efficacy, better safety and simpler administration compared to single target agents.
- *Chinese medicine internationalization and globalization.* The combination of Chinese medicine with modern scientific system has contributed to its internationalization and globalization. Along the continuous development and progress of modern science and technology, the quality identification, extraction and separation, analysis and detection of Chinese medicine become more mature and developed, which would contribute to Chinese medicine internationalization. In addition, favorable policies have been introduced to promote the globalization of Chinese medicine in China. In the “National 14th Five-Year Plan” period (2021-2025), Chinese medicine is given priority in reform and development of the industry. One of the ten critical tasks outlined in the “National 14th Five-Year Plan” for Chinese medicine is the expansion of its international trade. In addition, the “National 14th Five-Year Plan” for Chinese medicine announced that the internationalization of Chinese medicine should be achieved through integration of high-quality development of both Chinese medicine and the “Belt and Road Initiative”. For example, during the 2021 China International Fair for Trade in Services, the government pledged to build a global platform and push forward constructing a series of Chinese medicine globalization projects to improve the level of Chinese medicine service and trade. As of May 29, 2023, there are two FDA-approved innovative Chinese drugs and over 200 ongoing clinical trials globally, suggesting good trends of Chinese medicines.

OVERVIEW OF METABOLIC SYNDROME DRUG MARKET

Overview of MASH Drug Market

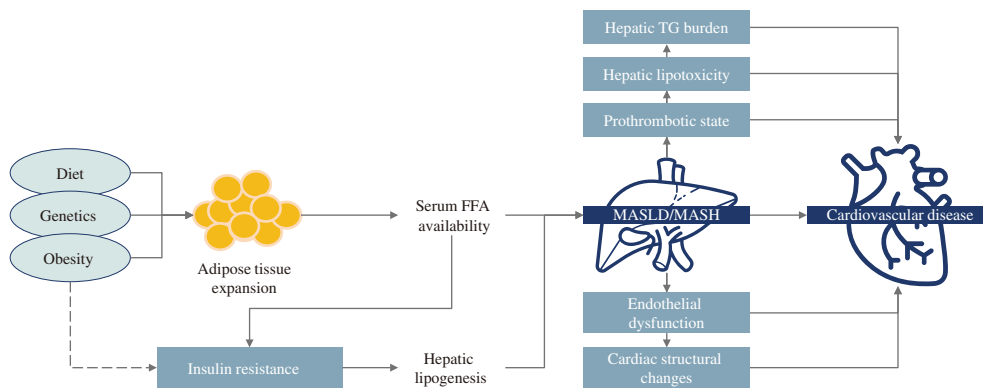
Introduction to MASH

MASH is liver inflammation and damage caused by a buildup of fat in the liver. It is the more severe form of metabolic dysfunction-associated steatotic liver disease (“MASLD”), an umbrella term for a range of liver conditions affecting people who drink little to no alcohol. If left untreated, MASH can cause scarring of the liver, which leads to permanent scarring (cirrhosis) and liver cancer. MASLD is characterized by steatosis of the liver, and MASH is a necro-inflammatory process whereby the liver cells become injured under steatosis. At EASL Congress 2023, the multinational liver societies leaders from La Asociación Latinoamericana para el Estudio del Hígado, American Association for the Study of Liver Diseases, and European Association for the Study of the Liver as well as the co-chairs of the MASLD Nomenclature Initiative announced that steatotic liver disease was chosen as an overarching term to encompass the various aetiologies of steatosis. MASLD will now be metabolic dysfunction-associated steatotic liver disease. Metabolic dysfunction-associated steatohepatitis is the replacement term for MASH.

INDUSTRY OVERVIEW

The complications of MASH include:

- **Fibrosis and cirrhosis:** The inflammation and liver cell damage will lead to fibrosis. If the patient is left untreated, scar tissue will continue to replace healthy liver tissue, thus leading to cirrhosis, which is an advanced, late stage of scarring. About 20% of people with MASH will progress to cirrhosis over several years.
- **Liver failure:** If cirrhosis is not treated, the liver will not be able to work well or cannot work at all. A liver transplant may be needed at this stage.
- **Liver cancer:** One complication of cirrhosis is liver cancer. MASH patients have increased risk of hepatocellular carcinoma.
- **Cardiovascular disease/type 2 diabetes mellitus (“T2DM”):** MASLD or MASH may further cause cardiovascular disease/T2DM, and cardiovascular disease is the most common cause of death in MASLD or MASH patients. Many patients with MASLD/MASH have a high prevalence of cardiac risk factors, such as obesity, diabetes, and dyslipidemia, which further contribute to both MASLD/MASH and cardiovascular disease. Patients often focus on liver enzymes, but neglect more critical cardiovascular health aspects. However, it is important to recognize that treating MASLD/MASH may also have a positive impact on cardiovascular health. For example, weight loss and optimal management of diabetes and dyslipidemia can improve hepatic histology and reduce cardiovascular morbidity. Thus, the mortality rate of these interrelated diseases including cardiovascular disease will not limit the market potential of the Core Product. The following chart demonstrates the pathophysiologic mechanisms linking hepatic steatosis to cardiovascular disease.



Abbreviations: FFA: free fatty acid; TG: triglyceride.

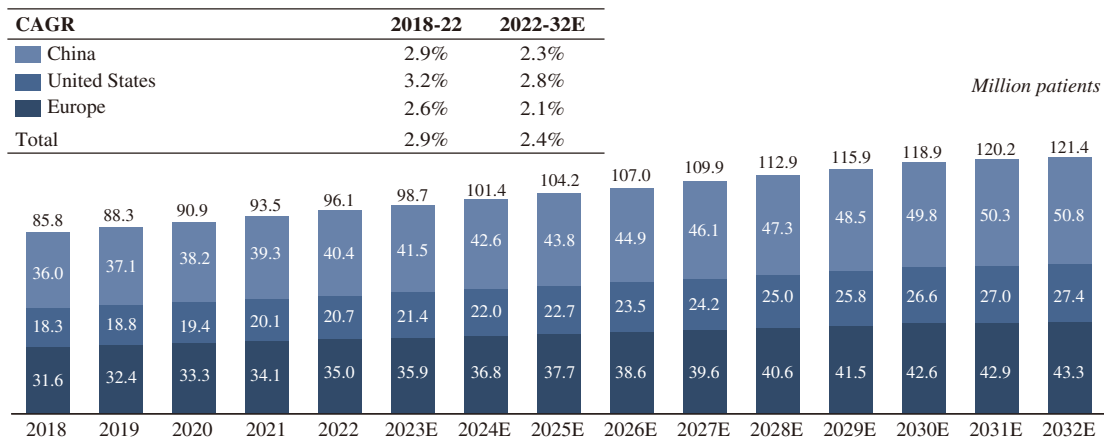
Source: HHS Public Access; CIC

INDUSTRY OVERVIEW

Prevalence of MASH in China, the United States and Europe

The following charts set forth the prevalence of MASH in China, the United States and Europe from 2018 to 2032.

Prevalence of MASH in China, the United States and Europe (2018-2032E)



Source: Expert interview, Literature research, CIC

Current Treatment Regimen

The global and China markets follow the same treatment regimen. The international and national guidelines recommend that management for MASLD and MASH patients varies depending on their risk of clinical liver fibrosis. Due to its complex pathogenesis, medication for MASH is still currently underdeveloped. In both the United States and China, no evidence-based pharmacological therapy is approved, and treatment of MASH and MASLD, which is also the prevention method, is currently limited to managing health conditions and making lifestyle changes, such as losing weight, controlling diabetes, avoiding alcohol, exercising regularly, reducing the total cholesterol level, and taking supplement with vitamin E. In addition, while there is no specific medication that directly treats MASH, taking metformin and statins treats the related metabolic disorders such as insulin resistance and high cholesterol, further facilitating the treatment of MASH. In addition, the American Association for the Study of Liver Diseases confirms that vitamin E and pioglitazone (a drug used to treat diabetes) are the two best drug choices for biopsy-confirmed MASH, but questions remain about safety, efficacy, and side effects.

INDUSTRY OVERVIEW

The Core Product is intended to be first-line treatment of MASH. The following table sets forth the recommendation for MASLD and MASH patient management according to international guidelines.

MASLD/MASH Clinical Care Pathway multidisciplinary task force — Recommended management of patients with MASLD/MASH			
Risk level	Low risk	Intermediate risk	High risk
Patient stratification	FIB-4 < 1.3 or LSM < 8 kPa or liver biopsy F0-F1	FIB-4 1.3–2.67 and /or LSM 8–12 kPa and liver biopsy not available	FIB-4 > 2.67 or LSM >12 kPa or liver biopsy F2-F4
Lifestyle intervention	All patients require regular physical activities, healthy diet, and avoid excess alcohol intake		
Weight loss recommended if overweight or obese	May benefit	Greater need	Strong need
	<ul style="list-style-type: none"> Structured weight loss programs Anti-obesity medications Bariatric surgery 		
Pharmacotherapy for MASH	Not recommended	No pharmacological agent is FDA-approved so far for MASH treatment; Patients with T2DM may benefit from some diabetes medications such as pioglitazone and some GLP-1 RAs; Vitamin E improves steatohepatitis in patients with MASH without diabetes, with less evidence in patients with T2DM	
		Not applicable	Pharmacotherapy for MASH cirrhosis is very limited and should be avoided
CVD risk reduction	Statins can be used safely in patients with steatohepatitis and liver fibrosis, but is to be avoided in decompensated cirrhosis		
Diabetes care	Standard of Care of diabetes	Medications with efficacy in MASH (pioglitazone, GLP-1 RA) preferred	

Abbreviations: *FIB-4*: fibrosis-4; *LSM*: liver stiffness measurement; *CVD*: cardiovascular disease; *GLP-1 RA*: glucagon-like peptide 1 receptor agonist

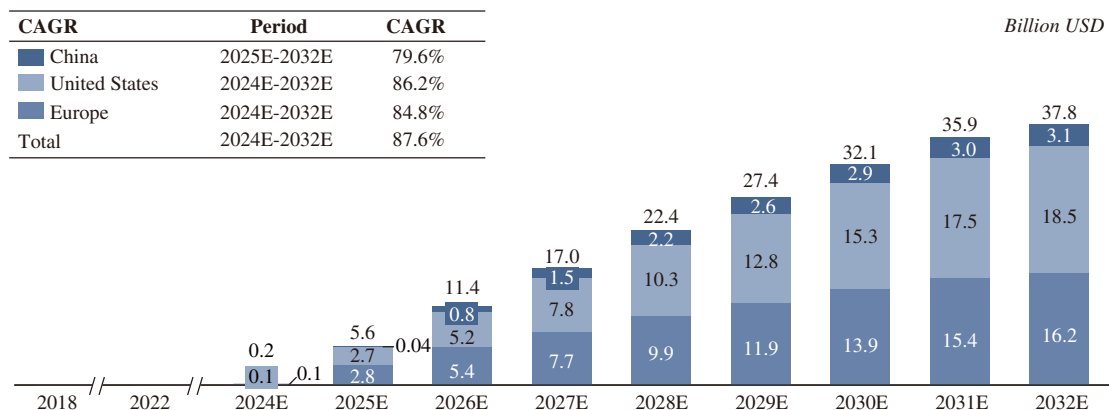
Note: *F0-F4* are stages of liver fibrosis that measure the amount of fibrosis. *F0* is no scarring (no fibrosis); *F1* is minimal scarring; *F2* is scarring that has occurred and extends outside the liver area (significant fibrosis); *F3* is fibrosis spreading and forming bridges with other fibrotic liver areas (severe fibrosis); and *F4* is cirrhosis or advanced scarring.

Source: Gastroenterology, CIC

MASH Drug Market Size

The following chart sets forth the market size of MASH drug in China, the United States and Europe from 2018 to 2032.

MASH Drug Market Size in China, the United States and Europe, 2018-2032E



INDUSTRY OVERVIEW

Note: The size and significant growth of MASH drug market in China, the United States and Europe is estimated with the following assumptions: (i) market is estimated as the average MASH drug price multiplied by the number of treated patients. In 2024, the number of MASH patients globally is expected to be 101.4 million and in 2032, this number is expected to reach 121.4 million. For details, see “— Prevalence of MASH in China, the United States and Europe” in this section above; (ii) the price assumption is based on the prices of other first-in-class drugs for chronic diseases; (iii) the MASH drugs expected to be approved in forecast period would not be covered in national or regional volume-based procurement program in China; (iv) the range of diagnosis rates of advanced stage (F3~F4) of fibrosis among MASH patients is expected to be within 14%~15%, 25%~30% and 25%~30% in China, the U.S. and Europe, respectively; the initial MASH-indicated drug adoption rates in total MASH patients are expected to be 0.3%, 0.3%, and 0.3% in 2028 in China, the U.S. and Europe, respectively, and the expected range of annual treatment cost of MASH indicated drug is expected to be within USD1,000~3,000, USD9,000~10,000 and USD5,000~6,000 in China, the U.S. and Europe, respectively; the price change in China, the United States and Europe is in line with the industry trend; (v) based on the current pipeline under development, in the United States and Europe, the first MASH drugs (resmetirom and dapagliflozin) are expected to be approved in 2024, and in China, the first MASH drug (dapagliflozin) is expected to be approved in 2025. The approval timeline is estimated on the trial status, duration of a Phase III trial and public announcements by the trial sponsors; (vi) a number of MASH drugs, including but not limited to cotadutide and IVA337 which are currently in the Phase III clinical stage, are expected to be approved and commercialized from 2025 onwards. For details, see “— competitive landscape of MASH drug market” in this section below; (vii) increased academic promotion and physician education by market players; (viii) the patient population that can be given MASH drugs continue to grow; (ix) because no medications specifically indicated for MASH have been approved, the treatment rate of drugs that are indicated for MASH is currently 0%. As the expected approval of drugs specifically indicated for MASH address the unmet clinical needs, MASH patients will quickly adopt these MASH-indicated drugs and the number of treated patients will then grow rapidly, leading to significant growth in market size after MASH-indicated drugs are approved.

In 2024, MASH drug market is expected to be null, US\$127.8 million and US\$118.6 million in China, the United States and Europe, respectively.

Source: Expert interview, Literature research, CIC

Competitive Landscape of MASH Drug Market

According to CIC, there is no medication currently approved for the treatment of MASH in the United States, the Europe and Mainland China. To date, only resmetirom from Madrigal Pharmaceutical has been filed with NDA seeking for accelerated approval from FDA. As of the Latest Practicable Date, there were more than 100 active clinical trials in the field of MASH treatment registered under ClinicalTrials and regulated by the FDA, including one drug candidate under NDA stage, seven drug candidates in Phase III clinical stage and more than 60 drugs in Phase II clinical stage regulated by the FDA. Intercept’s ocaliva, one of the most advanced MASH drugs in the clinical stage, filed the second application for MASH but it was rejected by the FDA in June 2023. The FDA concluded that benefits of ocaliva did not outweigh the risks in MASH patients with fibrosis based on current data. In addition, the FDA reviewers flagged increased risk of diabetes and liver injury from using the oral tablets, called obeticholic acid (“OCA”), for the treatment of MASH. Thus, Intercept announced in June 2023 that it discontinued the MASH clinical trial for ocaliva. The following chart sets forth the details of MASH drug candidates under NDA and Phase III clinical stage regulated by the FDA.

INDUSTRY OVERVIEW

Pipeline of MASH Drugs under NDA and Phase III Clinical Stage Regulated by the FDA

Drug Name	Target	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent Authority
Resmetrom	THR β	Madrigal	MASH with Liver Fibrosis	Oral	NDA	2022/08/15	NCT05500222	FDA
Cotadutide	Dual GLP-1/GCCR	AstraZeneca	Non-cirrhotic Non-alcoholic Steatohepatitis with Fibrosis	Injection	III	2022/05/06	NCT05364931	FDA
Lanifibranor (IVA337)	PPAR	Inventiva Pharma	MASH	Oral	III	2021/04/19	NCT04849728	FDA
Semaglutide	GLP-1	Novo Nordisk A/S	MASH	Injection	III	2021/03/30	NCT04822181	FDA
Belapectin	Galectin-3	Galectin	MASH	Injection	III	2020/04/28	NCT04365868	FDA
Aramchol ¹	SCD	Galmed	MASH	Oral	III	2019/09/26	NCT041104321	FDA
MSDC-0602K	MPC	Cirius Therapeutics	T2DM, MASH, MASLD	Oral	III	2019/05/31	NCT04618744	FDA
Dapagliflozin	SGLT-2	AZ/BMS	MASH	Oral	III	2018/10/29	NCT03723252	FDA
HTD1801	Multiple pathways	HighTide Biopharma	Fatty Liver (Nonalcoholic), MASLD, NFLD, MASH, T2DM, Digestive System Disease	Oral	II	2018/09/04	NCT03656744	FDA

Note: 1. The recruitment of this clinical trial is suspended, and the interim analysis of data from open-label part showed this part of the study met its objectives. The initiation of the double-blind part of the study has been delayed because aramchol meglumine needs to be formulated.

Source: ClinicalTrials; CIC

As of the Latest Practicable Date, there were more than 20 active clinical trials for MASH treatment regulated by the NMPA, including one drug candidate in Phase III clinical stage. The following chart sets forth the details of MASH drug candidates under Phase II and Phase III clinical stage regulated by the NMPA.

Pipeline of MASH Drugs in Phase II to III Clinical Stages Regulated by the NMPA

Drug Name	Target	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent Authority
Semaglutide	GLP-1	Novo Nordisk A/S	MASH	Injection	III	2021/07/27	CTR20211818	NMPA
Lanifibranor (IVA337)	PPAR	Inventiva Pharma	MASH	Oral	III	2023/09/11	CTR20232876	NMPA
HEC88473	Dual GLP-1/FGF21	Guangdong HEC Technology	MASH, T2DM, Obesity	Injection	II	2023/08/17	CTR20232481	NMPA
Coptis glycosides capsules	N/A	Tipr Pharmaceutical	MASH	Oral	II	2023/08/12	CTR20222042	NMPA
Recombinant human FGF21-Fc	FGF21	AMPSOURCE BIOPHARMA	MASH	Injection	II	2023/08/11	CTR20232280	NMPA
Fusion protein (AP025)	N/A	AstraZeneca	MASH	Injection	II	2023/07/11	CTR20232127	NMPA
AZD2693	N/A	Guangdong Zhongsheng Pharmaceutical	MASH	Oral	II	2022/12/30	CTR20223378	NMPA
ZSP1601 Capsule	PDE	Pharmaceutical	MASH	Oral	II	2022/12/30	CTR20223378	NMPA
ASC41 Capsule	N/A	Asclepis Pharma	MASH	Oral	II	2022/06/21	CTR20221529	NMPA
Chiglitazar Sodium	PPAR	Chipscreen	MASH	Oral	II	2021/12/07	CTR20213202	NMPA
BI 456906	GLP-1	Boehringer Ingelheim	MASH	Injection	II	2021/09/01	CTR20212081	NMPA
HEC96719	FXR	HEC pharmaceutical	MASH	Oral	II	2021/07/27	CTR20211428	NMPA
CZ130 Capsule	N/A	Hongjing	MASH	Oral	II	2021/05/13	CTR20210871	NMPA
PF-06865571	ACC, DGAT2	Pfizer	MASH	Oral	II	2021/03/15	CTR20210412	NMPA
MK-3655	KLB, FGFR1	Merck & Co.	MASH	Injection	II	2021/01/21	CTR20210074	NMPA
HSK-31679	THRβ	Haisco	MASH	Oral	II	2023/11/09	CTR20233629	NMPA
Eliopeglutide (MK-6024)	GLP1R; GCGR	Merck & Co.	MASH	Injection	II	2023/10/19	CTR20233311	NMPA

Source: ClinicalTrials; CDE; CIC

We have completed the HTD1801 Phase IIa clinical trial for MASH indication. The following chart shows the comparison of clinical results of HTD1801 Phase IIa clinical trial and selected clinical trials that entered Phase III stages with posted Phase II results.

INDUSTRY OVERVIEW

Comparing the HTD1801 Phase IIa Results for MASH Indication with Selected Trials Registered at ClinicalTrials⁽¹⁾

Drug name	Target	Company	Intent-to-treat	Administration	Endpoints in Phase II clinical trials		Results by study groups			
					Groups	Time frame: 18 week	500mg	1000mg	Placebo	
HTD1801	BUDC	HighTide	MASH and T2DM	Oral	Primary endpoint	Absolute change in LFC as measured by MRI-PDFF from Baseline to Week 18 [Absolute Change from Baseline to Week 18/Early Termination, LS mean]	-3.198	-4.681	-1.824	
					Additional LFC secondary endpoints	Relative change in LFC as measured by MRD-PDFF from Baseline to Week 18	-15.942%	-23.308%	-8.231%	
					Secondary endpoints	Changes in HbA1c from Baseline to Week 18 [Percent Change from Baseline to Week 18, mean]	-4.4%	-7.4%	1.3%	
						Changes in ALT from Baseline to Week 18 [Percent Change from Baseline to Week 18, mean]	-6%	-21%	-6%	
					Secondary endpoints	Changes in AST from Baseline to Week 18 [Percent Change from Baseline to Week 18, mean]	3%	-14%	-5%	
						Changes in GGT from Baseline to Week 18 [Percent Change from Baseline to Week 18, mean]	-23%	-29%	5%	
						Number (%) of Serious TEAE (Treatment-Emergent Adverse Events) in TEAE	1 (5%)	1 (4%)	1 (5%)	
					Groups	Time frame: 24 week	800mg	Placebo		
Lanifibranor	PPAR	Inventiva	MASLD and T2DM	Oral	Primary endpoint	Change in intrahepatic triglycerides (HTG) quantified by proton magnetic resonance and spectroscopy (H-MRS) [LS Means Relative Percent change from Baseline in Liver Fat at Week 24], FAS ²		-46%	-12%	
					Secondary endpoints	Proportion of patients with a decrease from baseline in HTG (quantified by H-MRS) to week 24 of $\geq 30\%$ [Percentage of patients achieving liver fat reduction $\geq 30\%$ at week 24], FAS ^{2b}		65%	22%	
					Secondary endpoints	Proportion of patients with MASLD resolution, defined as having $\leq 5.5\%$ HTG (quantified by H-MRS) [Percentage of patients achieving MASLD resolution at week 24], FAS		25%	0%	
						Change in glycemic control (HbA1c) [LS Mean absolute Change from Baseline to week 24], Completers		-0.9	-0.2	
						Improvement in muscle insulin sensitivity (Rd) [LS Mean absolute change from Baseline to week 24], Completers		2.2	-0.2	
						Number (%) of SAE in TEAE		1 (5%) ^{2b}	0 (0%) ^{2b}	
Resmetromir	THR B	Madrigal	Biopsyproven MASH (stage 1-3) with $\geq 10\%$ liver fat content on PDFF-MRI	Oral	Groups	Time frame: 12 and 36 week	80mg Week 12	Placebo Week 12	80mg Week 36	Placebo Week 36
					Primary endpoint	Relative change from baseline in hepatic fat fraction assessed by MRI-PDFF [LS mean]	-22.5%	-10.4%	-28.4%	-8.9%
					Secondary endpoints	Proportions of patients with 30% or more relative hepatic fat reduction assessed by MRI-PDFF	60.3%	18.4%	67.6%	29.4%
						Alanine Aminotransferase (ALT), (IU/L) [LS mean differences of change from baseline compared to placebo]	-3.0	n/a	-26.4	n/a
						Aspartate Aminotransferase (AST), (IU/L) [LS mean differences of change from baseline compared to placebo]	-4.8	n/a	-11.1	n/a
						Number (%) of SAE in TEAE			2 (5%) ^{2b}	6 (7%) ^{2b}

Notes:

- No head-to-head comparison of clinical studies was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and the non head-to-head comparison may not be representative of the overall data.
- FAS: Full analysis set. The FAS population consists of all subjects randomly assigned to treatment who received at least one dose of trial medication.
- The numbers shown represent total number of severe adverse events in treatment-emergent adverse events during treatment period.

Source: ClinicalTrials; Corporate presentation of Inventiva (June 2023); CIC

Market Drivers and Entry Barriers of MASH Drug Market

The MASH drug market growth has primarily been driven by the following key factors:

- Strengthened public awareness:** A growing number of people of different ages, genders, races and occupations in the world have been suffering from metabolic and digestive diseases, including MASH. Accordingly, the public, governments, medical institutions and social media pay more attention to metabolic and digestive diseases, which in turn strengthens public awareness for MASH disease. More diversified marketing channels can be used to educate doctors and MASH patients on disease diagnosis and pharmaceutical interventions. For example, the National Health Commission of China has initiated a specific training program for metabolism physicians from regional medical and health services since 2022, in order to ensure the correct diagnosis for metabolic diseases, including MASH. More MASH care clinics are also opened in China, allowing doctors to provide patients with more comprehensive treatment on rational medication use and lifestyle intervention. In addition, improvement of diagnostic techniques further drives the market forward of

INDUSTRY OVERVIEW

MASH disease. For example, more diagnostic techniques have become available to diagnose MASH, such as physical examination, imaging test and liver biopsy. During the physical examination, doctors usually examine body weight and height of subjects to calculate body mass index, and also examine liver and/or signs of insulin resistance or cirrhosis. If the subject has the body mass index over 30 kg/m² or has the enlarged liver or insulin resistance or cirrhosis, the subject is unhealthy and more likely to develop MASH. Furthermore, liver biopsy can prove a diagnosis of MASH and show clearly how severe the disease is. Doctors usually do not recommend liver biopsy method for suspected MASH patients, but if the subject is more likely to have MASH with advanced fibrosis or if other tests show signs of advanced liver disease or cirrhosis, doctors may recommend a liver biopsy to rule out other liver diseases and diagnose MASH. Thus, more subjects use physical examination, imaging test and liver biopsy to diagnose MASH, further increasing the demand for pharmaceutical interventions.

- *Expansion of vulnerable population:* As a metabolic disease, MASH is associated with risk factors including, among others, obesity, T2DM, age, obstructive sleep apnea, and abnormal fat levels in the blood. As the world's obesity and T2DM population grows, the MASH population will accordingly grow.
- *Novel treatments to fulfil unmet needs:* As of May 2023, in China, the United States and Europe, no medications indicated for MASH have been approved. As the public gains a better understanding of MASH disease and novel treatments indicated for MASH are expected to be approved, the MASH patients will quickly adopt these newly-approved drugs, thus driving significant growth of MASH drug markets.
- *Growing spending power:* Increased per capita disposable income in China has made it easier for patients to afford more expensive medical fees. With growing spending power, more and more patients will be able to afford novel medications, further driving the growth of MASH drug markets.

Despite the drivers discussed above, significant entry barriers remain in the MASH market:

- *Technological barrier:* The development of novel treatment for MASH requires advanced disease understanding and technological capabilities, especially when the pathogenesis of MASH still needs further research. Companies and manufacturers that are equipped with advanced technologies and know-how would have technological advantages in this market.
- *Regulatory barrier:* The development of drugs and medications is strictly regulated. Companies and manufacturers that have little experience in drug development or are unfamiliar with relevant regulations and compliance knowledge would be difficult to compete in this market.
- *Capital barrier:* Drug development process is a lengthy and capital-intensive activity, which requires enormous amount of capital investment and other kinds of resources to be consistently invested. New entrants of the market usually have limited financial capabilities and liquidity.

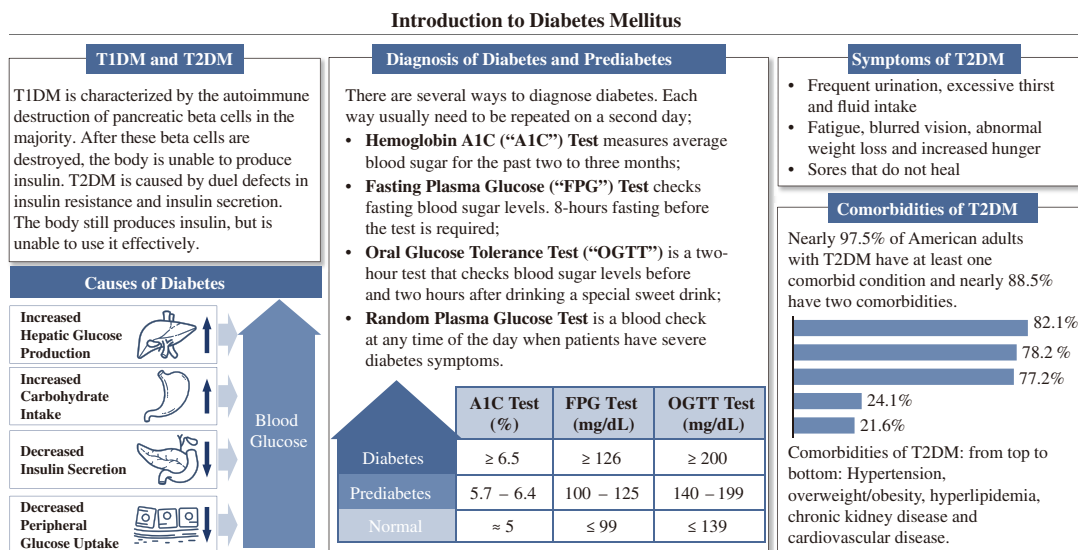
INDUSTRY OVERVIEW

- Talent barrier:** The innovative drug industry is a technology-intensive and multi-disciplinary industry, involving biology, pharmacology, and clinical research etc. Talents are highly sought-after in product development, registrational clinical research and market research. Therefore, it is difficult for newly-entered companies to hire more top talents with multi-domain knowledge in the short term, which directly leads to the slow development and low efficiency of newly-entered companies.
- Sales and marketing barrier:** Sales and marketing activities are critical in the pharmaceutical industry, especially for innovative treatments. Newly-entered companies usually have difficulty to construct a sales and marketing team with rich experiences.

Overview of T2DM Drug Market

Introduction to T2DM

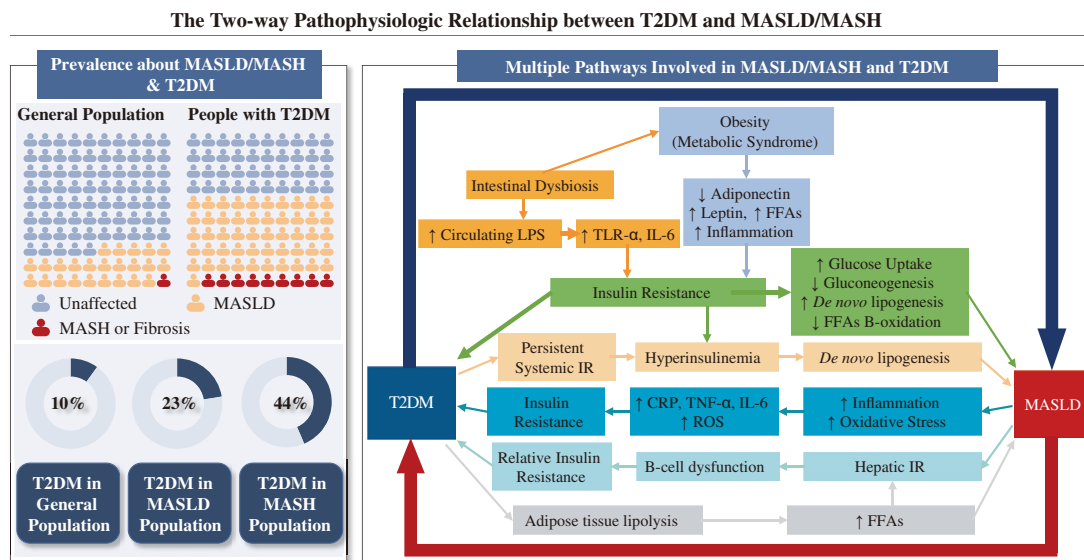
Diabetes is a disease in which blood glucose, or blood sugar, levels are too high. Glucose comes from the food, and insulin is a hormone produced by pancreas that helps the glucose get into cells to give them energy to maintain normal physiological function. With type 1 diabetes, body does not make insulin. With type 2 diabetes, body does not make or use insulin well. T2DM is an impairment in the way the body regulates and uses glucose as a fuel. It is a chronic condition resulting in too much sugar circulating in the bloodstream. The following chart illustrates the details of diabetes mellitus and T2DM.



Source: Medscape, American Diabetes Association, CIC

INDUSTRY OVERVIEW

In particular, worldwide prevalence of MASLD among people with T2DM is 55.5% in 2022. MASLD, also known as metabolic (dysfunction) associated steatotic liver disease, is excessive fat build up in the liver without another clear cause such as alcohol use. Most MASLD patients are asymptomatic, with fatigue or pain or discomfort in the upper right abdomen. A broad range of risk factors of MASLD include T2DM, high cholesterol, high triglycerides level, metabolic syndrome, polycystic ovary syndrome, hypothyroidism, hypopituitarism, obesity, and obesity particularly when fat is concentrated in the abdomen. The following diagram illustrates the details of two-way pathophysiological relationship between T2DM and MASLD or MASH. The relationship between MASLD/MASH and T2DM is not simply a one-to-one complement to each other. While the definitive mechanisms involved are still being investigated, the bidirectional pathophysiological relationship suggests that there are multiple pathways involved in this relationship.



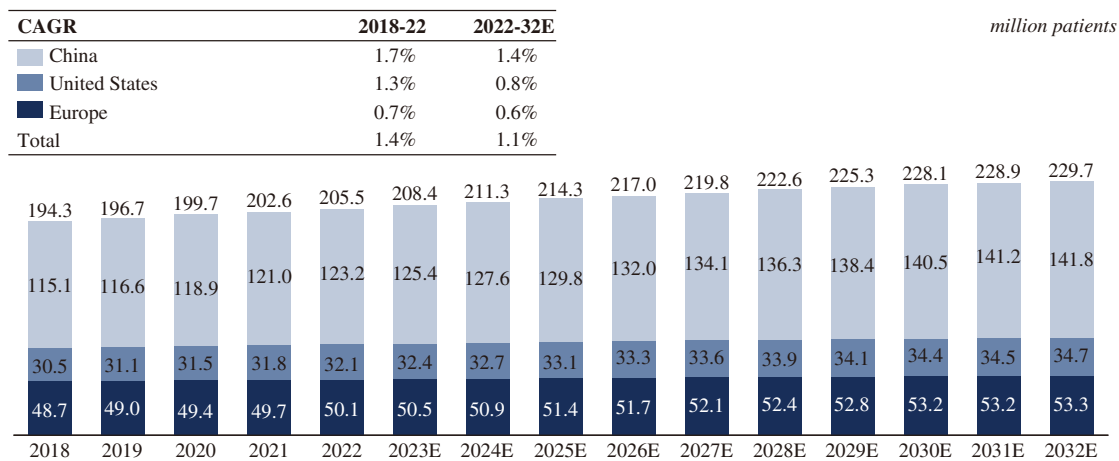
Source: Open Exploration, CIC

INDUSTRY OVERVIEW

Prevalence of T2DM in China, the United States and Europe

The following charts set forth the prevalence of T2DM in China, the United States and Europe from 2018 to 2032.

Prevalence of T2DM in China, United States and Europe, 2018-2032E



Source: Literature research, CIC

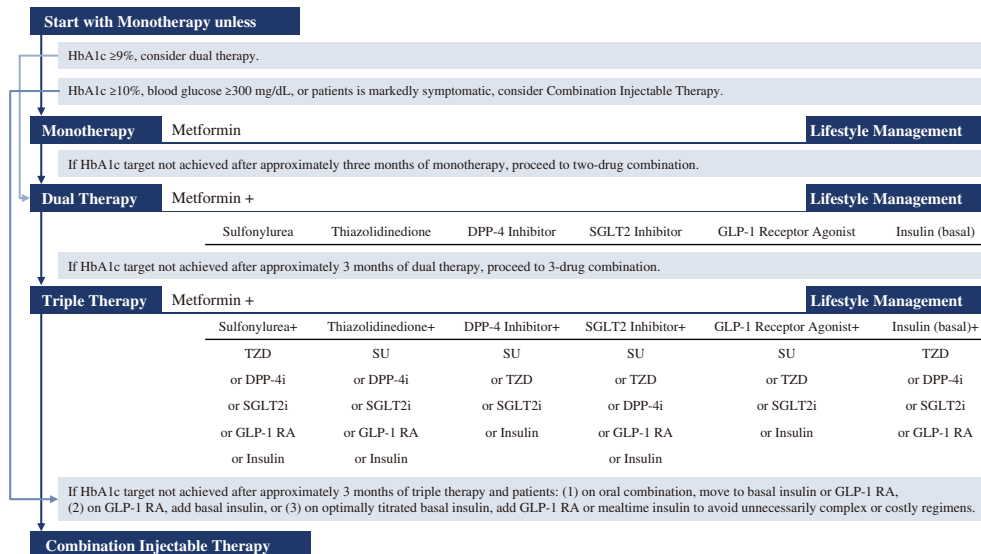
Current Treatment Regimen

The treatment regimen of T2DM, which is also the prevention method, includes healthy eating, regular exercise, weight loss and blood sugar monitoring. Other treatments include diabetes medication and insulin therapy, such as the use of insulin pump devices. If adequate glycemia cannot be achieved, metformin is the first-line therapy. Following metformin, many other therapies such as oral sulfonylureas, dipeptidyl peptidase-4 (“DPP-4”) inhibitors, glucagon-like peptide-1 (“GLP-I”) receptor agonists, sodium-glucose co-transporter-2 (“SGLT2”) inhibitors, pioglitazone, as well as alpha-glucosidase inhibitors and insulin especially for patients that have fatty liver disease, are available. In addition, insulin therapy can be prescribed if blood sugar targets are not met with lifestyle changes and other medicines. The weight-loss surgery changes the shape and function of the digestive system.

INDUSTRY OVERVIEW

The international guideline and national guideline follow the same treatment regimen. The Core Product is intended to be indicated as second or later-line treatment of T2DM. The following chart sets forth the treatment regimen according to American Diabetes Association (“ADA”):

Glucose-lowering Therapy in T2DM: General Recommendation from ADA



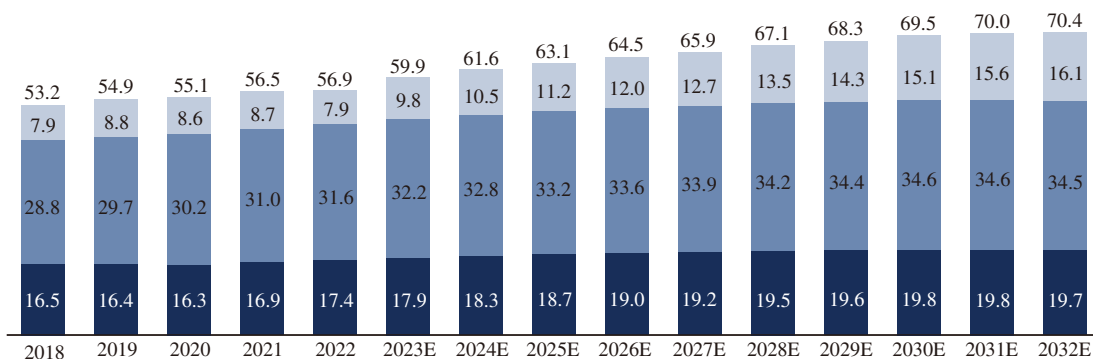
Source: ADA, CIC

T2DM Drug Market Size

The following charts set forth the market size of T2DM drugs in China, the United States and Europe from 2018 to 2032.

T2DM Drug Market Size in China, the United States and Europe, 2018-2032E

CAGR	2018-22	2022-32E	Billion USD
China	-0.2%*	7.5%	
United States	2.3%	0.9%	
Europe	1.4%	1.3%	
Total	1.7%	2.2%	



Note: Under the influence of COVID-19 pandemic, the China market size decreased from 2018 to 2022, with CAGR of -0.2%.

Source: CIC

INDUSTRY OVERVIEW

Competitive Landscape of T2DM Drug Market

According to ADA guidelines, T2DM glucose-lowering agents include metformin, alpha-glucosidase inhibitors (“AGIs”), DPP-4 inhibitors, SGLT2 inhibitors, glitazones, GLP-1R agonists, insulinotropic agents, insulin and others. Among the FDA-approved T2DM drugs, as of the Latest Practicable Date, a total of 302 drugs of metformin and 57 drugs of insulin had been approved. GLP-1R agonists primarily include dulaglutide, exenatide, and liraglutide, with two, five, and three cases approved, respectively.

The following table sets forth the details of top 10 T2DM drugs in terms of annual sales in 2022 approved by the FDA in recent years.

Top 10 T2DM Drugs in Terms of Sales in the United State in 2022

Rank	Drug name	Manufacturer	Therapeutic areas	MoA/target	Annual sales, 2022 (USD Billions)
1	OZEMPIC	Novo Nordisk	Diabetes	GLP-1R	8.6
2	TRULICITY	Eli Lilly	Diabetes	GLP-1R	7.4
3	JARDIANCE	Eli Lilly	Diabetes	SGLT2i	6.1
4	JANUVIA	Merck	Diabetes	DPP-4i	5.7
5	FARXIGA	AstraZeneca	Diabetes	SGLT2i	4.4
6	LANTUS SOLOSTAR	Sanofi	Diabetes	Insulin	2.4
7	HUMALOG	Eli Lilly	Diabetes	Insulin	2.1
8	RYBELSUS	Novo Nordisk	Diabetes	GLP-1R	1.7
9	Novorapid	Novo Nordisk	Diabetes	GLP-1R	1.4
10	Novomix	Novo Nordisk	Diabetes	Insulin	1.0

Source: Annual reports published by market players, Expert interview, Literature research, CIC

In total, more than 1,000 T2DM drugs have been approved by the NMPA. The following table sets forth the details of top 10 T2DM drugs in terms of annual sales in 2022 approved by the NMPA in recent years.

Top 10 T2DM Drugs in Terms of Sales in China in 2022

Rank	Generic name	Manufacturer	Indication	MoA/target	Annual sales, 2022 (RMB Billions)
1	Insulin Aspart 30 Injection	Novo Nordisk	Diabetes	Insulin	4.5
2	Dapagliflozin	Astra Zeneca	Diabetes	SGLT2i	3.7
3	Insulin Glargine Injection	Sanofi	Diabetes	Insulin	3.3
4	Metformin Hydrochloride Tablets	MSD	Diabetes	Metformin	2.7
5	Semaglutide Injection	Novo Nordisk	Diabetes	GLP-1R	2.4
6	Isophane Protamine Human Insulin Injection (30R)	Novo Nordisk	Diabetes	Insulin	2.3
7	Sitagliptin Phosphate Tablets	Merck	Diabetes	DPP-4i	2.3
8	Insulin Aspart Injection	Novo Nordisk	Diabetes	Insulin	2.1
6	Acarbose Tablets	Byer	Diabetes	α -glucosidase inhibitor	1.7
10	Liraglutide	Novo Nordisk	Diabetes	GLP-1R	1.7

Source: Annual reports published by market players, Expert interview, Literature research, CIC

INDUSTRY OVERVIEW

There are more than 70 and 60 Phase III clinical trials in the field of T2DM treatment regulated by the FDA and NMPA, respectively. The following table sets forth the T2DM drugs under Phase II clinical trials regulated by the FDA.

Pipeline of Phase II T2DM Drugs Registered at FDA

Drug Name	Target	Company	Indications	Admin.	Phase	First Posted Date	Trial Number	Competent Authority
ALN-KHK	ketohexokinase, KHK	Alnylam Pharmaceuticals	T2DM	Injection	II	2023/03/09	NCT05761301	FDA
GSBR-1290	GLP-1R	Gasherbrum Bio	Obesity, Overweight, T2DM	Oral	II	2023/03/09	NCT05762471	FDA
BMF-219	Menin	Biomea Fusion	T2DM	Oral	II	2023/02/16	NCT05731544	FDA
PF-07081532	GLP-1R	Pfizer	T2DM	Oral	II	2022/10/14	NCT05579977	FDA
Tofogliflozin SY-009	SGLT-2	Kowa Company	T2DM	Oral	II	2022/06/22	NCT05469659	FDA
IYA337	SGLT-1	Suzhou Yabao	T2DM	Oral	II	2022/06/21	NCT05426018	FDA
RGT001-075	PPAR	Inventiva Pharma	T2DM (Combined with Empagliflozin)	Oral	II	2022/02/09	NCT05232071	FDA
Liraglutide	GLP-1R	Regor Pharmaceuticals	T2DM	Oral	II	2022/03/25	NCT05297045	FDA
IMB-1018972	GLP-1R	BioLingus	T2DM	Oral	II	2022/03/07	NCT05268237	FDA
Hepalutide	N/A	Imbria Pharmaceuticals	T2DM, DCM, HFpE	Oral	II	2021/04/01	NCT04826159	FDA
Lanfibranor	NTCP	Shanghai HEP Pharmaceutical	T2DM	Injection	II	2020/12/10	NCT04662164	FDA
NPM-119	PPAR	Inventiva Pharma	T2DM, MASLD	Oral	II	2018/03/08	NCT03459079	FDA
HD-6277	GLP-1R	Vivani Medical, Medpace	T2DM	Injection	II	2023/01/04	NCT05670379	FDA
TG103	GPR40	Hyundai Pharm	T2DM	Oral	II	2022/12/27	NCT05666128	FDA
HRS-7535	GLP-1R	CSPC Baike (Shandong) Biopharmaceutical	T2DM	Injection	II	2021/10/01	NCT05063253	FDA
CT-868	GLP-1R	Shandong Suncaidia Medicine	T2DM	Oral	II	2023/03/08	NCT05759897	FDA
HR17031	DualGIPR/GLP-1R	Carmot Therapeutics	Obesity, T2DM	Injection	II	2021/11/08	NCT05110846	FDA
AMG133	GLP-1R/Insulin	Jiangsu HengRui Medicine	T2DM	Injection	II	2022/04/19	NCT05333835	FDA
HRS9531	Dual GIPR/GLP-1R	Amgen	Obesity, Overweight, T2DM	Injection	II	2023/01/03	NCT05669599	FDA
IBI362	Dual GIPR/GLP-1R	Fujian Shengdi Pharmaceutical	T2DM	Injection	II	2023/07/28	NCT05966272	FDA
Semaglutide	Dual GCGR/GLP-1R	Innovent Biologics (Suzhou)	T2DM	Injection	II	2021/07/16	NCT04965506	FDA
Tirzepatide (LY3298176)	GLP-1R	Novo Nordisk A/S	T2DM	Injection	II	2022/08/03	NCT05486065	FDA
LY3437943	DualGIPR/GLP-1R	Eli Lilly and Company	Obesity, Overweight, CKD, T2DM	Injection	II	2022/09/13	NCT05536804	FDA
CPL207280	Triple GLP-1R/GIPR/GCGR	Eli Lilly and Company	Obesity, Overweight, CKD, T2DM	Injection	II	2023/07/07	NCT05936151	FDA
afibercept	GPR40	Celon Pharma SA	T2DM	Oral	II	2022/02/21	NCT05248776	FDA
Finerenone (Kerendia, BAY94-8862)	Multiple pathways	Regeneron Pharmaceuticals	DME, T1DM, T2DM	Injection	II	2020/06/12	NCT04429503	FDA
MN-001	N/A	Bayer	CKD, T2DM	Oral	II	2020/02/24	NCT05254002	FDA
HU6	Multiple pathways	MediciNova	Hypertriglyceridemia, MASLD, T2DM	Oral	II	2022/07/19	NCT05464784	FDA
	N/A	Rivus Pharmaceuticals	Obesity, MASLD, MASH, T2DM	Oral	II	2023/08/07	NCT05979779	FDA

Source: ClinicalTrials; CIC

INDUSTRY OVERVIEW

The following table sets forth the T2DM drugs under Phase II clinical trials regulated by the NMPA.

Pipeline of Phase II T2DM Drugs Registered at CDE

#	Drug Name	Target	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent Authority
1	HRS9531	N/A	Hengrui/Suncadia	T2DM	Injection	II	2023/08/02	CTR20232258	NMPA
2	GZR18	GLP-1R	Ganlee	T2DM	Injection	II	2023/07/10	CTR20232069	NMPA
3	HS-20094	Dual GIP/GLP-1R	Hansoh	T2DM	Injection	II	2023/05/06	CTR20231357	NMPA
4	HRS-7535	GLP-1R	Hengrui/Suncadia	T2DM	Oral	II	2023/02/20	CTR20230393	NMPA
5	HR17301	GLP-1R and Insulin	Hengrui	T2DM patients, withoral non-insulin antidiabetic drugs are ineffective or the effect is unsatisfactory	Injection	II	2022/04/14	CTR20220857	NMPA
6	TG103	GLP-1R	I-MAB Pharma	T2DM	Injection	II	2022/04/01	CTR20220751	NMPA
7	HTD1801	BUDC	HighTide Biopharma	T2DM	Oral	II	2022/02/23	CTR20220346	NMPA
8	SY-009	SGLT-1	Yabao	T2DM	Oral	II	2022/01/25	CTR20220144	NMPA
9	TG103	GLP-1R	I-MAB Pharma	Patients with T2DM and Overweight/Obesity	Injection	II	2021/09/24	CTR20212332	NMPA
10	IBI362	Dual GCGR/GLP-1R	Innovent	T2DM	Injection	II	2021/07/28	CTR20211733	NMPA
11	Tianagliflozin	SGLT2	Tianjin Institute of Pharmaceutical Research	T2DM	Oral	II	2020/08/10	CTR20201558	NMPA
12	JY09	GLP-1R	Eastern Biotech	T2DM	Injection	II	2019/10/31	CTR20192166	NMPA
13	Lianmei Granules	N/A	Artepharm	T2DM	Oral	II	2020/07/31	CTR20191646	NMPA
14	PB-119	GLP-1R	Pegbio	T2DM	Injection	II	2018/08/20	CTR20180460	NMPA

Source: ClinicalTrials, CDE, CIC

Market Drivers and Entry Barriers of T2DM Drug Market

The T2DM drug market growth has primarily been driven by the following key factors:

- Strengthened public awareness:* A major concern in public health, governments, medical institutions and associations around the world increases public awareness of the T2DM disease. A growing number of people of different ages, genders and occupations have been suffering from metabolic and digestive diseases. As the market expands, there are diversified marketing channels to educate doctors and T2DM patients on pharmaceutical interventions. For example, the National Health Commission of China has initiated a specific training program for metabolism physicians from regional medical and health services since 2022, in order to ensure the correct diagnosis for metabolic diseases, including T2DM. Training books such as “Guidelines for the Diagnosis and Treatment of Diabetes” and “Wise Eyes on Sugar” were published in 2022 and 2023, respectively, and metabolic disease education for physicians and nurses were arranged accordingly. More T2DM care clinics are also opened in China, allowing doctors to provide patients with more comprehensive guidance on rational medication use and lifestyle intervention. As a result, patients will gain more access to medication knowledge and are more likely to accept the medication treatments. In addition, improvement of diagnostic techniques further drives the market forward. For example, more diagnostic techniques have become available for use to determine the concentration of glucose in the blood with a more user-friendly approach, such as the glucometer. The glucometer is a portable device to test the blood through a finger stick sample in a rapid and accurate manner. More and more patients use such device to monitor the glucose level during treatment or in their daily life, further increasing the demand for pharmaceutical interventions.

INDUSTRY OVERVIEW

- *Increase of diagnosis rate:* The increasing diagnosis rate of T2DM drives the growth of T2DM drug market, leading to a growing number of diagnosed patients. Accordingly, more patients would become aware of their T2DM status, promoting the sales of T2DM drugs.
- *Novel treatment:* Aside from metformin, more and more novel treatment and innovative drugs have entered the market, fulfilling unmet needs in the T2DM population. As innovative treatments targeting GLP-1, DPP-4 and SGLT-2 as well as other novel medications enter the T2DM drug market, the T2DM drug market will grow steadily.

Despite the drivers discussed above, significant entry barriers remain in the T2DM market:

- *Technological barrier:* The development of novel treatment for T2DM requires advanced disease understanding and technological capabilities. It requires companies and manufacturers to look for novel treatment targets for T2DM treatment. The overall level of technology in R&D of new entrants will not be sufficient to drive drug discovery and subsequent development.
- *Regulatory barrier:* The development of drugs and medications is strictly regulated. Companies and manufacturers that have little experience in drug development or are unfamiliar with relevant regulations and compliance knowledge would not be able to compete in this market.
- *Capital barrier:* Drug development process is a lengthy and capital-intensive activity, which requires enormous amount of capital investment and other kinds of resources. In the T2DM market, incumbents and large companies have been constantly investing in drug discovery and development. New entrants are expected to have limited financial capabilities and liquidity.
- *Talent barrier:* The innovative drug industry is a technology-intensive and multi-disciplinary industry, involving many disciplines such as biology, medicine, pharmacology, and clinical research etc. The research and development, and production of innovative treatments are in high demand for candidates with great talents, and thus many medical technicians, biological technicians and other professional staff are needed in product development, registrational clinical research and market research. Therefore, it is difficult for newly-entered companies to hire more top talents with multi-domain knowledge in the short term, directly leading to the slow business development and low efficiency of newly-entered companies.
- *Sales and marketing barrier:* Sales and marketing activities are critical in the pharmaceutical industry, especially for innovative treatments. Newly-entered companies will have difficulty to construct a sales and marketing team with rich experiences from scratch.

INDUSTRY OVERVIEW

Overview of Severe Hypertriglyceridemia (“SHTG”) Drug Market

Introduction to SHTG

Hypertriglyceridemia (“HTG”) is the presence of high amounts of triglycerides (“TGs”) in the blood. More specifically, it is defined as fasting serum TG levels of 150 mg/dL or higher, and is associated with increased risk of cardiovascular disease. SHTG is the presence of high levels of triglycerides, a type of fat, in the blood. SHTG is well known to be associated with other complex and serious disorders such as acute pancreatitis and CVDs. Dietary modifications is the current standard treatment for patients with SHTG. Existing pharmacological interventions primarily include the use of fibrates, omega-3 fatty acids, statins and niacin, but these treatment options either have limited efficacy or are associated with significant safety concerns. Furthermore, while the existing therapies for SHTG offer a benefit in treating high triglycerides, they offer limited benefit in the treatment of the constellation of metabolic issues in orbit around or underlying the triglycerides levels. It is clear that there remains a medical need for safe and effective therapies for the treatment of adult patients with SHTG, therapies that address not only triglycerides levels but also comorbid conditions.

The following chart illustrates the details of HTG, including SHTG.

Classification of HTG		Causes of Hypertriglyceridemia (HTG)		
Severity	Classification	Primary causes	familial chylomicronemia	familial combined hyperlipoproteinemia
Normal	Serum TG < 150mg/dL		Secondary causes	familial hypertriglyceridemia
Mild	Serum TG 150–199mg/dL	Renal Disease Uremia, Glomerulonephritis		Medication Estrogen, Isotretinoin
Moderate	Serum TG 200–499mg/dL	Autoimmune Disorders Hypothyroidism, systemic lupus erythematosus		Miscellaneous Pregnancy, paraproteinemia
Severe	Serum TG > 500mg/dL	Obesity, metabolic syndrome, alcohol, unhealthy diet		
<ul style="list-style-type: none"> • According to the 2018 AHA/ACC Guideline, SHTG is defined as serum TG>500 mg/dL • SHTG is usually caused by a combination of genetic and secondary factors. A detailed history that includes family history, medications, and alcohol consumption can often lead to the cause. Physical examination findings may stretch across multiple organ systems. Patients with SHTG should be admitted to the hospital for aggressive medical therapy if they develop symptoms such as abdominal pain or pancreatitis. 		Complications of HTG		
		Cardiovascular disease HTG increased risk of cardiovascular disease (CVD);		
		Pancreatitis Extreme elevations of triglycerides may cause acute pancreatitis;		
		Chylomicronemia Syndrome An often unrecognized and less severe condition, usually caused by triglyceride levels greater than 500 mg/dL.		

Abbreviation: AHA/ACC: American Heart Association/American College of Cardiology

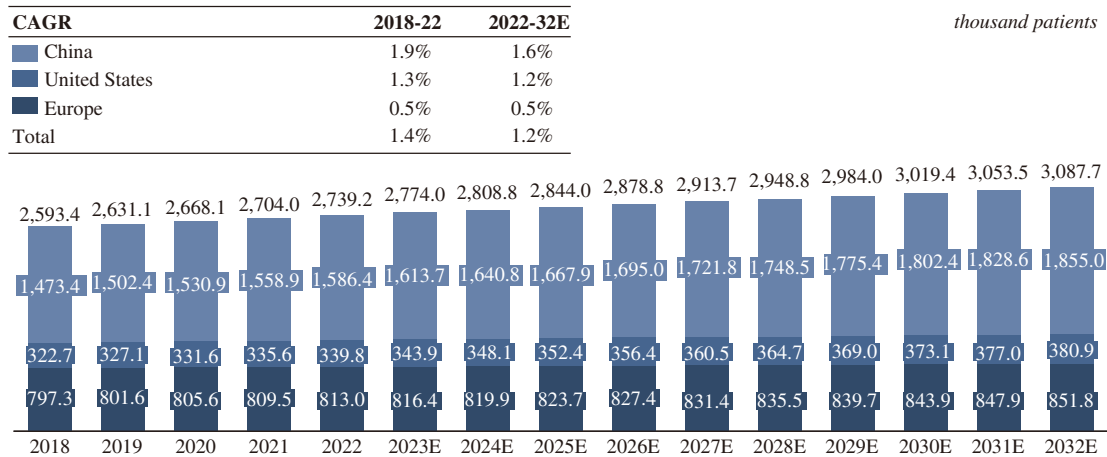
Source: *frontiers, CIC*

INDUSTRY OVERVIEW

Prevalence of SHTG in China, the United States and Europe

The following charts set forth the prevalence of HTG in China, the United States and Europe from 2018 to 2032.

Prevalence of SHTG in China, United States and Europe 2018-2032E



Source: Expert interview, Literature research, CIC

Current Treatment Regimen

The general treatment regimen for SHTG includes dietary restrictions and lipid-lowering drug treatment such as the use of medium-chain triglycerides (“MCT”), fibrates, omega-3-fatty acids (“omega-3-FA”), and nicotinic acid. Diet restrictions are also a prevention method, and remain the mainstay of treatment of SHTG, and the drug treatment may offer extra percentages of TG-lowering. Yet, drugs of first choice, such as fibrates, do not offer fast onset of action, while immediately acting drugs like omega-3-FA and MCT may not be powerful enough to lower excessively elevated TG levels rapidly. Since patients with excessively elevated TG levels are in urgent need of a fast and effective lowering of their TG levels in order to prevent a severe pancreatitis episode, further measures must be taken. Immediate apheretic treatment might thus be a potential option in order to rapidly lower excessively elevated TG levels and prevent acute pancreatitis in these patients. Recently, the successful use of plasmapheresis for treating patients with SHTG has not only been confirmed in a number of studies, but also been suggested by the American Society for Apheresis (“ASFA”) Committee on Clinical Applications.

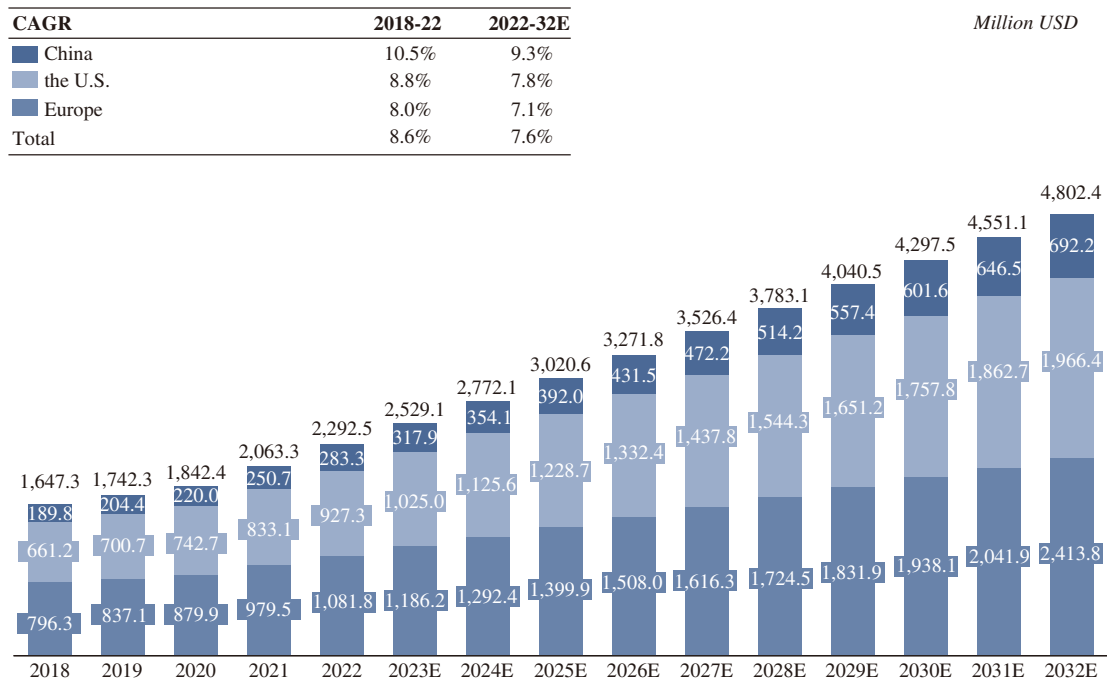
The Core Product is intended to be second or later-line treatment of SHTG.

INDUSTRY OVERVIEW

SHTG Drug Market Size

The following chart sets forth the SHTG drug market size in China, the United States and Europe from 2018 to 2032.

Market Size of SHTG Drug Market, 2018-2032E



Source: Annual reports published by market players, Expert interview, Literature research, CIC

Competitive Landscape of SHTG Drug Market

According to the SHTG/HTG treatment guidelines, SHTG/HTG drugs primarily include three categories of drugs: fenofibrate, nicotine acid and ethyl eicosapentaenoate acid. As of Latest Practicable Date, there were more than 100 SHTG/HTG drugs approved by each of FDA and NMPA.

INDUSTRY OVERVIEW

There are 15 SHTG drugs under clinical development regulated by the FDA, including 13 SHTG drugs in Phase II and Phase III clinical trials, and there is one SHTG drug under clinical development regulated by the NMPA. The following table sets forth the pipeline of SHTG drugs in clinical trials regulated by the FDA and the NMPA.

Pipeline of SHTG Drugs in Clinical Trials Registered at ClinicalTrials and CDE

#	Drug Name	Target	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent Authority
1	Pegzofermin	FGF21	89Bio	Severe Hypertriglyceridemia	Injection	III	2023/05/10	NCT05852431	FDA
2	Olezarsen	APOC3 mRNA	Ionis Pharmaceuticals	Severe Hypertriglyceridemia	Injection	III	2023/01/12	NCT05681351	FDA
3	Olezarsen	APOC3 mRNA	Ionis Pharmaceuticals	Patients with Hypertriglyceridemia and Atherosclerotic Cardiovascular Disease, or with Severe Hypertriglyceridemia	Injection	III	2022/11/09	NCT05610280	FDA
4	Olezarsen	APOC3 mRNA	Ionis Pharmaceuticals	Severe Hypertriglyceridemia	Injection	III	2022/09/23	NCT05552326	FDA
5	Olezarsen	APOC3 mRNA	Ionis Pharmaceuticals	Severe Hypertriglyceridemia	Injection	III	2021/10/15	NCT05079919	FDA
6	Ethyl lozapentate	N/A	Mochida	Severe Hypertriglyceridemia	Oral	III	2020/01/27	NCT04239950	FDA
7	K-877	PPAR α	Kowa Company	Severe Hypertriglyceridemia	Oral	III	2017/01/05	NCT03011450	FDA
8	MAR001	N/A	Marea Therapeutics	Patients With Metabolic Dysfunction (triglyceride levels > 2.8 mmol/L)	Injection	Ib/IIa	2023/07/22	NCT05896254	FDA
9	NST-1024	N/A	NorthSea Therapeutics B.V.	High Triglycerides	Oral	II	2023/06/05	NCT05889156	FDA
10	Olezarsen	APOC3 mRNA	Ionis Pharmaceuticals	Hypertriglyceridemia, Atherosclerotic Cardiovascular Disease, Severe Hypertriglyceridemia	Injection	II	2021/10/15	NCT05355402	FDA
11	ARO-APOC3	ApoC-III	Arrowhead	Severe Hypertriglyceridemia	Injection	II	2021/01/22	NCT04720534	FDA
12	Pegzofermin	FGFR1/ β -Klotho	89Bio	Severe Hypertriglyceridemia	Injection	II	2020/09/09	NCT04541186	FDA
13	ISIS 703802	ANGPTL3 mRNA	Akcea Therapeutics	Patients with Hypertriglyceridemia, T2DM and MASLD	Injection	II	2017/12/03	NCT03371355	FDA
14	VSA003	N/A	Visima Therapeutics HK Limited	Dyslipidemias, Familial Hypercholesterolemia, Hypertriglyceridemia	Injection	I	2023/05/09	NCT05851066	FDA
15	LY3875383	N/A	Eli Lilly	Hypertriglyceridemia	Injection	I	2022/11/08	NCT05609825	FDA
16	Ethyl lozapentate	N/A	Mochida	Severe Hypertriglyceridemia	Oral	III	2019/10/15	CTR20191474	NMPA

Note: The above table only includes pipeline of SHTG drugs in clinical trials regulated by the FDA and NMPA in which the inclusion criteria specify patients with triglyceride level ≥ 500 mg/dL or triglyceride levels > 2.8 mmol/L

Source: ClinicalTrials.gov; CIC

Market Drivers and Entry Barriers of SHTG Drug Market

The SHTG drug market growth has primarily been driven by the following key factors:

- *Expansion of vulnerable population:* Hypertriglyceridemia results from the combination of genetic factors and lifestyle causes such as excessive alcohol intake and foods rich in saturated fat. Hypertriglyceridemia also associates with other metabolic diseases, such as obesity, metabolic syndrome, and T2DM. These risk factors and comorbidities together contribute to the expansion of vulnerable population of SHTG.
- *Novel treatments to fulfil unmet needs:* The current treatment options for SHTG have their respective limitations. Significant unmet clinical needs prevail in SHTG treatment, especially the need to simultaneously reduce triglycerides and further improve lipid metabolism and weight management. After novel treatment choices are introduced to the market, the SHTG drug market is expected to grow steadily.

INDUSTRY OVERVIEW

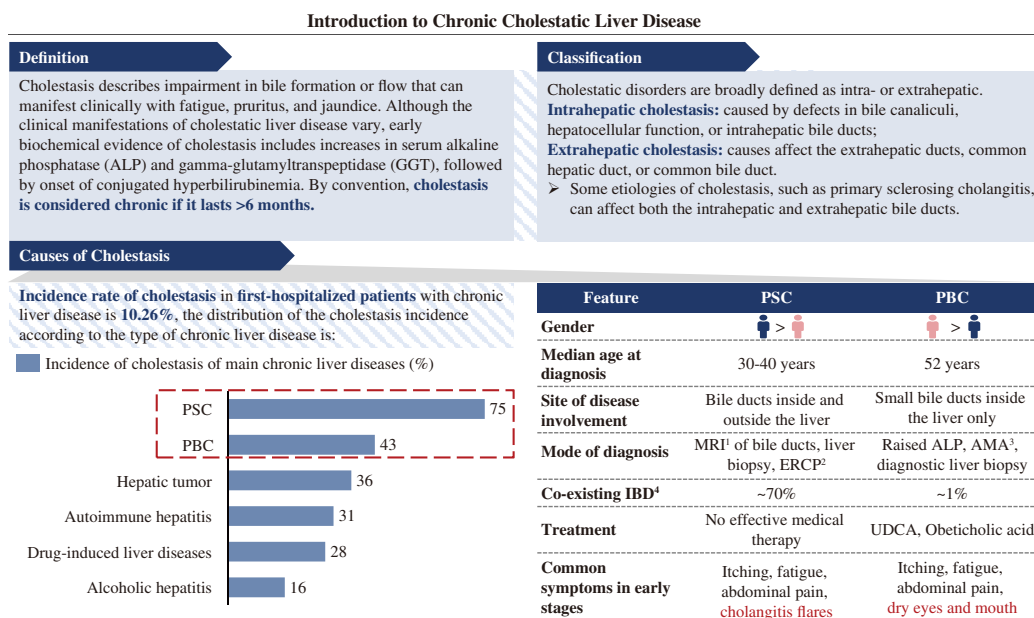
Despite the drivers discussed above, significant entry barriers remain in the SHTG market:

- Technological and talent barrier:** SHTG with complex pathogenesis and etiology is still under scientific research and needs further understanding. Drug development in this field requires multi-faceted talents who are familiar with regulations, clinical trials, the field of metabolic diseases and other areas that are key to the development and commercialization of innovative therapies in SHTG treatment. This presents a critical technological and talent barrier that prevents new entrants from entering the market and conducting clinical research and other business operations.
- Capital investment barrier:** Drug development process is a lengthy and capital-intensive activity, which requires enormous amount of capital investment and other kinds of resources. New entrants are expected to have limited financial capabilities and liquidity to sustain business operation and product development.

OVERVIEW OF CHRONIC CHOLESTATIC LIVER DISEASE DRUG MARKET

Cholestasis describes impairment in bile formation or flow that can manifest clinically with fatigue, pruritus, and jaundice. Although the clinical manifestations of cholestatic liver disease vary, early biochemical evidence of cholestasis includes increases in serum alkaline phosphatase and gamma glutamyltranspeptidase, followed by onset of conjugated hyperbilirubinemia. Incidence rate of cholestasis in first-hospitalized patients with chronic liver disease is 10.26%.

If cholestasis lasts longer than six months, it is considered as chronic cholestatic liver disease, with two major types of primary sclerosing cholangitis (“PSC”) and primary biliary cholangitis (“PBC”). The following diagram sets forth the introduction to chronic cholestatic liver disease.



Note: 1 Magnetic Resonance Imaging; 2 Endoscopic retrograde cholangiopancreatography; 3 positive disease specific antibodies; 4 inflammatory bowel disease.

Source: “Consensus on the Diagnosis and Treatment of Cholestasis Liver Diseases (膽汁淤積性肝病診斷和治療共識) (2015)”; CIC

INDUSTRY OVERVIEW

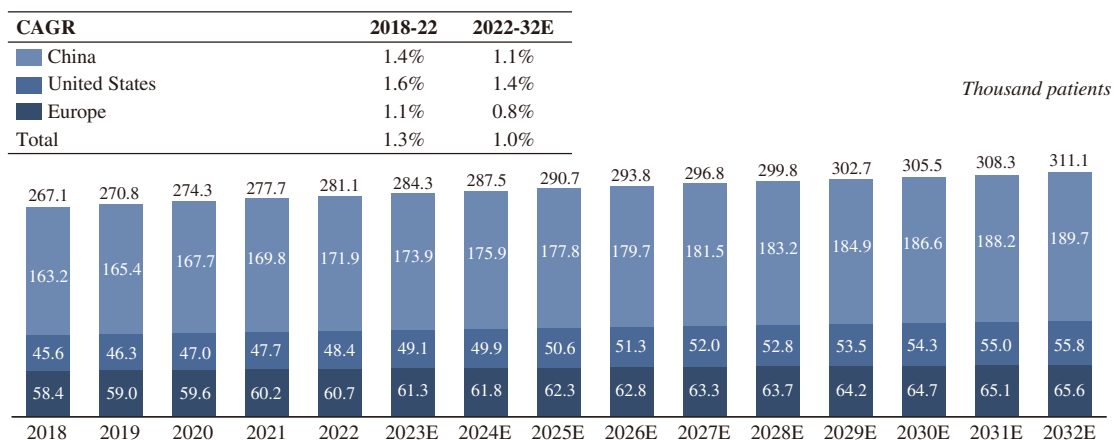
Overview of PSC Drug Market

PSC is a long term progressive disease and is characterized by inflammation and scarring of the bile ducts which normally allow bile to drain from the gallbladder. Though PSC advances very slowly, it eventually leads to liver failure, repeated infections, and tumors of the bile duct or liver. PSC affects all age groups, with the median age at onset of 30-40 years. Furthermore, PSC is more common in men, more than 60% of patients are men.

Prevalence of PSC in China, the United States and Europe

The following charts set forth the prevalence of PSC in China, the United States and Europe from 2018 to 2032.

Prevalence of PSC in China, the United States and Europe 2018-2032E



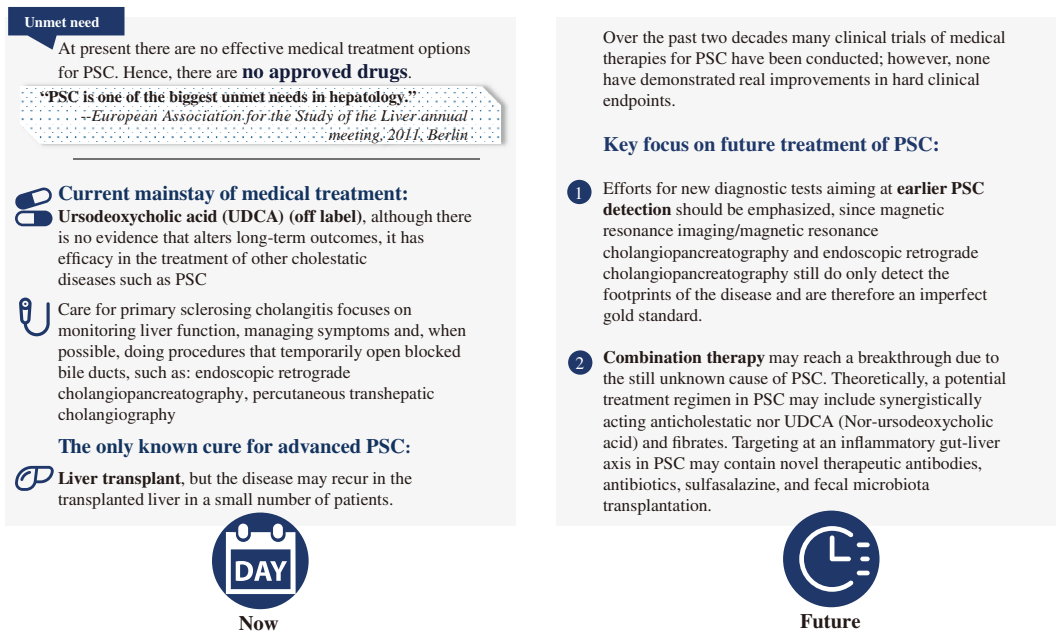
Source: Expert interview, Literature research, CIC

INDUSTRY OVERVIEW

Current Treatment Regimen

The treatment options for PSC include medication, endoscopic therapy, percutaneous therapy and surgery, such as liver transplant. In the global and China market, there are no effective medical treatment options for PSC. Ursodeoxycholic acid (“UDCA”) is used off-label to treat PSC as the current mainstay of medical treatment. In addition, prevention methods are also critical, which include alcohol consumption control, hepatitis A and B viruses vaccinations and low-fat diet. The Core Product is intended to be second or later-line treatment of PSC. The following table sets forth the treatment pathway for PSC according to international and national guidelines:

Treatment pathway for PSC



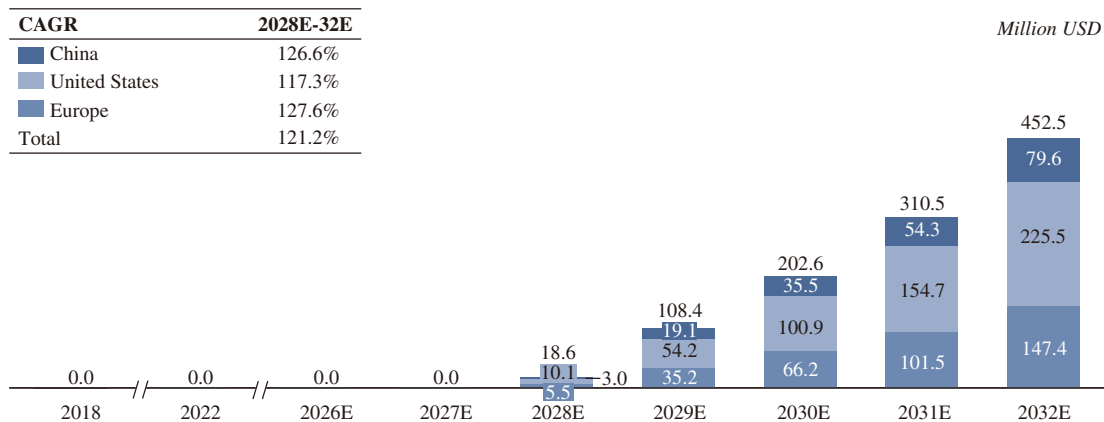
Source: Literature search, CIC

INDUSTRY OVERVIEW

PSC Drug Market Size

The following chart sets forth the PSC drug market size in China, the United States and Europe from 2018 to 2032.

Market Size of PSC Drug in China, the United States and Europe, 2018-2032E



Note: The size and the significant growth of PSC drug market is estimated with the following assumptions: (i) market is estimated as the average PSC drug price multiplied by the number of patients treated; (ii) the price assumption is based on the prices of other first-in-class drugs for chronic diseases; (iii) the PSC drugs expected to be approved in forecast period would not be covered in national or regional volume-based procurement program in China patients. In 2028, the number of PSC patients globally is expected to be 299.8 thousand and in 2032, this number is expected to reach 311.1 thousand. For details, see “— Prevalence of PSC in China, the United States and Europe” in this section above; (iv) From 2028 to 2032, the range of diagnosis rates among PSC patients is expected to be within 40%-50%, 50%-60% and 50%-60% in China, the U.S. and Europe, respectively. The initial PSC-indicated drug adoption rates in total PSC patients are expected to be 2.1%, 1.2%, and 0.8% in 2028 in China, the U.S. and Europe, respectively. The expected range of annual treatment cost of PSC-indicated drug is expected to be within USD600-1,300, USD16,000-17,000 and USD11,000-12,000 in China, the U.S. and Europe, respectively. The price change in China, the United States and Europe is in line with the industry trend; (v) the first drug (HTD1801) for the treatment of PSC is expected to be approved in the second quarter 2028 in China, the United States and Europe on the basis that (a) HTD1801 is the first drug candidate to complete Phase II clinical trial in China and (b) in September 2018, HTD1801 was granted the first fast track designation status by FDA in the field of PSC treatment; (vi) a number of PSC drugs are expected to be approved and commercialized from 2029 onwards, including but not limited to GS-9674 and norUDCA, which are in Phase III clinical stages. For details, see “— competitive landscape of PSC drug market” in this section below. The expected approval timeline was estimated based on the duration of Phase III trials and public announcements by the trial sponsors; (vii) increased academic promotion and physician education by market players; (viii) the patient population that can be given PSC drugs continue to grow; (ix) because no medications specifically indicated for PSC have been approved, the treatment rate of drugs that are indicated for PSC is currently 0%. As the expected approval of drugs specifically indicated for PSC address the unmet clinical needs, PSC patients will quickly adopt these PSC-indicated drugs and the treatment rate will then grow significantly.

Source: Expert interview, Literature research, CIC

INDUSTRY OVERVIEW

Competitive Landscape of PSC Drug Market

According to CIC, there is no medication currently approved for the treatment of PSC globally. There are 13 PSC drugs under clinical development regulated by the FDA and the NMPA, all of which are in Phase II and Phase III clinical stages. The following table sets forth the pipeline of PSC drugs under clinical trials regulated by the FDA and the NMPA.

Pipeline of PSC Drugs in Clinical Trials Registered at ClinicalTrials and CDE

#	Drug Name	Target	Company	Indications	Phase	Administration	Fast track/ orphan drug	First Posted Date	Trial Number	Competent Authority
1	GS-9674 (Cilofexor)	FXR	Gilead Sciences	PSC	III	Oral	Orphan drug	2019/03/26	NCT03890120	FDA
2	norUDCA	α 1ATZ	Dr. Falk Pharma GmbH	PSC	III	Oral	/	2019/03/13	NCT03872921	FDA
3	CS0159	FXR	Cascade	PSC	II	Oral	/	2023/06/09	NCT05896124	FDA
4	A3907	ASBT	Albireo	PSC	II	Oral	/	2022/12/08	NCT05642468	FDA
5	Elafibranor	PPAR- α / δ	Ipsen	PSC	II	Oral	/	2022/12/25	NCT05627362	FDA
6	EP547	MRGPRX4	Escient pharmaceuticals	PSC	II	Oral	Orphan drug	2022/09/01	NCT05525520	FDA
7	SHP626 (Volixibat)	IBAT	Mirum Pharmaceuticals	PSC	II	Oral	/	2020/12/11	NCT04663308	FDA
8	CM-101	Unidentified	ChemomAb Ltd.	PSC	II	Intravenous and subcutaneous	Orphan drug	2020/10/22	NCT04595825	FDA
9	PLN-74809	α , β / α , β ₁	Pliant Therapeutics,	PSC	II	Oral	Fast track, Orphan drug	2020/07/21	NCT04480840	FDA
10	MBX-8025 (Seladelpar)	PPAR- δ	CymaBay Therapeutics	PSC	II	Oral	/	2019/07/18	NCT04024813	FDA
11	HTD1801	BUDC	HighTide	PSC	II	Oral	Fast track, orphan drug	2017/11/07	NCT03333928	FDA
12	CS0159	FXR	Cascade	PSC	II	Oral	/	2023/05/22	CTR20231403	NMPA
13	HTD1801	BUDC	HighTide	PSC	II	Oral	/	2020/02/05	CTR20200049	NMPA

Source: Clinicaltrials; CDE; CIC

Market Drivers and Entry Barriers of PSC Drug Market

The PSC drug market growth has primarily been driven by the following key factors:

- Strengthened public awareness:** As more and more PSC patients emerge, governments, medical institutions and the public pay more attention to PSC disease, which lead to increased public awareness for PSC disease. In addition, a variety of media and channels can be used to educate doctors and PSC patients on disease diagnosis and pharmaceutical interventions. For example, the National Health Commission of China has initiated a specific training program for metabolism physicians from regional medical and health services since 2022, in order to ensure the correct diagnosis for metabolic diseases, including PSC. More PSC care clinics are also opened in China, allowing doctors to provide patients with more comprehensive treatment on rational medication use and lifestyle intervention. In addition, improvement of diagnostic techniques further drives the market forward of PSC disease. For example, more diagnostic techniques have become available to diagnose PSC, such as liver function blood test, magnetic resonance imaging of bile ducts and liver biopsy. The magnetic resonance imaging, the best choice to diagnose PSC with a user-friendly approach, makes images of liver and bile ducts directly. A

INDUSTRY OVERVIEW

liver biopsy is a procedure to remove a piece of liver tissue for laboratory testing, in order to determine the extent of damage to liver. Doctors usually use liver biopsy only when the diagnosis of PSC is still uncertain after using other less-invasive approaches. Thus, more subjects use magnetic resonance imaging and liver biopsy to diagnose PSC, further increasing the demand for pharmaceutical interventions.

- *Increase of diagnosis rate:* The pathogenesis of PSC has not yet been clearly identified. Multiple risk factors such as genetics, environment, autoimmune conditions and metabolism of bile acids could lead to PSC. The major population group susceptible to PSC is males aged between 20 and 57 years old. With more extensive understanding of PSC disease and its standard of diagnosis, the diagnosis rate will increase, further driving the growth of PSC market.
- *Novel treatments to fulfil unmet needs:* As of May 2023, no drugs indicated for PSC have been approved. This presents significant unmet needs to address for the PSC patients and improve their prognosis. After novel treatments that fulfill these unmet needs are approved, PSC patients are expected to adopt these innovative drugs, thus driving the growth of PSC market.

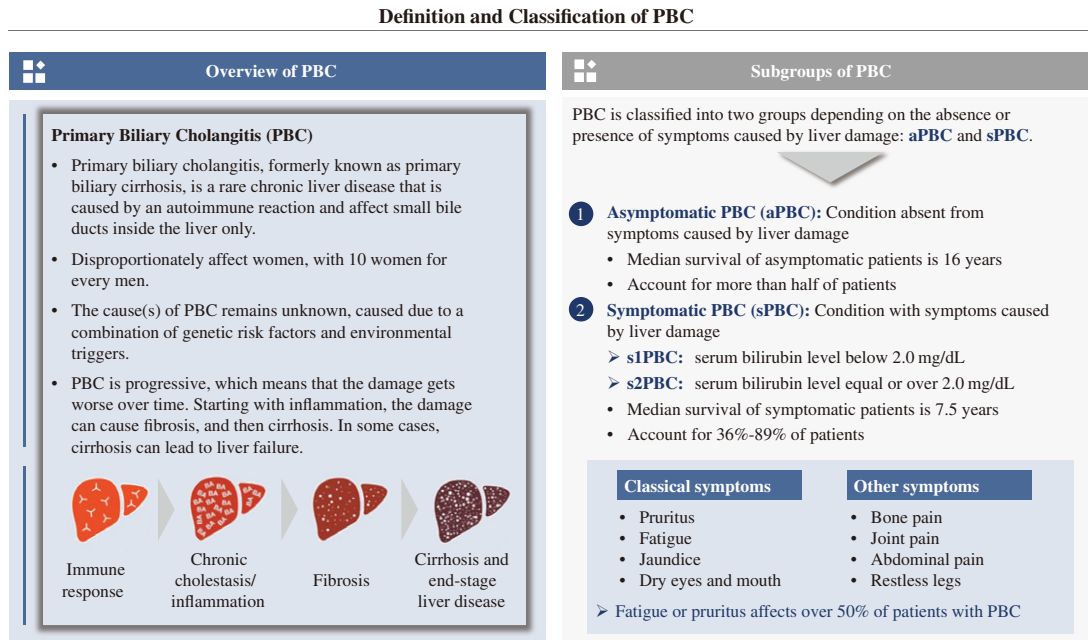
Despite the drivers discussed above, significant entry barriers remain in the PSC market:

- *Technological and talent barrier:* Scientific researches and clinical developments are constantly dedicated to the treatment of PSC, looking for pathways or targets to treat PSC. These activities typically demand high-level insights and technologies in areas of PSC, metabolism or autoimmunology, and require a team of talents with research focus on the underlying topics. This presents the technological and talent barrier for the PSC drug market.
- *Regulatory barrier:* The development of drugs and medications is strictly regulated. Companies and manufacturers that have little experience in drug development or are unfamiliar with relevant regulations and compliance knowledge would not be able to compete in this market.
- *Capital investment barrier:* Drug development process is a lengthy and capital-intensive activity, which requires enormous amount of capital investment and other kinds of resources. For example, with a relatively small PSC patient population, patient recruitment requires significant investment and resources. New entrants are expected to have limited financial capabilities and liquidity to sustain business operation and product development.

INDUSTRY OVERVIEW

Overview of PBC Drug Market

PBC, formerly known as primary biliary cirrhosis, is a rare chronic liver disease that is triggered by autoimmune reactions with unspecified causes, such as a combination of genetic risk factors and environmental factors. It affects small bile ducts inside the liver only, and may be progressive. Starting with inflammation, the damage can cause fibrosis, then cirrhosis, and eventually lead to liver failure in some cases. PBC disproportionately affects women, with the ratio of 10 women for one man. The following diagram sets forth the details of definition and classification of PBC:

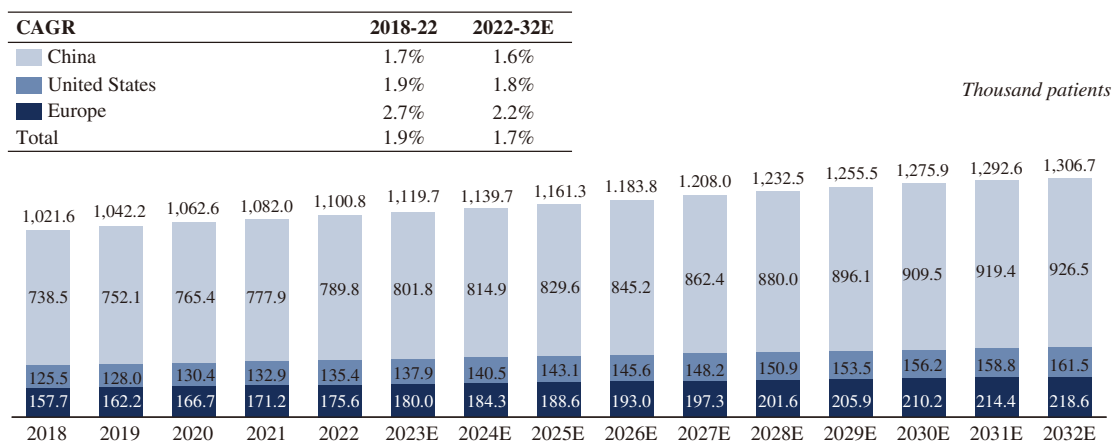


Source: 2018 practice guidance from American Association for the Study of Liver Disease ("AASLD"); EASL clinical practice guidelines; CIC

Prevalence of PBC in China, the United States and Europe

The following charts set forth the prevalence of PBC in China, the United States and Europe from 2018 to 2032E.

Prevalence of PBC in China, United States and Europe 2018-2032E








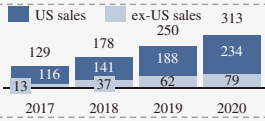
Source: CIC

INDUSTRY OVERVIEW

Current Treatment Regimen

PBC treatment’s primary goals are to slow down disease progression, manage symptoms, and prevent complications. The immediate treatment for PBC is using ursodeoxycholic acid (UDCA). UDCA helps improve liver function and bile flow, slowing down the progression of the disease. It is the standard treatment for PBC and has been shown to increase survival rates and delay the need for a liver transplant. In cases where UDCA alone is not effective or well-tolerated, obeticholic acid (“OCA”) may be prescribed. OCA is a medication that regulates bile acid synthesis and improves liver function. It is approved for use with UDCA for certain individuals with PBC. Medications such as antihistamines or bile acid binders may be prescribed to help alleviate symptoms such as itching (pruritus). These medications work by reducing bile acid levels in the blood, which can help relieve itching. A liver transplant may be considered in advanced cases of PBC where the liver function significantly deteriorates or complications such as cirrhosis develop. A liver transplant replaces the diseased liver with a healthy liver from a donor. In addition, prevention methods are also critical, which include alcohol consumption control, hepatitis A and B viruses vaccinations and low-fat diet.

UDCA is the first-line agent for the treatment of PBC, and OCA is recommended as the second-line agent used in combination with UDCA. None of the other drugs has been tested beneficial as single agent. The following table sets forth the treatment pathway for PBC according to international and national guidelines:

Treatment pathway for PBC			Other therapies	Unmet need		
Approved drugs	First-line	Second-line	<p>OCA is the only approved drug during the past 20 years since the approval of UDCA. Other drugs are tested, while none of them found as single agent to be benefit.</p> <p>Fibric acid derivatives</p> <ul style="list-style-type: none"> Fibrates can be considered as off-label alternatives for patients with PBC and inadequate response to UDCA. Use of OCA and fibrates is discouraged in patients with decompensated liver disease (Child-Pugh-Turcotte B or C). <p>Other drugs</p> <ul style="list-style-type: none"> Newer agents under consideration include the selective PPAR-agonist seladelpar and other FXR agonists. <p>Liver transplantation </p> <ul style="list-style-type: none"> Patients with manifestations of end-stage PBC should be referred for liver transplantation when they present with complications of cirrhosis, or their Model for End-Stage Liver Disease score exceeds 14. 			
	Ursodeoxycholic acid (UDCA)	Obeticholic acid (OCA)				
Representative drugs*						
Approval	FDA: 1987/12	FDA: 2016/5				
Dosage	13 to 15 mg/kg/day orally	Starting at 5 mg/day for inadequate responders to UDCA				
Manufacturer						
Annual cost	\$5,000-\$7,000	\$150,000-\$170,000				
Annual Sales (million dollars)	No public information disclosure					
Limitations	<ul style="list-style-type: none"> Up to 40% of PBC patients do not achieve a complete response to UDCA 	<ul style="list-style-type: none"> Black Box Warning Dosing higher than recommended in the drug label can increase the risk for liver decompensation, liver failure, and sometimes death 				

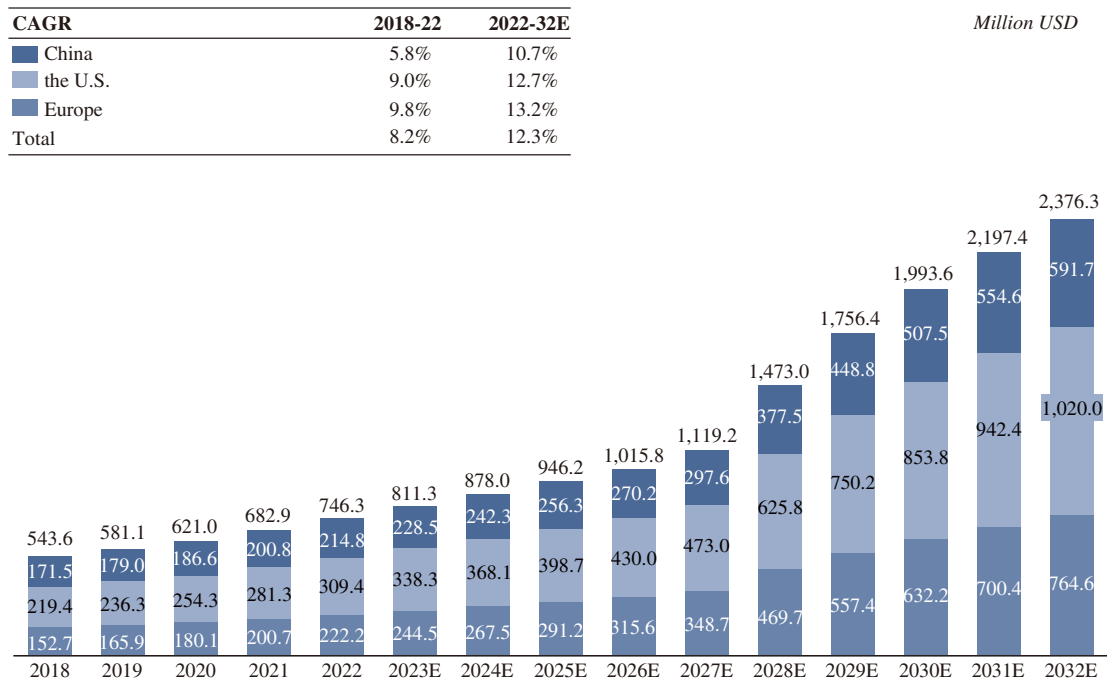
Source: Literature search, CIC

INDUSTRY OVERVIEW

PBC Drug Market Size

The following chart sets forth the market size of PBC drug in China, the United States and Europe from 2018 to 2032.

Market Size of PBC Drug Market, 2018-2032E



Source: Annual reports published by market players, Expert interview, Literature research, CIC

Competitive Landscape of PBC Drug Market

As of the Latest Practicable Date, only two drugs had been approved for PBC by the FDA. UDCA is the first-line agent for the treatment of PBC, and OCA is recommended as the second-line agent used in combination with UDCA. In China, only UDCA has been approved by the NMPA.

INDUSTRY OVERVIEW

Approved PBC Drugs by the FDA

Drug Name	Target	Manufacturer	Approval	Indications	Dosage	Annual cost	Limitations
Ursodeoxycholic acid (UDCA)	/	Allergan	1987/12	Primary Biliary Cholangitis	13 to 15mg/kg/day orally	5,000–7,000 USD	Up to 40% of PBC patients do not achieve a complete response to UDCA
Obeticholic acid (OCA)	FXR	Intercept	2016/5	Treatment of primary biliary cholangitis, previously known as primary biliary cirrhosis (PBC), in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA	Starting at 5 mg/day for inadequate responders to UDCA	150,000–170,000 USD	<ul style="list-style-type: none"> • Black Box Warning • Dosing higher than recommended in the drug label can increase the risk for liver decompensation, liver failure, and sometimes death

Note:

1. Annual cost calculated based on assumptions that i) medications are used in adults according to indications and usage in drug labels and ii) individual treatment maintains for a year of 52 weeks.

Source: Clinical Trials; NMPA; CIC

There are 18 PBC drugs under clinical development regulated by the FDA and the NMPA, including 16 PBC drugs in Phase II and Phase III clinical stages. The following table sets forth the PBC drugs under clinical trials regulated by the FDA and the NMPA.

Pipeline of PBC Drugs in Clinical Trials Registered at ClinicalTrials and CDE

#	Drug Name	Target	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent Authority
1	TQA3526	FXR/Bile Acid	Chia Tai Tianqing	PBC	Oral	III	2022/07/11	NCT05450887	FDA
2	MBX-8025 (Seladelpar)	PPAR-δ	CymaBay Therapeutics	PBC	Oral	III	2020/11/09	NCT04620733	FDA
3	MBX-8025 (Seladelpar)	PPAR-δ	CymaBay Therapeutics	PBC	Oral	III	2020/11/09	NCT03602560	FDA
4	GFT505 (Elafibranor)	dual PPAR-α/PPAR-δ	Genfit	PBC	Oral	III	2020/08/26	NCT04526665	FDA
5	Obeticholic Acid	FXR	Fudan-Zhangjiang Bio-Pharmaceutical	PBC	Oral	III	2021/08/16	CTR20211958	NMPA
6	TQA3526	FXR/Bile Acid	Chia Tai Tianqing	PBC	Oral	III	2021/08/16	CTR20211444	NMPA
7	TQA3526	FXR/Bile Acid	Chia Tai Tianqing	PBC	Oral	III	2021/06/17	CTR20211354	NMPA
8	Saroglitazar	PPAR α/γ	Zydu Therapeutics	PBC	Oral	IIb/III	2021/11/24	NCT05133336	FDA
9	ASC42	FXR	Ascleitis Pharmaceuticals	PBC	Oral	II	2022/01/13	NCT05190523	FDA
10	HTD1801	Multiple pathways	HighTide Biopharma Enanta	PBC	Oral	II	2020/10/27	NCT04604652	FDA
11	EDP-305	FXR	Pharmaceuticals	PBC	Oral	II	2018/01/09	NCT03394924	FDA
12	GKT137831	Nox4	Genkyotex SA	PBC	Oral	II	2017/07/21	NCT03226067	FDA
13	Saroglitazar	PPAR α/γ	Zydu Therapeutics	PBC	Oral	II	2017/04/13	NCT03112681	FDA
14	CS0159	FXR	Cascade Ascleitis	PBC	Oral	II	2023/05/12	CTR20231402	NMPA
15	ASC42	FXR	Pharmaceuticals/ Gannex	PBC	Oral	II	2021/12/10	CTR20213229	NMPA
16	TQA3526	FXR/Bile Acid	Chia Tai Tianqing COUR	PBC	Oral	IIa	2020/01/10	CTR20200055	NMPA
17	CNP-104	N/A	Pharmaceutical Development Company	PBC	Injection	I/IIa	2021/11/03	NCT05104853	FDA
18	MBX-8025 (Seladelpar)	PPAR-δ	CymaBay Therapeutics	PBC	Oral	I	2021/09/17	NCT04950764	FDA

Source: Clinical Trials; CDE; CIC

INDUSTRY OVERVIEW

Market Drivers and Entry Barriers of PBC Drug Market

The PBC drug market growth has primarily been driven by the following key factors:

- *Expansion of vulnerable population:* The pathogenesis of PBC has not been fully understood, and the major population group susceptible to PBC is older women. As the awareness and level of clinical diagnosis increase, with the growing aging population, PBC is expected to have a growing prevalence.
- *Novel treatments to fulfil unmet needs:* As of May 2023, UDCA and FXR antagonists are the only drugs approved for treatment of PBC. However, they have respective limitations that only 60% of the PBC patients respond well to UDCA, and FXR antagonists have black box warnings regarding their safety profile. The limitations in currently available treatments present significant unmet needs in PBC treatment, and novel treatments that fulfill unmet needs are expected to drive the growth of PBC drug market.

Despite the drivers discussed above, significant entry barriers remain in the PBC market:

- *Technological and talent barrier:* The pathogenesis of PBC is still under further research. In addition, due to the slow progression of PBC, sometimes surrogate endpoints are needed in clinical assessment. The complex activities involved in developing new drugs to treat PBC require high-level technological know-how and clinical development professionals. It is difficult for newly-entered enterprises to recruit talents with specific knowledge in such a short term, which directly leads to the slow product development of newly-entered enterprises.
- *Regulatory barrier:* The development of drugs and medications is strictly regulated. Companies and manufacturers that have little experience in drug development or are unfamiliar with relevant regulations and compliance knowledge would not be able to compete in this market.
- *Capital investment barrier:* Drug development process is a lengthy and capital-intensive activity, which requires enormous amount of capital investment and other kinds of resources. Similar to PSC, PBS population is also small, and patient recruitment requires significant investment and resources. New entrants are expected to have limited financial capabilities and liquidity to sustain business operation and product development.

REPORT COMMISSIONED BY CHINA INSIGHTS CONSULTANCY

In connection with the [REDACTED], we commissioned CIC, an Independent Third Party, to prepare a report on global and China's markets regarding metabolic and digestive diseases. Except as otherwise noted, all data and forecasts in this section come from the CIC Report. We have agreed to pay a total of RMB954,000 in fees for the preparation of the CIC Report. CIC is a market research and consulting company that provides market research on a variety of industries including healthcare. In preparing the report, CIC collected and reviewed publicly available data such as government-derived information, annual reports and industry association statistics, as well as market data collected by conducting interviews with key industry experts and leading industry participants. CIC has exercised due care in collecting and reviewing the information so collected.

REGULATORY OVERVIEW

PRC LAWS AND REGULATIONS

Our business operations are subject to extensive supervision and regulation by the government of the People’s Republic of China (the “**PRC**” or “**China**”). This section summarizes the principal laws and regulations in the PRC that may have a significant impact on our business.

Laws and regulations in relation to Drugs

Major Regulatory Authorities

The drug industry in the PRC is mainly administered by three governmental agencies: the National Medical Products Administration (國家藥品監督管理局) (the “**NMPA**”), a department under the State Administration for Market Regulation (國家市場監督管理總局) (the “**SAMR**”), the National Health Commission (國家衛生健康委員會) (the “**NHC**”) and the National Healthcare Security Administration (國家醫療保障局) (the “**NHSA**”).

The NMPA, which inherits the drug supervision function from its predecessor the China Food and Drug Administration, or the CFDA (before March 2018), is the primary drug regulator responsible for almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical researches, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution and pharmacovigilance.

The NHC, formerly known as the National Health and Family Planning Commission, is China’s chief healthcare regulator. It is primarily responsible for drafting national healthcare policy and regulating public health, medical services, and health contingency system, coordinating the healthcare reform, and overseeing the operation of medical institutions and practicing of medical personnel.

The NHSA, a new authority established in May 2018, 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 disposables and healthcare services; formulating and administering the bidding and tendering policies for drugs and medical disposables.

Reform of the Drug Approval System

On August 9, 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) (the “**Reform Opinions**”), which established a framework for reforming the evaluation and approval system for drugs and medical devices. The Reform Opinions indicated enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

On March 4, 2016, the General Office of the State Council promulgated the Guiding Opinions on Promoting the Sound Development of the Medical Industry (《關於促進醫藥產業健康發展的指導意見》), which aims to accelerate the development of innovative drugs and biological products with major clinical needs, to speed up the promotion of green and intelligent pharmaceutical production technologies, to strengthen scientific and efficient supervision, and to promote the development of industrial internationalization.

REGULATORY OVERVIEW

On October 8, 2017, the General Office of Chinese Communist Party’s Central Committee and the General Office of the State Council jointly issued the Opinions on Strengthening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation (《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》) (the “**Innovation Opinions**”), which seek to streamline the clinical trial process and shorten the time line. The Innovation Opinions provided for special fast-track approval for new drugs and devices in urgent clinical need, and drugs and devices for rare diseases.

On December 21, 2017, the CFDA promulgated the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》), which further clarified that a fast track clinical trial approval or drug registration pathway will be available to innovative drugs. The Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation was replaced by the Announcement of NMPA on Promulgating Three Documents including the Working Procedures for Evaluation of Breakthrough Therapy Designation Drugs (Trial) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》), which was issued and implemented on July 7, 2020, refined the requirements and scope of the fast track, and the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation was repealed simultaneously.

On May 17, 2018, the NMPA and NHC jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the clinical trial approval process.

On July 24, 2018, the NMPA promulgated the Circular on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), which provides that if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the Center for Drug Evaluation under the NMPA (the “**CDE**”).

Regulations in relation to the Registration of New Drugs

Non-Clinical Research and Animal Testing

The non-clinical safety evaluation study for drugs for the purpose of applying for marketing approval shall be conducted in accordance with the Administrative Measures for Good Laboratories Practice for Non-Clinical Laboratory (《藥物非臨床研究質量管理規範》), which was promulgated on August 6, 2003 and revised on July 27, 2017 by the CFDA. On April 16, 2007, the State Food and Drug Administration, the predecessor of the CFDA, or the “SFDA” (before March 2013) issued the Circular on Measures for Certification of Good Laboratory Practice for Non-Clinical Laboratory (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and will come into effect on July 1, 2023, which sets forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake drug non-clinical research.

The State Science and Technology Commission, now known as the Ministry of Science and Technology, promulgated the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) on November 14, 1988, which were most recently

REGULATORY OVERVIEW

amended by the State Council on March 1, 2017. The State Science and Technology Commission and the State Bureau of Quality and Technical Supervision jointly promulgated the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) on December 11, 1997. The Ministry of Science and Technology and other regulatory authorities promulgated the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) on December 5, 2001. All of these laws and regulations require a Certificate for Use of Laboratory Animals for performing experimentation on animals.

Clinical Trial Application

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “**Registration Measures**”), which was promulgated on February 28, 2005 and last amended on January 22, 2020 and took effect on July 1, 2020, the CDE is responsible for the application of conducting new drug clinical trials. According to Registration Measures, drug clinical trials shall be divided into Phase 1 clinical trial, Phase 2 clinical trial, Phase 3 clinical trial, Phase 4 clinical trial, and bioequivalence trial.

After obtaining the clinical trial authorization from the NMPA, the applicant must register the clinical trial at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect on September 6, 2013. The applicant shall complete the pre-registration within one month after obtaining the clinical trial authorization and complete follow-up registrations before the first subject’s enrollment in the trial.

Conduction of Clinical Trial and the Communication with CDE

Clinical trials must be conducted in accordance with the Announcement on Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》), which was promulgated by the NMPA and NHC on April 23, 2020 and took effect on July 1, 2020, which also sets forth the requirements for conducting the clinical trial, including preparation of clinical trials, clinical trial protocol, duties of the sponsor and investigators and protection of the trial subjects.

The drug clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements of the Good Clinical Practice for Drug Trials (the “**GCP**”) and relevant technical guidelines for clinical trials according to the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which was promulgated by the NMPA and NHC on November 29, 2019 and came into effect on December 1, 2019.

According to the Registration Measures, applicants could communicate with the CDE the key issues before applying for drug clinical trials, through the clinical trials, before applying for marketing authorization, or during other key stages. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), promulgated by the CDE on December 10, 2020, during the research and development periods and in the registration applications of drugs, the applicants may propose to conduct the communication session with the CDE. The communication session can be classified into three types. Type 1 meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough

REGULATORY OVERVIEW

therapeutic drugs. Type 2 meetings are held during the key research and development periods of drugs, mainly including meetings before the Investigational New Drug application (the "IND"), meetings upon the completion of Phase 2 trials and before the commencement of Phase 3 trials, meetings before submitting a marketing application for a new drug, and meetings for risk evaluation and control. Type 3 meetings refer to meetings not classified as Type 1 or Type 2.

Regulations relating to Multi-Regional Clinical Trials and Acceptance of Overseas Clinical Trial Data

The International Multi-Center Clinical Trial Guidelines (Trial), or the Multi-Center Clinical Trial Guidelines, which was promulgated by the CFDA in January 2015 and came into effect in March 2015, provided guidance on the implementation of Multi-Regional Clinical Trials, or the MRCT, in China. According to the Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the international multi-center clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the Drug Administration Law, the Implementing Regulations of the Drug Administration Law and the Registration Measures, execute the GCP Rules, make reference to universal international principles such as the ICH-GCP and comply with the laws and regulations of the countries involved in the international multi-center clinical trials. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines, Registration Measures and other related laws and regulations.

In April 2020, the NMPA and the NHC promulgated the Revised GCP Rules, which came into effect in July 2020. The Revised GCP Rules summarize the requirements for initiating an MRCT, that is, before initiating an MRCT: (i) the applicant shall ensure that all the centers participating in the clinical trial comply with the trial protocol; (ii) the applicant shall provide each center with the same trial protocol, and each center shall comply with the same unified evaluation criterion for clinical trial and laboratory data and the same guidance for case report form; (iii) each center shall use the same case report form to record the data of each human subject obtained during the trial; (iv) before initiating a clinical trial, a written document is required to specify the responsibilities of the investigators of each center; and (v) the applicant shall ensure the communication among the investigators of each center.

Data derived from international multi-center clinical trials can be used for the new drug applications with the NMPA. When using international multi-center clinical trial data to support new drug applications in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with the content and format requirements under the International Conference on Harmonization-Common Technical Document. Subgroup research results summary and comparative analysis shall also be conducted concurrently. Leveraging the clinical trial data derived from international multi-center clinical trials conducted by our partners, we may avoid unnecessarily repetitive clinical trials and thus further accelerate the NDA process in China.

REGULATORY OVERVIEW

The CFDA released the Decision on Adjusting Items concerning the Administration of Imported Drug Registration in October 2017, which includes the following key points:

- If the International Multicenter Clinical Trial, or the IMCCT, of a drug is conducted in China, Phase I clinical trial of the drug is allowed simultaneously. The IMCCT drug does not need to be approved or to enter into either a Phase II or III clinical trial in a foreign country, except for preventive biological products;
- If the IMCCT is conducted in China, the application for drug marketing authorization can be submitted directly after the completion of the IMCCT. The Registration Measures and relevant laws and regulations shall be complied with for registration application;
- With respect to applications for the clinical trial and marketing of the imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required; and
- With respect to drug applications that have been accepted before the release of this Decision, if relevant requirements are met, importation permission can be granted if such applications request exemption of clinical trials for the imported drugs based on the data generated from the IMCCT.

New Drug Application

Pursuant to Registration Measures, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes, and preparation for acceptance of verification and inspection for drug registration, the applicant may apply to the NMPA for approval of NDA. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain approval of NDA before the drugs can be manufactured and sold in the China market. According to Registration Measures, for (1) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm the efficacy and forecast the clinical value of the drugs; (2) drugs which are urgently needed for public health and data of clinical trials can reveal the efficacy and forecast the clinical value of the drugs; (3) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, and the benefit is assessed outweigh the risk, such drugs can apply for conditional approval.

Reclassification of Drugs

According to the Registration Measures, drug marketing registration applications shall be subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. Among them, the registration applications of chemical drugs shall be categorized by innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

REGULATORY OVERVIEW

On March 4, 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Drugs (《化學藥品註冊分類改革工作方案》) (the “**Drug Reclassification Plan**”), which outlined the reclassifications of drug applications. Under the Drug Reclassification Plan, Category 1 refers to new drugs that have not been marketed anywhere in the world containing a new compound with a specific structure, pharmacological effects and clinical value. Improved new drugs that are not marketed anywhere in the world fall into Category 2, which refers to drugs with obvious clinical advantages that is optimized on the basis of known active ingredients in terms of structure, dosage form, prescription technology, route of drug administration and indications, etc.. Generic drugs, that have equivalent quality and efficacy to the originator’s drugs have been marketed abroad but not yet in China, fall into Category 3. Generic drugs, that have equivalent quality and efficacy to the originator’s drugs and have been marketed in China, fall into Category 4. Category 5 drugs are drugs which have already been marketed abroad but are not yet approved in China. The Chemical Drug Registration Classification and Application Data Requirements (《化學藥品註冊分類及申報資料要求》) which was promulgated by NMPA on June 29, 2020, and took effect on July 1, 2020, reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan for Registration Category of Chemical Drugs, and made minor adjustments to the subclassifications of Category 5. According to such rule, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

On June 29, 2020, the NMPA issued the Registration Category of Biological Products and the Data Requirements for Declaration (《生物製品註冊分類及申報資料要求》), which took effect on July 1 2020 stipulated that the therapeutic biological products should be classified into 3 categories, in which Category 1 refers to therapeutic biological products that have not been marketed anywhere in the world; Category 2 refers to improved new therapeutic biological products; and, Category 3 refers to therapeutic biological products that have been marketed in China or abroad.

Prioritized Examination and Approval for Registration of Certain Drugs

On November 11, 2015, the CFDA promulgated the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》), which provides that a fast track clinical trial approval or drug registration pathway can be available for the applications for certain drugs, including the registration of innovative new drugs treating HIV, cancer, serious infectious diseases and orphan diseases; and registration of pediatric drugs, etc.

On July 7, 2020, the NMPA promulgated the Announcement on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (Trial), which stipulates that during clinical trial period, innovative drugs or modified new drugs that are used to prevent and treat the disease that is serious life-threatening or severely affecting the quality of life and there is no effective prevention and treatment method, or compared with existing treatment methods that have sufficient evidence to show that they have obvious clinical advantages, then any applicant can apply for breakthrough therapeutic drug programs during Phase 1 and 2 clinical trials, but usually no later than the commencement of Phase 3 clinical trials.

On 23 October 2018, the NMPA and NHC jointly issued the Notice regarding Relevant Matters on the Review and Approval of Overseas New Drugs with Urgent Clinical Needs (《關於臨床急需境外新藥審評審批相關事宜的公告》), which provided a special approval system for the following new drugs with urgent clinical needs that have been marketed in the United States, Europe or Japan within the last decade: (1) drugs for rare diseases; (2) drugs for serious or

REGULATORY OVERVIEW

life-threatening diseases that lack effective treatment or prevention methods; (3) drugs for serious or life-threatening diseases with distinctive treatment advantages.

Special Examination and Approval Procedures

On November 18, 2005, the SFDA promulgated the Procedures of the SFDA for the Special Examination and Approval of Drugs (《國家食品藥品監督管理局藥品特別審批程序》), which stipulates that in the case of any threatening or actual public health emergency, the SFDA shall take a series of measures to facilitate the approval procedures so that the drugs needed in responding to the public health emergency can be approved as soon as possible.

Marketing Authorization Holder System

Pursuant to the PRC Drug Administration Law, which was promulgated on September 20, 1984 by the Standing Committee of the National People's Congress and recently revised on August 26, 2019, and came into effect on December 1, 2019, the Drug Marketing Authorization Holder Mechanism (the "MAH System") is applicable throughout the country. Under the MAH System, domestic drug research and development institutions and enterprises are eligible to be holders of drug registrations. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs. And holders of drug registrations shall establish a pharmaceutical quality assurance system, equipped with specialized staff solely responsible for the quality of medicines management.

Sampling and Collecting Human Genetic Resources Filing

On June 10, 1998, the Ministry of Science and Technology and the Ministry of Health promulgated the Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》), which established the rules for protecting and utilizing human genetic resources in the PRC. According to the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《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》) issued by the Ministry of Science and Technology on July 2, 2015 and the Circular on Implementing the Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) issued by the Ministry of Science and Technology on August 24, 2015, the sampling and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be required to be filed with the China Human Genetic Resources Management Office through the online system. On October 26, 2017, 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》), which simplifies the approval of sampling and collecting human genetic resources for the purpose of marketing a drug in the PRC.

REGULATORY OVERVIEW

The Regulations of the PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council on May 28, 2019 and implemented on July 1, 2019, stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s human genetic resources at clinical institutions without exporting of human genetic resource materials. However, the two parties shall file the type, quantity and usage of the human genetic resource to be used with the administrative department of science and technology under the State Council before clinical trials. On March 21, 2022, the Ministry of Science and Technology issued the Implementing Rules of the Administrative Regulations on Human Genetic Resources (for Public Comments) (人類遺傳資源管理條例實施細則(徵求意見稿)) (the “**Human Genetic Resources Implementing Rules**”) for public comments, which provided specific provisions on the collection, preservation, utilization and external provision of human genetic resources of the PRC. As of the Latest Practicable Date, the Human Genetic Resources Implementing Rules has not been officially issued and implemented.

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

Administrative Protection and Monitoring Periods for New Drugs

According to the Implementing Rules for PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) issued on March 2, 2019 and the Drug Reclassification Plan, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new Category 1 drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs. During the monitoring period of a new drug, the NMPA will not approve any other enterprises’ applications to manufacture or import the said drug.

Regulations in relation to the Manufacturing and Supply of Drugs

Drug Manufacturing Permit

Pursuant to the PRC Drug Administration Law, a drug manufacturer must obtain a Drug Manufacturing Permit from the NMPA before it starts to manufacture drug products. Prior to granting such permit, the relevant government authority will inspect the applicant’s production facilities, and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards. And according to the Implementing Rules for PRC Drug Administration Law and the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》) last amended in January 2020 and came into effect in July 2020, each Drug Manufacturing Permit is valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date and will be subject to reassessment by the authority in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal.

REGULATORY OVERVIEW

Good Manufacturing Practice

The drug manufacturer must conduct the manufacturing process according to the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) (2010 version) issued by the Ministry of Health on January 17, 2011, which sets forth the requirements on the manufacturer’s organization and staff qualifications, manufacture premises and facilities, equipment, hygiene conditions, manufacture management, product management, maintenance of sales records and the procedure of handling customer complaints and adverse reaction reports.

On August 2, 2011, the SFDA 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 Good Manufacturing Practice certification (the “**GMP certification**”) in accordance with the Drug Administration Law Implementing Regulations (《藥品管理法實施條例》). 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.

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 cancelled 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 consistently in compliance with statutory requirements.

On May 24, 2021, the NMPA issued the Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) which became effective on the same day, and the Administrative Measures for the Certification of Good Manufacturing Practice (《藥品生產質量管理規範認證管理辦法》) 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 licenses, 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.

REGULATORY OVERVIEW

Contract Manufacturing of Drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) issued by the CFDA on August 14, 2014 (the “**Contract Manufacturing Regulations**”), in the event a drug manufacturer in China that has obtained a drug marketing authorization temporarily lacks manufacturing conditions as a result of technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, it can entrust the manufacturing of that drug to another domestic drug manufacturer. Such contract manufacturing arrangements needs to be approved by the provincial branch of the CFDA. The Contract Manufacturing Regulations prohibit the contract manufacturing arrangement of certain special drugs, including narcotic drugs, psychoactive drugs, biochemical drugs and active pharmaceutical ingredients.

The PRC Drug Administration Law specifies that drug marketing authorization holders may produce drugs by themselves or entrust drug manufacturers with the production of such drugs. A drug marketing authorization holder that intends to manufacture drugs on its own shall obtain a drug manufacturing permit; if it intends to manufacture drugs on a commissioned basis, it shall entrust a qualified drug manufacturer. Drug marketing authorization holders and the commissioned manufacturers shall enter into an entrustment agreement and a quality agreement, and strictly perform the obligations under such agreements. Blood products, anesthetics, psychotropic pharmaceuticals, toxic pharmaceuticals for medical treatment, and pharmaceutical precursor chemicals may not be produced through entrustment, except as otherwise prescribed by the department of drug supervision and administration of the State Council.

Drug Operation Permit

According to the Drug Administration Law, the Provisions for Supervision and Administration of Drug Distribution (《藥品流通監督管理辦法》), which was issued by the SFDA on January 31, 2007 and came into effect on May 1, 2007, detailed provisions are imposed on aspects such as the purchase, sale, transportation and storage of medicines. The engagement of a wholesale pharmaceutical distribution of a company requires the approval of the provincial medicine administrative authorities. Upon approval, the authority will grant a Drug Operation Permit in respect of the wholesale drugs distribution company. The grant of such permit is subject to an inspection of the operator’s facilities, warehouse, hygiene environment, quality control systems, personnel (including of whether pharmacists and other professionals have the relevant qualifications) and equipment. Under the Measures on the Administration of Drug Operation Permit (《藥品經營許可證管理辦法》) promulgated on February 4, 2004 and became effective from April 1, 2004 and amended on November 17, 2017 by the NMPA, a Drug Operation Permit is valid for five years. Each holder of the Drug Operation Permit must apply for an extension of its permit six months prior to expiration, and extensions are granted only after a reexamination of the permit holder by the authority which issued the permit.

REGULATORY OVERVIEW

Good Supply Practices

According to the Good Supply Practice for Drugs (《藥品經營質量管理規範》) (the “**Good Supply Practice**”) newly amended by the CFDA on July 13, 2016, drug distributors shall strictly implement the Good Supply Practice. Enterprises shall take effective measures for quality control at such stages as procurement, storage, sales and transportation of drugs to ensure the quality of drugs and shall develop a drug traceability system as per relevant requirements of the state to realize the traceability of drugs. In addition, the CFDA revised the Guidelines for On-site Inspection of Drug Operation and Quality Management Specifications (《藥品經營質量管理規範現場檢查指導原則》) in 2016, in order to further regulate the organization of the supervision and inspection of drug distributors.

Regulations in relation to the Medical Insurance Program

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 Urban Resident Basic Medical Insurance. In addition, on January 3, 2016, the Opinions of the State Council 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.

Medical Insurance Catalogue

According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》), which promulgated by the NHSA, on July 30, 2020 and took effect on September 1, 2020, the scope of drugs covered by the basic medical insurance shall be administered through a reimbursement drug list.

The National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or the National Reimbursement Drug List, or the NRDL, which promulgated by the NHSA and the Ministry of Human Resources and Social Security (the “**MOHRSS**”), on January 13, 2023 and took effect on March 1, 2023, sets forth the payment standard for pharmaceutical products under the basic medical insurance, work-related injury insurance and maternity insurance funds. The local government shall strictly implement the National Drug Catalog, and shall not adjust the contents

REGULATORY OVERVIEW

contained in the Catalogue at their own discretion. Medicines listed in the NRDL are divided into two parts, List A and List B. List A drugs are widely used clinical treatments with good efficacy and lower prices compared to similar drugs, while List B drugs are clinical treatments with good efficacy and slightly higher prices compared to List A drugs.

According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance, a Provincial Reimbursement Drug List (“**PRDL**”) must be made by the provincial healthcare security authorities. The provincial healthcare security authorities have the right to add ethnic drugs and preparations of medical institutions as List B drugs in the PRDL in accordance with relevant rules.

According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance, patients purchasing List A drugs can directly obtain reimbursement under the basic medical insurance program. Patients purchasing List B drugs shall pay a certain percentage of the purchase price first and then obtain reimbursement under the basic medical insurance program.

National Essential Drug List

On August 18, 2009, the Ministry of Health (the “**MOH**”) and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National Essential Drug List (《國家基本藥物目錄管理辦法(暫行)》), which was revised by NHFPC on February 13, 2015, and the Guidelines on the Implementation of the National Essential Drug List System (《關於建立國家基本藥物制度的實施意見》), which aims to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National Essential Drug List. NHC promulgated the National Essential Drug List (2018) (《國家基本藥物目錄(2018年版)》), the “**National Essential Drug List**”) on September 30, 2018, replacing the National Essential Drug List (2012) (《國家基本藥物目錄(2012年版)》) which was promulgated on March 13, 2013. According to these regulations, basic healthcare institutions funded by 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 National Essential Drug List. The drugs listed in National Essential Drug List shall be purchased by centralised tender process and shall be subject to the price control by the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會). Remedial drugs 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.

Regulations in relation to the Price Control and Two-invoice System

Instead of direct price controls which were historically used in China, the government regulates prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards, and strengthening regulation of medical and pricing practices.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralized Tender Procurement of Drugs by Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定》) promulgated 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》) promulgated on July 23, 2001, not-for-profit

REGULATORY OVERVIEW

medical institutions established by county or higher level government are required to implement centralized tender procurement of drugs.

The Ministry of Health promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralized Tender and Price Negotiations (Trial) (《醫療機構藥品集中招標採購和集中議價採購工作規範(試行)》) on March 13, 2002, which provides rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. According to the Notice on the Issue of Opinions on Further Regulating Centralized Procurement of Drugs by Medical Institutions (《印發進一步規範醫療機構藥品集中採購工作的意見》) promulgated by the MOH and five other ministries and commissions on January 17, 2009, not-for-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralized procurement. Each provincial government shall formulate its catalogue of drugs subject to centralized procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines, in principle, all drugs used by not-for-profit medical institutions shall be covered by the catalogue of drugs subject to centralized procurement. The Opinions of the General Office of the State Council on Improvement of the Policy of Production, Circulation and Use of Drugs (《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 on January 24, 2017 by the General Office of the State Council aims to deepen the reform of medicine health system, improve the quality of the drug and regulate the distribution and use of the drug. The Notice of the General Office of the State Council on Issuing Pilot Plan of Centralized Procurement and Use of the Drug Organized by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》) promulgated on January 1, 2019 aims to improve the pricing mechanism of the drug, which also further regulates the scope and mode of centralized procurement.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. The centralized tender process is in principle conducted once every year in the relevant province or city in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralized tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical System Reforms (《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, the "Two-invoice System" (兩票制) is fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) (《印發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)的通知》), which came into effect on December 26, 2016, the two-invoice system means one

REGULATORY OVERVIEW

invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the hospital.

Regulations in relation to Company Establishment and Foreign Investment

Company Establishment

The establishment, operation and management of corporate entities in China 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 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 and October 26, 2018. Pursuant to the Company Law, companies are classified into 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.

The Company Law is the principal law governing dividend distributions of PRC companies. PRC companies may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting principles. In addition, PRC companies are required to set aside each year at least 10% of their after-tax profit based on PRC accounting principles to their statutory general reserves funds until the cumulative amount of such reserve fund reaches 50% of their registered capital. These reserves or funds are not distributable as dividends. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year. Upon approval of the competent governmental authorities, foreign investors may utilize RMB dividends to invest or re-invest in enterprises established in China.

Foreign Investment

The Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法》) (the “**FIL**”), which was promulgated by the National People’s Congress on March 15, 2019 and came into effect on January 1, 2020, provides that the foreign investment refers to the investment activities in China carried out directly or indirectly by foreign natural persons, enterprises or other organizations, including the following: (1) Foreign Investors establishing foreign-invested enterprises in China alone or collectively with other investors; (2) Foreign Investors acquiring shares, equities, properties or other similar rights of Chinese domestic enterprises; (3) Foreign Investors investing in new projects in China alone or collectively with other investors; and (4) Foreign Investors investing through other ways prescribed by laws and regulations or the State Council. The State adopts the management system of pre-establishment national treatment and negative list for foreign investment. The pre-establishment national treatment refers to granting to Foreign Investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments; the negative list refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. The State will grant national treatment to foreign investments outside the negative list. The negative list will be released by or upon approval of the State Council.

REGULATORY OVERVIEW

Foreign investment in China is subject to the Catalogue for the Encouraged Investment Industries (2022 Edition) (《鼓勵外商投資產業目錄(2022年版)》) issued on October 26, 2022 and took effect on January 1, 2023, and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2021 Edition) (《外商投資准入特別管理措施(負面清單)(2021年版)》) issued on December 27, 2021 and took effect on January 1, 2022, which together comprise the encouraged foreign-invested industries catalogue and the special administrative measures for the access of foreign investments to the restricted or the prohibited foreign-invested industries. The latter sets out restrictions such as percentage of shareholding and qualifications of senior management. According to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》) which took effective on January 1, 2020, foreign investments that are not subject to special access administrative measures and are only required to complete an online filing to the commerce departments.

Regulations in relation to Intellectual Properties

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》) promulgated by the NPCSC on March 12, 1984, as amended on September 4, 1992, August 25, 2000, December 27, 2008 and October 17, 2020, and 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 and as amended on December 28, 2002 and January 9, 2010, there are three types of patents in the PRC: invention patents, utility model patents and design patents. The protection period is 20 years for an invention patent, 10 years for a utility model patent and 15 years for a design patent, commencing from their respective application dates. Any individual or entity that utilizes a patent or conducts any other activity in infringement of a patent without prior authorization of the patent holder shall pay compensation to the patent holder and is subject to a fine imposed by relevant administrative authorities and, if constituting a crime, shall be held criminally liable in accordance with the law.

According to the Amendments to the Patent Law of the PRC which became effective from June 1, 2021, for the purpose of compensating for the time taken to evaluate and approve a new drug to be put on market, the patent administrative department under the State Council shall grant compensation for duration of patent rights for invention of a new drug approved to be put on market in China upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug approved to be put on market shall not exceed 14 years.

Trade Secrets

According to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), promulgated by the NPCSC in September 1993, as amended in November 4, 2017 and April 23, 2019 respectively, the term "trade secrets" refers to technical, operational or other business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2)

REGULATORY OVERVIEW

disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any confidentiality obligations or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigate, entice or help others to obtain, disclose, use or permit others to use the trade secrets in violation of any confidentiality obligations or any requirements of the legal owners or holders to keep such trade secrets in confidence. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed an infringement of the others' trade secrets. The parties whose trade secrets are being infringed may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Trademarks

According 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, amended on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019 and effective from November 1, 2019, 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 twelve months prior to the date of expiry, if intending 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 renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to law.

Copyright

Copyright in the PRC is primarily protected by the Copyright Law of the PRC (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990, last amended on November 11, 2020 and became effective on June 1, 2021, and Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and last amended on January 30, 2013. These law and regulation provide provisions on the classification of works and the obtaining and protection of copyright.

Domain Names

Domain names are protected under the Administrative Measures on the 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 took effect from November 1, 2017, and the Implementing Rules on Registration of National Top-level Domain Names (《國家頂級域名註冊實施細則》) issued by China Internet Network Information Center and came into effective on June 18, 2019. The MIIT is the main regulatory body responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

REGULATORY OVERVIEW

Other Regulations in relation to Our Business

Enterprise Income Tax and Value Added Tax

According to the Enterprise Income Tax Law (《中華人民共和國企業所得稅法》) promulgated by the National People’s Congress on March 16, 2007, which became effective on January 1, 2008 and was amended on February 24, 2017 and December 29, 2018, and the Implementation Rules of 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》) promulgated by the State Council on December 6, 2007, which became effective on January 1, 2008, and amended on April 23, 2019, other than a few exceptions, the income tax rate for both domestic enterprises and foreign-invested enterprises is 25%. Enterprises are classified as either “resident enterprises” or “non-resident enterprises”. Besides enterprises established within the PRC, enterprises established outside China whose “de facto management bodies” are located in China are considered “resident enterprises” and subject to the uniform 25% enterprise income tax rate for their global income. A non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC but which have an establishment or place of business in the PRC, or which do not have an establishment or place of business in the PRC but have income sourced within the PRC. An income tax rate of 10% will normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or that have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC.

According to the Temporary Regulations on Value Added Tax of the PRC (《中華人民共和國增值稅暫行條例》) (the “**VAT Regulations**”), which was promulgated by the State Council on December 13, 1993, came into effect on January 1, 1994, and was amended on November 10, 2008, on February 6, 2016 and November 19, 2017 respectively, and the Detailed Rules for the Implementation of the VAT Regulations (《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 and came into effect on December 25, 1993 and was amended on December 15, 2008 and October 28, 2011, all taxpayers selling goods, providing processing, repairing or replacement services or importing goods within the PRC shall pay value added tax. Other than those as specified in the VAT Regulations, the tax rate of 17% shall be levied on general taxpayers selling or importing various goods; the tax rate of 17% shall be levied on the taxpayers providing processing, repairing or replacement service; the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated. According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Notice of the Ministry of Finance, the State Administration of Taxation and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform (《關於深化增值稅改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the value added tax rate was reduced to 13% and 9%, respectively.

REGULATORY OVERVIEW

According to an Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (the “**Double Tax Avoidance Arrangement**”) issued on August 21, 2006, and other applicable PRC laws, if a Hong Kong resident enterprise is determined by the competent PRC tax authority to have satisfied the relevant conditions and requirements under such Double Tax Avoidance Arrangement and other applicable laws, the 10% withholding tax on the dividends the Hong Kong resident enterprise receives from a PRC resident enterprise may be reduced to 5%. However, based on the Circular on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties (《關於執行稅收協定股息條款有關問題的通知》) issued on February 20, 2009 by the SAT, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment; and based on the Announcement on Certain Issues with Respect to the “Beneficial Owner” in Tax Treaties (《國家稅務總局關於稅收協定中「受益所有人」有關問題的公告》) issued by the SAT on February 3, 2018 and effective from April 1, 2018, if an applicant’s business activities do not constitute substantive business activities, it could result in the negative determination of the applicant’s status as a “beneficial owner”, and consequently, the applicant could be precluded from enjoying the above-mentioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement.

Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated by the NPCSC on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018, is the principal governing law relating to the supervision and administration of product quality, which clarified liabilities of the manufactures and sellers. Manufactures shall not be liable when they are able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects. A seller shall pay compensation if it can neither indicate the manufacturer nor the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim compensation from the manufacturer or the seller.

According to the Civil Code of PRC (《中華人民共和國民法典》), promulgated by the NPC on May 28, 2020 and effective on January 1, 2021, manufacturers shall assume tort liability where the defects in relevant products cause damage to others. The aggrieved party may claim compensation from the manufacturer or the seller of the relevant product in which the defects have caused damage.

Safety Management Supervision

Pursuant to the Law on Work Safety of the PRC (《中華人民共和國安全生產法》) (Order No. 70 of the PRC President, effective on November 1, 2002 and amended on August 27, 2009, August 31, 2014 and June 10, 2021 respectively), enterprises engaged in production activities must strengthen safety production management, establish and improve the responsibility system for safe production and ensure a safe production environment. The state establishes and implements a system for the accountability of production safety accidents. If the company fails to comply with

REGULATORY OVERVIEW

the provisions of the Law on Work Safety, the supervisory authority on production safety may issue a rectification order, impose a fine, order the company to cease production and operation, or revoke the relevant permit.

Some chemical materials needed for new drug research and development, such as toluene and hydrochloric acid, are hazardous chemicals. Pursuant to the Regulations on Safety Management of Hazardous Chemicals (《危險化學品安全管理條例》) (Order No. 344 of the State Council, effective on March 15, 2002 and amended on March 2, 2011 and December 7, 2013, respectively), the production, storage, use, operation, and transportation of hazardous chemicals must be in accordance with the safety management regulations. The hazardous chemical units shall oblige to the safety conditions required by laws and administrative regulations and state and industry standards, establish and improve safety management rules and post safety responsibility systems, and provide safety education and legal education and occupation technical training for employees. Employees should accept such education and training, and may begin working only after qualifying the relevant assessment. Where it requires employees to have certain qualification to assume a post, an enterprise shall only designate employees having such qualification to assume the post.

Environmental Protection

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), promulgated by the NPCSC on December 26, 1989 and amended on April 24, 2014, all enterprises and institutions which discharge pollutants shall adopt measures to prevent and control pollution and damage to the environment from waste gas, waste water, waste residues, medical waste, dust, malodorous gases, radioactive substances, noise, vibration, ray radiation and electromagnetic radiation generated in the course of production, construction or other activities. The relevant authorities are authorized to impose various types of penalties on the persons or entities in violation of the environmental regulations, including fines, restriction or suspension of operation, shut-down, detention of office-in-charge, etc.

According to the Environmental Protection Law of the PRC, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the NPCSC on October 28, 2002 and amended on July 2, 2016 and December 29, 2018 respectively, the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), promulgated by the State Council on November 29, 1998 and amended on July 16, 2017, and other relevant environmental laws and regulations, enterprises which plan to construct projects shall provide the environmental assessment reports, assessment form, or registration form on the environmental impact of such projects with relevant environmental protection administrative authority for approval or filing. Enterprises planning to construct projects may entrust a technical entity to conduct environmental impact assessment and compose assessment reports and assessment forms of the construction project. If the enterprise has the technical capability of environmental impact assessment, it may conduct environmental impact assessment of its construction project and prepare assessment reports and assessment form by itself. Enterprises shall, after the completion of the construction project for which the environmental assessment reports, assessment form is prepared, according to standards and procedures prescribed by the environmental protection administrative department of the State Council, conduct acceptance check of the constructed supporting environmental protection facilities and prepare the acceptance check report.

REGULATORY OVERVIEW

Pursuant to the Measures for Pollutant Discharge Permitting Administration (for Trial Implementation) (《排污許可管理辦法(試行)》) (Order No. 48 of the Ministry of Environmental Protection, effective on January 10, 2018 and amended on August 22, 2019), enterprises, institutions and other producers and operators (the “**pollutant discharge enterprises**”) that have been included in the Classification Administration List of Pollutant Discharge Permitting for Fixed Pollution Sources (《固定污染源排污許可分類管理名錄》) shall apply for and obtain a discharge permit in accordance with the prescribed time limit. The pollutant discharge enterprises that are not included in the Classification Management List do not need to apply for a pollutant discharge permit. The pollutant discharge enterprise shall hold a pollutant discharge permit in accordance with the law and discharge pollutants in accordance with the discharge permit. Pursuant to the Notice of the General Office of the State Council on Issuing the Implementation Plan for the Permit System Controlling Pollutant Emission (《國務院辦公廳關於印發控制污染物排放許可制實施方案的通知》) (No. 81 [2016] of the General Office of State Council, effective on November 10, 2016) and the Classification Administration List of Pollutant Discharge Permitting for Fixed Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) (Order No. 11 of the Ministry of Ecology and Environment, the State implements focused, simplified and registered management of emission permits based on factors such as the amount of pollutants produced by enterprises and other production operators discharging pollutants, the amount of their emissions and the impact on the environment.

Labor and Social Insurance

According to the PRC Labor Law (《中華人民共和國勞動法》), which was promulgated by the NPCSC on July 5, 1994 and effective from January 1, 1995, and amended on August 27, 2009 and December 29, 2018 respectively, the PRC Labor Contract Law (《中華人民共和國勞動合同法》), which was promulgated by the NPCSC on June 29, 2007 and effective from January 1, 2008, and amended on December 28, 2012 and effective from July 1, 2013, and the Implementing Regulations of the Employment Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council on September 18, 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages cannot be lower than local minimum wage. The employers must establish a system for labor safety and sanitation, strictly abide by State rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with State rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the NPCSC on October 28, 2010 and effective from July 1, 2011, and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and to housing provident funds. Any employer who fails to contribute may be fined and ordered to make good the deficit within a stipulated time limit.

REGULATORY OVERVIEW

Foreign Exchange Control

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》) which was promulgated by the State Council on January 29, 1996, became effective on April 1, 1996 and was subsequently amended on January 14, 1997 and August 5, 2008 and the Regulations on the Administration of Foreign Exchange Settlement, Sale and Payment (《結匯、售匯及付匯管理規定》) which was promulgated by PBOC on June 20, 1996 and became effective on July 1, 1996. Pursuant to these regulations and other PRC rules and regulations on currency conversion, Renminbi is freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of the SAFE or its local counterpart is obtained.

Foreign-invested enterprises are permitted to convert their after-tax dividends into foreign exchange and to remit such foreign exchange out of their foreign exchange bank accounts in the PRC. However, foreign exchange transactions involving overseas direct investment or investment and exchange in securities, derivative products abroad are subject to registration with SAFE and approval from or filing with the relevant PRC government authorities (if necessary).

SAFE promulgated the Notice on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign-invested Enterprises (《關於改革外商投資企業外匯資金結匯管理方式的通知》) (“**SAFE Circular 19**”) on March 30, 2015, further expanding the extent of convertibility under direct investment. SAFE Circular 19 stipulates that the use of capital funds and exchange settlement funds by foreign-invested enterprises shall be subject to foreign exchange management regulations, and implement negative list management.

On June 9, 2016, the SAFE promulgated the Circular on Reforming and Regulating Policies on the Management of the Settlement of Foreign Exchange 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**”). The SAFE Circular 16 unifies the policies of Discretionary Foreign Exchange Settlement for all the domestic institutions. The Discretionary Foreign Exchange Settlement means that the foreign exchange capital in the capital account which has been confirmed by the relevant policies subject to the Discretionary Foreign Exchange Settlement (including foreign exchange capital, foreign loans and funds remitted from the proceeds from the overseas listing) can be settled at the banks based on the actual operational needs of the domestic institutions. The proportion of Discretionary Foreign Exchange Settlement of the foreign exchange capital is temporarily determined as 100%. Violations of SAFE Circular 19 or SAFE Circular 16 could result in administrative penalties in accordance with the Regulations of the People’s Republic of China on Foreign Exchange Control and relevant provisions.

Furthermore, SAFE Circular 16 stipulates that the use of foreign exchange incomes of capital accounts by foreign-invested enterprises shall follow the principles of authenticity and self-use within the business scope of enterprises. The foreign exchange incomes of capital accounts and capital in Renminbi obtained by the FIE from foreign exchange settlement shall not be used for the following purposes: (i) directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; (ii) directly or indirectly used for investment in securities or financial schemes other than bank’s

REGULATORY OVERVIEW

principal guaranteed products unless otherwise provided by relevant laws and regulations; (iii) used for granting loans to non-connected enterprises, unless otherwise permitted by its business scope; and (iv) used for the construction or purchase of real estate that is not for self-use (except for the real estate enterprises).

In October 2019, SAFE issued the Notice of the State Administration of Foreign Exchange on Further Promoting the Facilitation of Cross-border Trade and Investment (《關於進一步促進跨境貿易投資便利化的通知》), or SAFE Circular 28, pursuant to which foreign-invested enterprises whose approved business scope does not include equity investments are allowed to use their capital funds obtained from foreign exchange settlement to make domestic equity investments in China, provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws.

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 and effective on April 10, 2020 by the SAFE, the reform of facilitating the payments of incomes under the capital accounts shall be promoted nationwide. Under the prerequisite that the use of funds is genuine and in compliance with laws and complying with the prevailing administrative provisions on use of income from capital accounts, enterprises which satisfy the criteria are allowed to use income under the capital account, such as capital funds, foreign debt and overseas listing, etc., for domestic payment, without the need to provide proof materials for veracity to the bank beforehand for each transaction.

Dividend Distribution

According to the PRC Company Law, Foreign Investment Law and Regulation for Implementing the Foreign Investment Law, foreign-invested enterprises in the PRC may pay dividends only out of their accumulated profits as determined in accordance with PRC accounting standards and regulations. An enterprise is required to set aside at least 10% of its respective accumulated profits to its statutory common reserve where it distributes its after-tax profits of the current year, until the accumulative amount of such reserve reaches 50% of its registered capital. If the aggregate balance of the enterprise's statutory common reserve is not enough to make up for the losses of the enterprise of the previous year, the current year's profits shall first be used for making up the losses before the statutory common reserve is drawn. After the enterprise has drawn statutory common reserve from the after-tax profits, it may, upon a resolution made by the shareholders' meeting, draw a discretionary common reserve from the after-tax profits. After the losses have been made up and common reserves have been drawn, the remaining profits shall be distributed to shareholders.

According to the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control (《國家外匯管理局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》) promulgated by the SAFE on January 26, 2017, (1) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (2) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when proceeding with the registration procedures in connection with an outbound investment.

REGULATORY OVERVIEW

SAFE Circular 37

In July 2014, SAFE promulgated the Notice of the State Administration of Foreign Exchange on Issues concerning Foreign Exchange Administration of the Overseas Investment and Financing and the Round-tripping Investment Made by Domestic Residents through Special-Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or the SAFE Circular 37, which replaces the Notice of the State Administration of Foreign Exchange on Relevant Issues concerning Foreign Exchange Administration for Domestic Residents to Engage in Financing and in Return Investment via Overseas Special Purpose Companies (《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》), or the SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities.

According to the Circular on Further Simplifying and Improving the Direct Investment related Foreign Exchange Administration Policies (《關於進一步簡化和改進直接投資外匯管理政策的通知》), which was promulgated by the SAFE on February 13, 2015 and came into effect on June 1, 2015, registrations under Circular 37 will be handled directly by the bank that has obtained the financial institution identification codes issued by the foreign exchange regulatory authorities and that has opened the capital account information system at the local foreign exchange regulatory authority. Foreign exchange regulatory authorities will perform indirect regulation over the direct investment-related foreign exchange registration via the banks.

Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), which prescribed that PRC citizens or non-PRC citizens residing in China for a continuous period of no less than one year (except for foreign diplomatic personnel in China and representatives of international organizations in China) who participate in any stock incentive plan of an overseas publicly listed company shall, through the domestic company to which the said company is affiliated, collectively entrust a domestic agency (may be the Chinese affiliate of the overseas publicly listed company which participates in stock incentive plan, or other domestic institutions qualified for asset trust business lawfully designated by such company) to handle foreign exchange registration, and entrust an overseas institution to handle issues like exercise of options, purchase and sale of corresponding stocks or equity, and transfer of corresponding funds. In addition, the domestic agency is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan.

M&A Rules

On August 8, 2006, MOFCOM, the State-owned Assets Supervision and Administration Commission of the State Council, the SAT, the State Administration of Industry and Commerce, the China Securities Regulatory Commission and SAFE jointly issued the Rules on the Acquisition of Domestic Enterprises by Foreign Investors (as amended, re-promulgated and effective on June 22, 2009) (《關於外國投資者併購境內企業的規定》) (the "M&A Rules"). According to the M&A Rules, the merger and acquisition of the domestic companies by foreign investors means that the

REGULATORY OVERVIEW

foreign investors purchase or subscribe for the equity or shares of a non-foreign invested PRC company or that the foreign investors establish a foreign-invested PRC company to acquire or operate the assets of a non-foreign-invested PRC company by agreement. The M&A Rules require that an application be made to MOFCOM for examination and approval in relation to the acquisition of any company inside China affiliated with a domestic company, enterprise or natural person, which is made in the name of an overseas company lawfully established or controlled by such domestic company, enterprise or natural person. The M&A Rules also provide that the overseas listing of a special purpose company controlled directly or indirectly by PRC companies or individuals on an overseas stock market must be approved by the China Securities Regulatory Committee.

The M&A Rules, and other recently adopted regulations and rules concerning mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. For example, the M&A Rules require that MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that impact or may impact national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand.

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 National Development and Reform Commission (the “NDRC”) on December 26, 2017, and effective from March 1, 2018, if an enterprise in the territory of the PRC (the “Investor”) intends to make outbound investments (the “Project”), it shall be subject to approval or filing for the Project, report relevant information, and cooperate in the supervisory inspections. The sensitive Projects invested directly by the Investor or through the foreign enterprises controlled by the Investor shall be subject to approval. The non-sensitive Projects invested directly by the Investor, which involve the direct contribution of assets, rights and interests, or provision of financing or guarantee by the Investor, shall be subject to filing.

Information Security and Data Privacy

On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) (the “Data Security Law”), which became effective from September 1, 2021. According to the Data Security Law, a data classification protection system shall be established to protect data by classification. Entities engaged in data processing activities shall, in accordance with the laws and regulations, establish a sound whole-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

According to the Civil Code, personal information of natural persons is protected by law. Any organization or individual that needs to obtain personal information of others shall obtain legally and ensure the information security, and shall not illegally collect, use, process, transmit, trade, provide or disclose personal information of others. The Personal Information Protection

REGULATORY OVERVIEW

Law of the PRC (《中國人民共和國個人信息保護法》) promulgated by the SCNPC on August 20, 2021 and effective from November 1, 2021 further emphasized the duties and responsibilities of the processing personnel for the protection of personal information, and provided stricter protection measures for processing sensitive personal information.

On November 7, 2016, the SCNPC promulgated the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) (the “**Cybersecurity Law**”), which became effective from June 1, 2017. According to the Cybersecurity Law, network operators shall abide by the principles of legality, legitimacy and necessity when collecting and using personal information. Network operators shall disclose the rules for collection and use, specify the purpose, methods and scope of collection and use of information, and obtain consent from the persons whose personal information is collected, when collecting and using personal information. Network operators shall not collect the personal information irrelevant to the services they provide, nor disclose, tamper with or damage the personal information they collect, and shall not provide relevant personal information to others without the prior consent of the persons whose personal information is collected, except for the personal information that cannot be identified and restored after processing.

On July 7, 2022, the CAC issued the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) (the “**Cross-border Data Transfer Measures**”) which became effective on September 1, 2022. Pursuant to the Cross-border Data Transfer Measures, the security assessment of outbound data transfer shall adhere to the integration of prior assessment and continuous supervision and the integration of risk self-assessment and security assessment, so as to prevent security risks arising from outbound data transfer and ensure the orderly and free flow of data in accordance with the law. A data processor shall expressly agree on the data security protection responsibilities and obligations in the legal documents concluded with the overseas recipient.

On July 12, 2018, the NHC issued the Administrative Measures on National Health and Medical Care Big Data Standards, Security and Services (Trial) (《國家健康醫療大數據標準、安全和服務管理辦法(試行)》) (the “**Measures on Health and Medical Care Big Data**”), which became effective on the same day. The Measures on Health and Medical Care Big Data provided the guidelines and principles of health and medical big data standard management, security management and service management. According to the Measures on Health and Medical Care Big Data, the NHC, together with other relevant departments, is responsible for the management of national health and medical care big data, while the authorities of health above the county level, together with other relevant departments, are responsible for the management of health and medical care big data within their respective administrative regions. Medical institutions and relevant enterprises, including those engaged by medical institutions to store or operate health and medical care big data, shall take measures, such as data classification, important data backup and encryption, to ensure the security of health and medical care big data, and provide secured channels for the query and replication of information. The responsible parties shall, pursuant to the Cybersecurity Law, strictly control the authorization to users at different levels to access and use data, and ensure the use of data within the scope of authorization. Without authorization, no unit or individual shall use or disseminate any health and medical care big data or data beyond the scope of authorization, nor obtain any data in illegal ways. The responsible parties shall abide by the relevant regulations when disclosing health and medical care big data, shall not divulge state secrets, trade secrets or personal privacy, shall not infringe upon the interests of the state or the public, and shall not infringe upon the legitimate rights and interests of citizens, enterprise entities or other organizations.

REGULATORY OVERVIEW

Overseas Listing

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of the 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》) (the “**Overseas Listing Trial Measures**”) and relevant five guidelines, which became effective on March 31, 2023. The Overseas Listing Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas [REDACTED] and [REDACTED] of PRC domestic companies’ securities and regulate both direct and indirect overseas [REDACTED] and [REDACTED] of PRC domestic companies’ securities by adopting a filing-based regulatory regime.

According to the Overseas Listing Trial Measures, a domestic company seeking direct overseas [REDACTED] and [REDACTED] shall file with the CSRC, submit the filing report, legal opinions and other relevant materials as required under the Overseas Listing Trial Measures, and state the shareholders’ information and other matters in a truthful, accurate and complete manner. Where a domestic company submits an [REDACTED] for [REDACTED] to the competent overseas regulators, such domestic company shall file with the CSRC within three business days after such [REDACTED] is submitted. The Overseas Listing Trial Measures also require subsequent reports to be filed with the CSRC on material events, such as a change-of-control event, or voluntary or forced [REDACTED] of the issuer who has completed the overseas [REDACTED] and [REDACTED]. If the issuer fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, it may be subject to administrative penalties, such as order 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.

On the same day, the CSRC also held a press conference for the release of the Overseas Listing Trial Measures and issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which, among others, clarified that, a domestic company that has already obtained the approval document from the CSRC for overseas [REDACTED] and [REDACTED] may proceed with the overseas [REDACTED] within the validity period of the approval document. Where the overseas [REDACTED] has not been completed upon the expiration of the approval document, filing procedures specified in the Overseas Listing Trial Measures shall be made as required.

LAWS AND REGULATIONS IN THE UNITED STATES AND EU

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

U.S. Government Regulation of Drug and Biological Products

In the United States, the Food and Drug Administration (“**FDA**”) regulates drugs under the Food, Drug, and Cosmetic Act (“**FDCA**”) and its implementing regulations, and the FDA regulates biologics under the FDCA and the Public Health Service Act (the “**PHSA**”) and their respective 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 to manufacture or market drugs and biologics in the United States and the

REGULATORY OVERVIEW

subsequent compliance with appropriate federal, state, local, and non-U.S. applicable 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 proceedings, administrative actions, government prosecution, judicial sanctions or any combination of them in the United States. 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 administrative proceeding on action or any judicial enforcement action could have a material adverse effect on our business, financial condition and results of operations as well as the market's acceptance of our products and our reputation. Outside the United States, drugs and biologics are regulated under other statutory and regulatory systems with which we would need to comply if we were to manufacture or market drugs or biologics outside the United States, and failure to comply there could also subject us to administrative actions, government prosecution or judicial sanctions (or any combination of them).

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA's Good Laboratory Practice regulations. A sponsor of an Investigational New Drug application ("**IND**") must submit the results of the preclinical tests (such as animal tests), 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. Although information a sponsor submits in an IND is confidential information, general clinical trial information such as the number of patients involved and the type of adverse events studied can be made public information and can be available for public review through publication on government websites such as www.clinicaltrials.gov.

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 ("**GCPs**") and human subject protection 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**"), often under the auspices of a university and sometimes a private, independent organization, 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 human subject research regulations or if the product has been associated with unexpected serious harm to subjects and the IRB believes patients are at risk.

REGULATORY OVERVIEW

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 in 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 pharmacokinetics and pharmacodynamics 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 before marketing approval is received. 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 FDA's current Good Manufacturing Practices ("cGMP").

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a New Drug Application ("NDA"). Unless deferred or waived, NDAs, or supplements, must contain data adequate to assess the safety and efficacy of the product at the proposed commercial dosing regimen and administration for the claimed indications in all relevant populations, including any pediatric subpopulations. The submission of an NDA is subject to the payment of a user fee and an annual prescription drug product program fee to the FDA although in certain circumstances the FDA may waive the annual prescription drug product program fee if the drug qualifies for orphan drug designation.

REGULATORY OVERVIEW

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

The FDA may refuse to approve the NDA 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 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 withdraw the application and resubmit the NDA when all the data addressing all of the deficiencies identified in the letter is available, or the applicant may 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.

MRCTs

FDA has acknowledged the increasing globalization of drug development and the importance that data from multiregional clinical trials (MRCTs) can be accepted by regulatory authorities across regions and countries as the primary source of evidence to support marketing approval of drugs. MRCTs conducted according to FDA Guidance "E17 General Principles for Planning and Design of Multiregional Clinical Trials Guidance for Industry" dated July 2018 allows for the investigation of treatment effects, including safety evaluations in the overall population, and investigation of the potential impact of intrinsic and extrinsic factors on the treatment effect. MRCTs, which are properly designed and executed according to FDA Guidance "E17 General Principles for Planning and Design of Multiregional Clinical Trials" dated July 2018, may facilitate more efficient drug development and increase the possibility of submitting marketing authorization applications to multiple regulatory authorities in different regions simultaneously, thus providing earlier access to new drugs worldwide. In addition, MRCTs conducted according to FDA Guidance "E17 General Principles for Planning and Design of Multiregional Clinical Trials" dated July 2018 may enhance scientific knowledge about how treatment effects vary across regions and populations under the umbrella of a single-study protocol and how this variation may be explained by intrinsic and extrinsic factors.

REGULATORY OVERVIEW

The following basic principles for designing MRCTs are included in the FDA's July 2018 MRCT guidance:

- Strategic use of MRCTs in drug development programs, properly designed and executed according to this guidance, can increase efficiency of drug development. MRCTs may enable simultaneous submission of marketing authorization applications and support regulatory decision-making in multiple regions, allowing earlier access to new drugs worldwide. Although MRCTs may generally become the preferred option for investigating a new drug for which regulatory submission is planned in multiple regions, the potential for regional differences to have an impact on the interpretability of study results should be carefully considered.
- The intrinsic and extrinsic factors important to the drug development program should be identified early. The potential impact of these factors could be examined in the exploratory phases before the design of confirmatory MRCTs. Information about them should also be collected during the confirmatory trial for evaluation of their impact on treatment effects.
- MRCTs are planned under the assumption that the treatment effect applies to the entire target population, particularly to the regions included in the trial. Strategic allocation of the sample size to regions allows an evaluation of the extent to which this assumption holds.
- Prespecified pooling of regions or subpopulations, based on established knowledge about similarities, may help provide flexibility in sample-size allocation to regions, facilitate the assessment of consistency in treatment effects across regions, and support regulatory decision-making.
- A single primary analysis approach for hypothesis testing and estimation of the overall treatment effect should be planned so that it will be acceptable to all concerned regulatory authorities. A structured exploration to examine the consistency of treatment effects across regions and subpopulations should be planned.
- In light of diverse regional practices, ensuring high quality of study design and conduct in accordance with ICH E6 in all regions is of paramount importance to ensure the study results are interpretable. Careful attention to quality during trial planning, investigator training, and trial monitoring will help achieve consistently high trial quality required for a successful MRCT.
- Efficient communication among sponsors and regulatory authorities is encouraged at the planning stage of MRCTs, with the goal of obtaining acceptance of a global approach to study design across the different regulatory regions.

REGULATORY OVERVIEW

All sites participating in MRCTs should meet applicable quality, ethical, and regulatory standards. Specifically, MRCTs should be conducted in compliance with ICH E6 good clinical practice ("GCP") standards in all regions and sites, including making sites available for GCP inspections by regulatory authorities. Monitoring plans and other quality checks should be prespecified and implemented to address potential risks to subject rights, safety and well-being, and the reliability of study results. The primary endpoint should be relevant to the target population. In MRCTs, this relevance should be considered for all regions in the trial and with respect to the various drug, disease, and population characteristics represented in those regions.

For MRCTs, the primary endpoint, whether efficacy or safety, should satisfy these criteria, as well as being acceptable to all concerned regulatory authorities, to ensure that interpretation of the success or failure of the MRCT is consistent across regions and among regulatory authorities. Agreement on the primary endpoint ensures that the overall sample size and power can be determined for a single (primary) endpoint based on the overall population and also agreed upon by the regulatory authorities. If agreement cannot be reached because of well-justified scientific or regulatory reasons, a single protocol should be developed with endpoint-related subsections tailored to meet the respective requirements of the regulatory authorities.

Expedited Development and Review Programs

Fast Track Designation

Fast Track is a process designed to facilitate the development, and expedite the review of, drugs to treat serious conditions and fill an unmet medical need. Fast Track designation must be requested by the drug company. The request can be initiated at any time during the drug development process. FDA will review the request and make a decision within sixty days based on whether the drug fills an unmet medical need in a serious condition. Determining whether a disease is serious is a matter of judgment, but generally the FDA considers whether the proposed drug will affect factors such as survival, day-to-day functioning, and the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. To address an unmet medical need, the proposed drug may be developed as a treatment or preventative measure for a disease that does not have a current therapy. The type of information necessary to demonstrate unmet medical need varies with the stage of drug development: early in development, nonclinical data, mechanistic rationale, or pharmacologic data will suffice; later in development, clinical data should be utilized. If there are existing therapies, a fast track eligible drug must show some advantages over available treatments, such as:

- Showing superior effectiveness, effect on serious outcomes or improved effect on serious outcomes
- Avoiding serious side effects of an available therapy
- Improving the diagnosis of a serious condition where early diagnosis results in an improved outcome
- Decreasing a clinical significant toxicity of an available therapy that is common and causes discontinuation of treatment
- Ability to address emerging or anticipated public health need

REGULATORY OVERVIEW

The impacts on the clinical development and registration of a drug that receives a Fast Track designation, include, among others:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written correspondence from FDA about such things as the design of the proposed clinical trials
- Eligibility for accelerated approval or priority review if the requisite criteria are met. Accelerated approval is meant for drugs that demonstrate an effect on a surrogate, or intermediate endpoint reasonably likely to predict clinical benefit. Priority review shortens the FDA review process for a new drug from ten months to six months, and is appropriate for drugs that demonstrate significant improvements in both safety and effectiveness of an existing therapy. A fast track application is automatically considered for both of these designations
- Rolling review, which means that a drug company can submit completed sections of its NDA for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire application to the FDA

A sponsor may request Fast Track designation when the sponsor files an IND application or any time thereafter prior to the receipt of marketing approval. If a new drug product meets the requisite criteria for Fast Track designation, the FDA should grant the application. However, the FDA may rescind fast track designation, if the FDA determines the criteria for fast track designation are no longer met. The FDA will notify the sponsor in writing of its intent to rescind the designation through a "Intent to Rescind Fast Track Designation" letter, which will include the criteria for making the determination and provide the sponsor with an opportunity to submit additional data and justification to support the continuing designation and request a meeting to discuss the designation for the product. The rescinding of a fast track designation does not necessarily mean the product is not promising or that the product may not receive marketing approval. It means that the criteria for fast track designation are no longer met. The sponsor may request the designation to be rescinded/withdrawn. The impact of revocation is that the sponsor will lose all of the benefits of Fast Track designation, which include more frequent meetings and written communication with FDA, rolling review, and eligibility for Accelerated Approval and priority review.

Based on our favorable clinical results of HTD1801 for MASH and PSC, and our frequent communications with the FDA, we believe that the likelihood of revocation of Fast Track designation for MASH and PSC is low.

REGULATORY OVERVIEW

Accelerated Approval

Under the 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 trials 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 Designation

Another program potentially 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 an IND, and according to FAQs published by the FDA (current as of February 3, 2022), the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the United States. 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. The impacts on the clinical development and registration of drugs receiving Orphan Drug designation are: the sponsors may be provided with (1) a tax credit of 50 percent of the cost of conducting human clinical trials, and (2) federal research grants for clinical testing of new therapies to treat and/or diagnose rare diseases; (3) eligibility for seven-year marketing exclusivity and (4) a waiver of NDA PDUFA fees. The approval of an orphan drug designation request does not alter the standard regulatory requirements and processes for obtaining marketing approval. Sponsors must establish safety and efficacy of a compound to treat a rare disease through adequate and well-controlled studies.

REGULATORY OVERVIEW

FDA may revoke orphan-drug designation for any drug if the agency finds that:

- The request for designation contained an untrue statement of material fact; or
- The request for designation omitted required or material information; or
- FDA subsequently finds that the drug in fact had not been eligible for orphan-drug designation at the time of submission of the request.

For an approved drug, revocation of orphan-drug designation also suspends or withdraws the sponsor's exclusive marketing rights for the drug but not the approval of the drug's marketing application.

Where a drug has been designated as an orphan drug because the prevalence of a disease or condition (or, in the case of vaccines, diagnostic drugs, or preventive drugs, the target population) is under 200,000 in the United States at the time of designation, its designation will not be revoked on the ground that the prevalence of the disease or condition (or the target population) becomes more than 200,000 persons.

If FDA revokes an orphan-drug designation, FDA will publicize that the drug is no longer designated in accordance with 21 CFR 316.28. The sponsor may request the designation to be rescinded/withdrawn. The impact of revocation is that the sponsor will lose all the benefits of Orphan Drug designation. Based on our favorable clinical results of HTD1801 for PSC, and the prevalence of PSC in the United States, we believe that the likelihood of revocation of Orphan Drug designation for HTD1801 for PSC is low.

In Europe, the EMA is responsible for reviewing applications from sponsors for orphan designation. To qualify for orphan designation, a medicine must meet a number of criteria:

- it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating;
- the prevalence of the condition in the EU must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development;
- no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorised, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

Orphan medicines benefit from ten years of market exclusivity once they receive a marketing authorisation in the EU. This measure is intended to encourage the development of medicines for rare diseases, by protecting them from competition from similar medicines with similar indications, which cannot be marketed during the exclusivity period.

REGULATORY OVERVIEW

Post-Marketing Requirements

Following approval of a new product, the manufacturer of the approved product is subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse events (“AEs”) 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 such as the Department of Justice 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 as well as potential tort liability. 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 according to approved manufacturing processes and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products 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. The manufacturer is ultimately responsible for its products and the manufacturing practices of its contract manufacturers, therefore the manufacturer must take responsibility for the failure for the contract manufacturers to manufacture according to cGMPs.

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, any of which could have a material adverse effect on our business, financial condition and results of operations.

REGULATORY OVERVIEW

Once an approval is granted, if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market, the FDA may take enforcement actions such as issuing Warning Letters or Untitled Letters, ordering removal of the product from the market until deficiencies are remedied, withdrawing the approval of the product, or imposing civil and criminal penalties. Corrective action in response to these enforcement activities could delay drug distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug, 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 which could arise from such regulatory violations include, among other things:

- restrictions on the marketing or manufacturing of the drug, 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 approvals; drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

Patient Protection and Affordable Health Care Act

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the "ACA") became law in the United States in March 2010, and have driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare is financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through expansion of the Medicaid program and mandatory increased rebates for both generic and brand drugs reimbursed by Medicaid programs, the exclusion of certain manufacturer discounts from the average manufacturer price (AMP), extended eligibility for Medicaid rebates provided through Medicaid managed care plans mandatory discounts for certain Medicare Part D beneficiaries and accessed new federal taxes in the form of an annual fee based on pharmaceutical companies' share of sales to federal health care programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future. Starting in January 2017, President Trump signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal, or repeal and replace, all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the

REGULATORY OVERVIEW

implementation of certain taxes under the ACA have passed including, for example, the Tax Cuts and Jobs Act (TCJA) enacted by the Congress in 2017, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently repealed, effective January 1, 2020, the ACA- mandated "Cadillac" tax on high-cost employer-sponsored health coverage and the medical device tax. There may be other efforts to challenge, repeal or replace the ACA. Most recently, the United States Supreme Court, on June 17, 2021, ruled 7-2 that Republican states, led by Texas, lack standing to challenge the individual mandate. The decision represents the third time that the Supreme Court has upheld the ACA. The most recent Supreme Court opinion did not address issues of constitutionality or severability, which may create the basis for future legal challenge.

On March 11, 2021, President Biden signed into law the American Rescue Plan (ARP) Act of 2021. This ARP Act increases and expands eligibility for ACA premium subsidies for certain people enrolled in marketplace health plans. The Act helps progress toward improving prescription access and cost through expanded coverage. President Biden also signed into law the Inflation Reduction Act (IRA) on August 16, 2022. The IRA affects the most significant reform for the payment of pharmaceuticals and biologics since the creation of the Medicare Part D program as part of the Medicare Modernization Act of 2003 (MMA). The drug pricing provisions in Subtitle B of Title I of the IRA, entitled "Prescription Drug Pricing Reform," are the culmination of a multi-year effort by the Biden Administration and the United States Congress to enact government price negotiation authority over pharmaceuticals and biologics for the Medicare program. Although the legislation is now enacted, questions remain regarding its implementation. The market expects implementation of the IRA will take place through a combination of guidance, program instruction, agreements with manufacturers, and notice-and-comment rulemaking. Throughout 2023, the Centers for Medicare & Medicaid Services ("CMS") has adopted changes to IRA requirements and has been preparing to implement key features of the law that will become effective in the next few years. CMS published numerous guidance documents and created the Medicare Drug Rebate and Negotiations Group, which is responsible for administering the Medicare Prescription Drug Inflation Rebate Program and the Medicare Drug Price Negotiation Program. CMS also published a list of 10 Part D selected drugs for negotiation for 2026 on September 1, 2023. Under the IRA, the deadline for sponsors of drugs selected for the Medicare Drug Negotiation Program to sign a required and proscribed template contract in order to participate in the negotiation process for 2026 is October 1, 2023.

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 NDA/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 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 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

REGULATORY OVERVIEW

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 a BLA has not been submitted.

LAWS AND REGULATIONS OF AUSTRALIA

Laws and Regulations of Clinical Development

Clinical trials conducted in Australia are regulated by the Therapeutic Goods Administration ("TGA"). Clinical trials must comply with a number of laws and regulations in Australia at the Commonwealth and State/Territory levels, including the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth). Clinical trials must also comply with: the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines for Good Clinical Practice, as adopted and annotated by the TGA (the "**ICH GCP Guidelines**"); and the National Statement on Ethical Conduct in Human Research (the "**National Statement**").

There are two schemes for the approval of clinical trials in Australia: the Clinical Trial Notification ("**CTN**") scheme; and the Clinical Trial Approval ("**CTA**") scheme. The CTN scheme involves the TGA being notified of the clinical trial, but not undertaking any evaluation of the clinical trial. The CTA scheme involves the TGA not only being notified of the clinical trial, but also conducting an evaluation and assessment of the clinical trial prior to its commencement. The CTN scheme is generally used for earlier phase studies when there is adequate preclinical information about the product, particularly in relation to safety. The CTA scheme is generally used for high-risk or novel treatments, where there is little known or no knowledge about the safety of the goods. The decision regarding which scheme to follow is generally up to the sponsor of the trial and the applicable Human Research Ethics Committee ("**HREC**"), although the CTA scheme is mandatory for certain types of biological medicines. Clinical trials in Australia require the approval of the research institute that is conducting the trial, following a review by its HREC before the trial commences. HRECs are also responsible for overseeing clinical trials.

Clinical trials conducted in Australia must have a trial sponsor that is an Australian company. It is permissible for a foreign corporation to engage an Australian company to act as the sponsor of a clinical trial in Australia, often referred to as the Local Sponsor. In this situation, the foreign corporation does not, itself, need to obtain any licenses or authorizations in respect of the clinical trial. The Australian trial sponsor is responsible for the initiation, management and financing (or arranging the financing) for the clinical trial and is legally responsible for the conduct of the clinical trial, including obtaining the requisite licenses or authorizations. The trial sponsor does not need to be the manufacturer of the product being trialed. The product manufacturer may rely on the results the trial when seeking to have the product registered on the Australian Register of Therapeutic Goods.

REGULATORY OVERVIEW

Clinical trials in Australia must follow the ICH GCP Guidelines as annotated by the TGA. The TGA's annotations provide additional guidance regarding compliance with the National Statement, obtaining informed consent in special cases, responsibility for the conduct of the trial (including management, data handling and record keeping), the manufacturing, packaging, labelling and coding of investigational products, and reporting for adverse drug reactions. The approval of a clinical trial in Australia is conditional upon compliance with the ICH GCP Guidelines as annotated by the TGA.

Clinical trials in Australia must also comply with the National Statement. The National Statement sets out the Australian ethical standards against which all research involving humans, including clinical trials, are reviewed. The approval of a clinical trial in Australia is conditional upon compliance with the National Statement.

In relation to safety reporting requirements, clinical trials conducted in Australia must follow: the Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95), as annotated by the TGA; and the National Health and Medical Research Council ("NHMRC") Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods.

Additionally, per the ICH GCP Guidelines as annotated by the TGA, products used in clinical trial must comply with the applicable good manufacturing practices ("GMP"). For investigational products manufactured in Australia, the relevant manufacturing standards are set out in the *Therapeutic Goods (Manufacturing Principles) Determination 2020 (Cth)*. Generally, therapeutic goods (other than blood, blood components, haematopoietic progenitor cells and biologicals that do not comprise or contain live animal cells, tissues or organs) must be manufactured in accordance with the Guide to Good Manufacturing Practice of Medicinal Products (PE 009-15, 1 May 2021) published by PIC/S.

Under both the CTN and CTA schemes, the clinical trial sponsor for a trial involving medicines or biological products must provide to the TGA information about the proposed dosage form, route of administration, formulation, dosage, and frequency of administration of the product (amongst other information), prior to the commencement of the clinical trial. If a change to the dosage is proposed to be made following the completion of a phase I clinical trial, then that change must be either notified to the TGA (if the clinical trial falls under the CTN scheme), or approved by the TGA (if the clinical trial falls under the CTA scheme). The change would also require review and approval by the HREC overseeing the trial.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OVERVIEW

We are a biopharmaceutical company specializing in the discovery, development and commercialization of multifunctional, multi-targeted therapies for the treatment of metabolic and digestive diseases. The history of our Group can be traced back to November 15, 2011, when Dr. Liu, our founder, executive Director and chief executive officer, established Shenzhen HighTide together with our Angel Investor, Hepalink. For more information on the background of Dr. Liu, please refer to the section headed “Directors and Senior Management” in this document.

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on February 28, 2018 and has been an investment holding company since incorporation. As a part of the Reorganization, our Company became the holding company and the [REDACTED] vehicle of our Group.

MILESTONES OF DEVELOPMENT

The following is a summary of our major business development milestones:

<u>Year</u>	<u>Event</u>
November 2011	Shenzhen HighTide was established by Dr. Liu and we completed the Angel Round Investment (as defined below).
March 2013	We filed the first PCT patent application covering the compound of HTD4010.
April 2014	We initiated the discovery study of our Core Product, HTD1801.
March 2015	We initiated the pre-clinical study of our Core Product, HTD1801.
July 2015	We filed the first PCT patent application covering the compound of our Core Product, HTD1801.
October 2015	We initiated Phase I clinical trial of HTD4010 in Australia.
March 2016	We completed Phase I clinical trial of HTD4010 in Australia.
August 2016	HTD1801 was granted Orphan Drug Designation for PSC indication by FDA.
December 2016 ⁽¹⁾	We completed the Series A Investment (as defined below).
February 2018	We initiated Phase II clinical trial of HTD1801 for PSC in the United States and Canada.
April 2018	We initiated Phase Ib/IIa trial of HTD1801 for hypercholesterolemia in Australia.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

<u>Year</u>	<u>Event</u>
September 2018	Fast Track Designation was granted by FDA for HTD1801 PSC indication.
November 2018	Fast Track Designation was granted by FDA for HTD1801 MASH indication.
November 2018	We initiated Phase II clinical trial of HTD1801 in adult MASH and T2DM patients in the United States.
December 2018	We completed Phase Ib/IIa trial of HTD1801 for hypercholesterolemia in Australia.
December 2018 ⁽¹⁾	We completed the Series B-1 Investment (as defined below).
April 2019 ⁽¹⁾	We completed the Series B-2 Investment (as defined below).
March 2020	We completed Phase IIa clinical trial of HTD1801 in adult MASH and T2DM patients in the United States.
August 2020	We completed Phase II clinical trial of HTD1801 in adult PSC patients in the United States and Canada.
May 2021	We initiated Phase II clinical trial of HTD1801 in adult PBC patients in the United States.
May 2021 ⁽¹⁾	We completed the Series B+ Investment (as defined below).
September 2021	We initiated Phase I clinical trial in healthy volunteers for HTD1801 T2DM indication in the PRC.
November 2021 ⁽¹⁾	We completed Series C Investment (as defined below).
March 2022	We initiated Phase II clinical trial of HTD1801 in adult T2DM patients in China.
May 2022	We completed Phase II clinical trial of HTD1801 in adult PBC patients in the United States.
December 2022 ⁽¹⁾	We completed Series C+ Investment (as defined below).
December 2022	We initiated Phase IIb clinical trial of HTD1801 in adult with MASH and liver fibrosis who have T2DM or pre-diabetes in the United States.

Note:

- (1) The time refers to the time when the last installment of the investments comprising the relevant series of investments has been irrevocably settled.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OUR GROUP

Our Company

Our Company was incorporated as an exempted company with limited liability in the Cayman Islands on February 28, 2018. Please refer to the paragraph headed “Shenzhen HighTide — Establishment and Angel Round Investment” in this section for further details. Immediately after its incorporation, one Share was issued and transferred to the Founder BVI, which was then wholly-owned by Dr. Liu.

For information and further shareholding change of our Company, please refer to the paragraph headed “— Reorganization.”

Our Principal Operating Entities

As at the Latest Practicable Date, the Group consisted of ten subsidiaries, among which we had four principal operating entities, namely Shenzhen HighTide, Australia HighTide, U.S. HighTide and Shanghai Fusion, which made material contribution to our results of operation during the Track Record Period. The details of our principal operating entities are set forth below:

Name of Entity	Principal Business Activities	Date of Establishment/ Incorporation	Place of Establishment
Shenzhen HighTide . . .	Pharmaceutical research, preclinical study and clinical study of drug candidates in our pipeline	November 15, 2011	Shenzhen, PRC
Australia HighTide	Early stage clinical trials conducted in Australia	July 15, 2015	Sydney, Australia
U.S. HighTide	Assisting the management of overseas clinical trial operations for our Group	January 24, 2018	Maryland, United States
Shanghai Fusion	Assisting the management of preclinical study for our Group	May 20, 2021	Shanghai, PRC

Shenzhen HighTide

Establishment and Angel Round Investment

In 2011, Dr. Liu was introduced to Hepalink, our Angel Investor, through an acquaintance of Mr. Shan Yu, the executive director of Hepalink. Hepalink is a leading China-based pharmaceutical company with global pharmaceutical, innovative biotech and CDMO businesses. Dr. Liu has approximately 20 years of drug research and development experience. Both Hepalink and Dr. Liu considered it to be in line with their respective business objectives and a mutual beneficial and complementary commercial decision to establish Shenzhen HighTide together. On November 15, 2011, Shenzhen HighTide was established by Dr. Liu and Hepalink with an initial registered capital of RMB35 million, among which Dr. Liu agreed to subscribe for RMB15 million and Hepalink agreed to subscribe for RMB20 million (the “**Angel Round Investment**”). As at November 30, 2011, the registered capital of Shenzhen HighTide had been fully paid by Dr. Liu with intangible assets appraised by an independent valuation expert at RMB15 million and by Hepalink with RMB20 million in cash. As part of the Reorganization, our Company was incorporated on February 28, 2018 and became the ultimate holding company of Shenzhen HighTide in September 2018.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The shareholding structure of Shenzhen HighTide upon establishment and completion of the Angel Round Investment is set forth below:

Name of Shareholder	Amount of Registered Capital	Shareholding Percentage
	<i>(RMB)</i>	
Dr. Liu	15 million	42.86%
Hepalink	20 million	57.14%

Series A Investment

On June 17 and December 19, 2016, Shenzhen HighTide entered into two investment agreements with (i) Xinjiang Taitong Equity Investment Partnership (新疆泰同股權投資合夥企業有限合夥)) (“**Xinjiang Taitong**”) and Shenzhen Qianhai Haichuang Fund Partnership (Limited Partnership) (深圳市前海海創基金合夥企業(有限合夥)) (“**Qianhai Haichuang**”); and (ii) Hepalink and Tibet Ningfeng Equity Investment Partnership (西藏寧豐股權投資合夥企業(有限合夥)) (“**Tibet Ningfeng**”), respectively, pursuant which Hepalink, Qianhai Haichuang, Tibet Ningfeng and Xinjiang Taitong agreed to subscribe for RMB4.13 million, RMB1.4 million, RMB1.05 million and RMB420,000 of the registered capital of Shenzhen HighTide at subscription price of RMB59 million, RMB20 million, RMB15 million and RMB6 million, respectively (the “**Series A Investment**”). The subscription price was determined after arm’s length negotiation taking into account that (i) HTD4010 had entered into clinical stage in October 2015 and (ii) HTD1801 was granted Orphan Drug Designation for PSC indication by the FDA in August 2016. The last installment of the Series A Investment was fully settled in cash on December 26, 2016.

The shareholding structure of Shenzhen HighTide following the completion of the Series A Investment is set forth below:

Name of Shareholder	Amount of Registered Capital	Shareholding Percentage
	<i>(RMB)</i>	
Hepalink	24,130,000	57.45%
Dr. Liu	15,000,000	35.71%
Qianhai Haichuang	1,400,000	3.33%
Tibet Ningfeng	1,050,000	2.50%
Xinjiang Taitong	420,000	1.00%
Total	42,000,000	100%

For information and further shareholding changes of Shenzhen HighTide during the Reorganization, please refer to the paragraph headed “— Reorganization”.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Australia HighTide

Australia HighTide was incorporated as a proprietary company limited by shares in Australia on July 15, 2015. Since August 11, 2015, it has been wholly-owned by Shenzhen HighTide. Australia HighTide has been principally engaged in early stage clinical trials conducted in Australia.

Shanghai Fusion

Shanghai Fusion was established in the PRC as a limited liability company on May 20, 2021. The initial registered capital of Shanghai Fusion was RMB1 million and had been paid up as at the Latest Practicable Date. Since its establishment, it has been wholly-owned by Shenzhen HighTide. Shanghai Fusion has been principally engaged in assisting the management of preclinical study for our Group.

U.S. HighTide

U.S. HighTide was incorporated in the United States as a limited liability company on January 24, 2018. Since its incorporation, U.S. HighTide has been principally engaged in assisting the management of overseas clinical trial operations for our Group. U.S. HighTide was wholly-owned by Dr. Steven LINBERG at the time of its incorporation. Dr. Steven LINBERG has more than 20 years of experience in clinical operation and biologics development. From 2017 to 2019, Dr. Steven LINBERG provided U.S. registration regulations and clinical development consulting services in relation to HTD1801 to our Company. On January 1, 2019, our Company and Dr. Steven LINBERG entered into a membership interest purchase agreement, pursuant to which Dr. Steven LINBERG transferred all of his right, title and interest in and to U.S. HighTide to our Company at the consideration of US\$2. The consideration was determined after arm’s length negotiation taking into account the total assets of U.S. HighTide as of the time of the purchase.

[REDACTED] INVESTMENTS

We have received the seven rounds of [REDACTED] investments since our establishment.

Angel Round Investment and Series A Investment

For the information of the Angel Round Investment and Series A Investment, please refer to the paragraphs headed “— Establishment and Angel Round Investment” and “— Series A Investment”.

Transfer of Interest in Our Group by Xinjiang Taitong to Able Holdings

On March 14, 2019, Xinjiang Taitong entered into an equity transfer agreement with HK HighTide, and Able Holdings International Limited (“**Able Holdings**”) entered into a share purchase agreement with, among others, our Company, pursuant to which (i) Xinjiang Taitong agreed to transfer its equity interests in Shenzhen HighTide to HK HighTide at a consideration of RMB6 million; and (ii) Able Holdings agreed to subscribe for a number of Series A Preferred Shares on a pro-rata basis with reference to Xinjiang Taitong’s equity interests in Shenzhen HighTide, which is 378,000 Series A Preferred Shares, at the same consideration. The

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

consideration of the transfer was determined with reference to investment amount of Xinjiang Taitong in the Series A Investment and was fully paid by Able Holdings on December 2, 2019 and by HK HighTide (in an equivalent amount in United States dollars) on November 27, 2019. On March 25, 2019, our Company issued and allotted 378,000 Series A Preferred Shares to Able Holdings.

Series B-1 Investment

Our Company entered into a share purchase agreement (the “**Series B-1 Investment Agreement**”) with Green Pine Growth Fund I LP (“**Green Pine**”), Greaty Investment Limited (廣源國際投資有限公司) (“**Greaty Investment**”) and ZT Global Energy Investment Fund I LLP (“**ZT Global Energy**”) on September 25, 2018, pursuant to which Green Pine, Greaty Investment and ZT Global Energy agreed to subscribe for 700,000, 1,166,667 and 1,166,667 Series B-1 Preferred Shares at an aggregate subscription price of US\$3 million, US\$5 million and US\$5 million, respectively (the “**Series B-1 Investment**”). The last installment of the Series B-1 Investment was fully settled in cash on December 6, 2018.

Series B-2 Investment

Our Company entered into a share purchase agreement (the “**Series B-2 Investment Agreement**”, together with the Series B-1 Investment Agreement the “**Series B Agreements**”) with Blue Ocean Healthcare Project I, Ltd. (“**Blue Ocean**”) and Orient Champion Investment Limited (“**Orient Champion**”) on December 29, 2018, pursuant to which Blue Ocean and Orient Champion agreed to subscribe for 466,667 Shares and 1,633,333 Series B-2 Preferred Shares at an aggregate subscription price of US\$2 million and US\$7 million, respectively (the “**Series B-2 Investment**”, together with the Series B-1 Investment, the “**Series B Investments**”). The last installment of the Series B-2 Investment was fully settled in cash on April 25, 2019.

The subscription price of the Series B Investments was determined after arm’s length negotiation taking into account that our Core Product, HTD1801, entered clinical stage, completed the Phase Ia trial of HTD1801 in healthy volunteers and initiated Phase Ib/IIa clinical trial of HTD1801 in hypercholesterolemia in Australia.

As a result of dilution from the issuance by our Company of 4,200,000 ordinary Shares on March 25, 2019 to the 2020 ESOP Platform (see the paragraph headed “— 2020 ESOP Platform” for details) and our Series B Investments, which Hepalink did not participate in, Hepalink’s shareholding interest in our Company decreased to approximately 47.02% upon the completion of the Series B Investments. Following the exercise of directors’ appointment rights of the Series B Investors, the financial results of our Company were no longer consolidated into the consolidated financial statement of Hepalink as Hepalink no longer controlled the composition of the Board.

Pursuant to the Sixth Amended and Restated Shareholders Agreement and the Existing M&A, prior to [REDACTED], Dr. Liu shall have the right to designate one Director (the “**Founder Director**”), and may remove or designate another person in his/her stead with or without cause in like manner of any Founder Director so designated, and the Hepalink Entities (being Hepalink and Hepalink Biotechnology II Limited) shall have the right to jointly designate one Director (the “**Hepalink Director**”) and may remove or designate another person in his/her stead with or without cause in like manner of any Hepalink Director so designated. Such director

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

appointment rights of Dr. Liu and the Hepalink Entities will be terminated upon [REDACTED]. After the [REDACTED], pursuant to the [Amended and Restated] Memorandum of Association and the [Amended and Restated] Articles of Association to be adopted upon [REDACTED], the Directors have the power to appoint any person as a Director and any Director so appointed shall hold office only until the first annual general meeting of the Company after his appointment and shall then be eligible for re-election. A Director may be removed by an ordinary resolution of the Company before the expiration of his term of office and Shareholders may by ordinary resolution appoint another in his place. For the details, please refer to “Appendix III — Summary of the Constitution of the Company and Cayman Islands Company Law — (b) Directors — (i) Appointment, retirement and removal”.

Transfer of Shares to 2020 ESOP Platform by Series B Investors

Pursuant to valuation adjustment provisions contained in the Series B Investment Agreements, the pre-money valuation of the Series B-1 Investment and the Series B-2 Investment shall be automatically (i) adjusted from US\$180 million to US\$200 million regarding the Series B-1 Investment, and (ii) adjusted from US\$193 million to US\$213 million regarding the Series B-2 Investment upon occurrence of certain events, and each of the Series B-1 Investors and the Series B-2 Investors shall transfer certain number of Shares to 2020 ESOP Platform in no consideration according to a formula as agreed among the Shareholders in the Series B Investment Agreements.

Accordingly, after the occurrence of the relevant valuation adjustment triggering event defined in the valuation adjustment provisions contained in the Series B Investment Agreements (i.e. Phase Ib/IIa trial of HTD1801 in hypercholesterolemia was completed in Australia in 2018, ZT Global Energy, Greaty Investment and Green Pine transferred 105,105, 105,105 and 63,063 (in aggregate, 273,273) Series B-1 Preferred Shares, respectively, and Orient Champion and Blue Ocean transferred 147,147 and 42,042 (in aggregate, 189,189) Series B-2 Preferred Shares, respectively, to 2020 ESOP Platform on August 12, 2019. On the same day, such transferred Shares were reclassified into 462,462 ordinary Shares on a one-to-one basis.

Series B+ Investment

Our Company entered into a share purchase agreement with a number of investors (as listed in the shareholding structure table below, the “**Series B+ Investors**”) on August 28, 2020, pursuant to which our Company agreed to (i) issue and allot to offshore Series B+ Investors an aggregate of 7,027,600 Series B+ Preferred Shares at a consideration of US\$33,100,000 and (ii) issue to each of the Series B+ Investors that were established in the PRC a warrant (together the “**Warrants**”) that underlies an aggregate of 5,650,954 Series B+ Preferred Shares at a consideration of US\$26,616,000 (the “**Series B+ Investment**”). The subscription price of the Series B+ Investment was determined after arm’s length negotiation after taking into consideration that our Core Product, HTD1801, completed the 1b/2a trials trial in hypercholesterolemia. On August 24, 2021, the Warrants were fully converted into Series B+ Preferred Shares. The last installment of the Series B+ Investment was fully settled in cash on May 14, 2021.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The shareholding and voting right structure of our Company following the completion of the Series B+ Investment and full exercise of the Warrants is set forth below:

Name of Shareholder	Series of Shares	Number of Shares	Shareholding Percentage	Percentage of Voting Rights Held
The AIC Group				
Dr. Liu ⁽¹⁾	Ordinary Shares	13,500,000	22.93%	30.85%
Greaty Investment	Series B-1 Preferred Shares	1,061,562	1.80%	1.80%
ZT Global Energy	Series B-1 Preferred Shares	1,061,562	1.80%	1.80%
Orient Champion	Series B-2 Preferred Shares	1,486,186	2.52%	2.52%
Subtotal of the AIC Group		17,109,310	29.06%	36.98%
2020 ESOP Platform ⁽¹⁾	Ordinary Shares	4,662,462	7.92%	nil
Hepalink	Ordinary Shares	18,000,000	30.58%	30.58%
Hepalink	Series A Preferred Shares	3,717,000	6.31%	6.31%
Qianhai Haichuang	Series A Preferred Shares	1,260,000	2.14%	2.14%
Able Holdings	Series A Preferred Shares	378,000	0.64%	0.64%
Green Pine	Series B-1 Preferred Shares	636,937	1.08%	1.08%
Blue Ocean	Series B-2 Preferred Shares	424,625	0.72%	0.72%
Shenzhen Taixun Enterprise Management Consulting Partnership (Limited Partnership) (“Shenzhen Taixun”)	Series B+ Preferred Shares	3,184,713	5.41%	5.41%
Poly Platinum Enterprises Limited (“Poly Platinum”)	Series B+ Preferred Shares	3,184,713	5.41%	5.41%
Hongkong Tigermed Co., Limited (“HK Tigermed”).	Series B+ Preferred Shares	2,123,142	3.61%	3.61%
Pluto Connection Limited (“Pluto”)	Series B+ Preferred Shares	1,507,431	2.56%	2.56%
Xinyu Cowin Guosheng Sci-Tech Innovation Investment Partnership (Limited Partnership) (“Xinyu Cowin”)	Series B+ Preferred Shares	1,061,571	1.80%	1.80%
Shenzhen Winzac Jingfeng Venture Capital Enterprise (Limited Partnership) (“Shenzhen Winzac”)	Series B+ Preferred Shares	520,594	0.88%	0.88%
Sichuan Rongxin Zhiyuan Industrial Co., Ltd. (“Sichuan Rongxin”)	Series B+ Preferred Shares	459,448	0.78%	0.78%
Ningbo Borui Allen Equity Investment Partnership (LLP) (“Ningbo Borui”)	Series B+ Preferred Shares	424,628	0.72%	0.72%
Shenzhen BioResearch Investment Fund, L.P. (“Shenzhen BioResearch”)	Series B+ Preferred Shares	212,314	0.36%	0.36%
Total		58,866,888	100%	100%

Note:

(1) Dr. Liu, being the investment advisor of the Family Trust, is entitled to exercise the voting rights attached to the 13,500,000 Shares held by the Founder BVI. Dr. Liu was also granted power of attorney to exercise the voting rights attached to the 8,849,294 Shares held by the 2020 ESOP Platform. For details, please refer to the paragraph headed “— 2020 ESOP Platform”.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Transfer of Interest in Our Group by Tibet Ningfeng to Goldlink

On June 10, 2021, Tibet Ningfeng entered into an equity transfer agreement with HK HighTide, and Goldlink Capital Fund SPC - Goldlink Greater China Fund SPV (“**Goldlink**”) entered into a share purchase agreement with, among others, our Company, pursuant to which (i) Tibet Ningfeng agreed to transfer its equity interests in Shenzhen HighTide to HK HighTide at the consideration of the transfer of US\$4,005,885; and (ii) Goldlink agreed to subscribe for a number of Series A Preferred Shares on a pro-rata basis with reference to Tibet Ningfeng’s equity interests in Shenzhen HighTide, which is 945,000 Series A Preferred Shares, at the same consideration. The consideration was determined after arm’s length negotiations with reference to the cost per Share paid in the Series B+ Investment and was fully paid by Goldlink on June 16, 2021 and by HK HighTide on August 17, 2021. On August 24, 2021, our Company issued and allotted 945,000 Series A Preferred Shares to Goldlink.

Series C Investment

Our Company entered into a Series C share purchase agreement (the “**Series C Investment Agreement**”) with, among others, BAIYI Capital Limited (“**BAIYI Capital**”) and Hongtu Capital Limited (“**Hongtu Capital**”) on October 18, 2021, pursuant to which BAIYI Capital and Hongtu Capital agreed to subscribe for 4,571,359 Shares and 7,618,932 Series C Preferred Shares at considerations of US\$30 million and US\$50 million, respectively (the “**Series C Investment**”). The subscription price of the Series C Investment was determined after arm’s length negotiation taking into account the R&D progress and clinical development of our pipeline products since the Series B+ Investment. The last installment of the Series C Investment was fully settled in cash on November 16, 2021.

Inner-group Transfer of Interest by Hepalink

In December 2021, Hepalink transferred its 18,000,000 ordinary Shares in the Company to its indirectly wholly-owned subsidiary, Hepalink Biotechnology II Limited. On December 30, 2021, the relevant registration was completed.

Series C+ Investment

Our Company entered into a Series C+ share purchase agreement with, among others, Guangdong Chinese Medicine Comprehensive Health Equity Investment Fund Partnership (Limited Partnership) (廣東中醫藥大健康股權投資基金合夥企業(有限合夥)) (“**Traditional Chinese Medicine Fund**”) and Guangzhou Yuexiu Jinchan Phase IV Investment Fund Partnership (Limited Partnership) (廣州越秀金蟬四期投資合夥企業(有限合夥)) (“**Yuexiu Jinchan IV**”) on September 5, 2022 and April 26, 2022, respectively (the “**Series C+ Investment Agreements**”), pursuant to which Traditional Chinese Medicine Fund and Yuexiu Jinchan IV agreed to subscribe for 2,987,795 Series C+ Preferred Shares and 985,972 Series C+ Preferred Shares at considerations of US\$20,000,000 and US\$6,600,000, respectively (the “**Series C+ Investment**”). The subscription price of the Series C+ Investment was determined after taking into account the R&D progress and clinical development of our pipeline products since the Series C Investment. The last installment of the Series C+ Investment was fully settled in cash on November 15, 2022 and December 16, 2022, respectively. The post-money valuation of our Company after the Series C+ Investments increased to approximately US\$536 million, primarily because our Company

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

completed the Phase I clinical trial of HTD1801 for T2DM in November 2021 and initiated the Phase II clinical trial of HTD1801 for T2DM in China in March 2022. The valuation of our Company is expected to further increase after the Series C+ Investments because our Company initiated the Phase IIb study (HTD1801.PCT014) for MASH in the United States in December 2022 and in Hong Kong in October 2023, initiated the Phase II study (HTD1801.PCT103) for T2DM in China in March 2022, and completed the Phase II study (HTD1801.PCT103) for T2DM in January 2023.

Transfer of Interest in Our Group by Hepalink to Yuexiu Jinchan IV, Pingtan Rongjing and MPCAPITAL

On April 26, 2022, May 25, 2022, June 1, 2022 and September 5, 2022, respectively, Hepalink entered into an equity transfer agreement, as amended, with Yuexiu Jinchan IV, pursuant to which Hepalink agreed to transfer 631,811 Series A Preferred Shares to Yuexiu Jinchan IV at a consideration of USD3,400,000. The relevant registration was completed on November 25, 2022.

On September 15, 2022, Hepalink entered into an equity transfer agreement with Pingtan Rongjing Investment Partnership (Limited Partnership) (平潭榮景投資合夥企業(有限合夥)) (“**Pingtan Rongjing**”), pursuant to which Hepalink agreed to transfer 461,000 Series A Preferred Shares to Pingtan Rongjing at the consideration of USD2,480,803.96. The relevant registration was completed on November 18, 2022.

On October 18, 2022, Hepalink entered into an equity transfer agreement with MPCAPITAL INTERNATIONAL COMPANY LIMITED (“**MPCAPITAL**”), pursuant to which Hepalink agreed to transfer 371,654 Series A Preferred Shares to MPCAPITAL at the consideration of USD2,000,000. The relevant registration was completed on January 18, 2023.

The share price for the above-mentioned transfer of Series A Preferred Shares by Hepalink was lower than the subscription price of the Series C+ Preferred Shares in the Series C+ Investments, primarily because the special rights attached to the Series A Preferred Shares are less preferential compared to the special rights attached to the Series C+ Preferred Shares. For instance, certain special rights granted to the Shareholders of the Series C+ Preferred Shares, including the right to preferred liquidation, right of co-sale and redemption rights, are not granted to the Shareholders of the Series A Preferred Shares. Therefore, the prices for the transfer of Series A Preferred Shares by Hepalink and for the subscription of the Series C+ Preferred Shares were not determined solely based on the valuation of Company at the relevant times and the R&D progress of the Core Product, which is correlative with the sequence of the relevant share transfers and subscriptions, but were also determined based on the terms and conditions attached to the relevant preferred shares involved in the relevant share transfers and subscriptions, which is not correlative with the sequence of the relevant share transfers and subscriptions.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The shareholding and voting right structure of our Company following the completion of the Series C+ Investment and the transfer of interest by Hepalink is set forth below:

Name of Shareholder	Series of Shares	Number of Shares	Shareholding Percentage	Percentage of Voting Rights Held
The AIC Group				
Dr. Liu ⁽¹⁾	Ordinary Shares	13,500,000	16.84%	27.88%
Greaty Investment	Series B-1 Preferred Shares	1,061,562	1.32%	1.32%
ZT Global Energy	Series B-1 Preferred Shares	1,061,562	1.32%	1.32%
Orient Champion	Series B-2 Preferred Shares	1,486,186	1.85%	1.85%
Subtotal of the AIC Group		17,109,310	21.34%	32.38%
2020 ESOP Platform ⁽¹⁾	Ordinary Shares	8,849,294	11.04%	nil
Hepalink Biotechnology II Limited	Ordinary Shares	18,000,000	22.45%	22.45%
Hepalink	Series A Preferred Shares	2,252,535	2.81%	2.81%
Qianhai Haichuang	Series A Preferred Shares	1,260,000	1.57%	1.57%
Goldlink	Series A Preferred Shares	945,000	1.18%	1.18%
Able Holdings	Series A Preferred Shares	378,000	0.47%	0.47%
Yuexiu Jinchan IV	Series A Preferred Shares	631,811	0.79%	0.79%
Pingtang Rongjing	Series A Preferred Shares	461,000	0.58%	0.58%
MPCAPITAL	Series A Preferred Shares	371,654	0.46%	0.46%
Green Pine	Series B-1 Preferred Shares	636,937	0.79%	0.79%
Blue Ocean	Series B-2 Preferred Shares	424,625	0.53%	0.53%
Shenzhen Taixun	Series B+ Preferred Shares	3,184,713	3.97%	3.97%
Poly Platinum	Series B+ Preferred Shares	3,184,713	3.97%	3.97%
HK Tigermed	Series B+ Preferred Shares	2,123,142	2.65%	2.65%
Pluto	Series B+ Preferred Shares	1,507,431	1.88%	1.88%
Xinyu Cowin	Series B+ Preferred Shares	1,061,571	1.32%	1.32%
Shenzhen Winzac	Series B+ Preferred Shares	520,594	0.65%	0.65%
Sichuan Rongxin	Series B+ Preferred Shares	459,448	0.57%	0.57%
Ningbo Borui	Series B+ Preferred Shares	424,628	0.53%	0.53%
Shenzhen BioResearch	Series B+ Preferred Shares	212,314	0.26%	0.26%
Hongtu Capital	Series C Preferred Shares	7,618,932	9.50%	9.50%
BAIYI Capital	Series C Preferred Shares	4,571,359	5.70%	5.70%
Traditional Chinese Medicine Fund	Series C+ Preferred Shares	2,987,795	3.73%	3.73%
Yuexiu Jinchan IV	Series C+ Preferred Shares	985,972	1.23%	1.23%
Total		80,162,778	100%	100%

Note:

- (1) Dr. Liu, being the investment advisor of the Family Trust, is entitled to exercise the voting rights attached to the 13,500,000 Shares held by the Founder BVI. Dr. Liu was also granted power of attorney to exercise the voting rights attached to the 8,849,294 Shares held by the 2020 ESOP Platform. For details, please refer to the paragraph headed “— 2020 ESOP Platform”.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The shareholding interest of Hepalink in our Company as of December 31, 2022 was approximately 25.73%, being an aggregate of 20,624,189 Shares held by Hepalink divided by 80,162,778 Shares issued in total by our Company as of December 31, 2022. As disclosed in Hepalink’s annual report for the year ended December 31, 2022, Hepalink held approximately 40.19% interest in our Company as of December 31, 2022, being an aggregate of 20,624,189 Shares held by Hepalink divided by 51,320,166 Shares issued by our Company to Shareholders holding ordinary Shares, Series A Preferred Shares, Series B-1 Preferred Shares and Series B-2 Preferred Shares as of December 31, 2022. As confirmed by Hepalink, such discrepancy in the disclosure of shareholding is due to the reason that, when calculating its interest in our Company, Hepalink did not count our Shares issued to Shareholders holding Series B+ Preferred Shares, Series C Preferred Shares and Series C+ Preferred Shares into the total issued Shares of our Company because such Shares were deemed as debt instruments instead of equity due to their redeemable attributes based on equity methods as our Company is considered as an associate company of Hepalink for accounting treatment.

Details of [REDACTED] Investments

The following table sets forth a summary of the details of the [REDACTED] Investments.

	Angel Round	Series A	Series B-1	Series B-2	Series B+	Series C	Series C+
Number of Shares subscribed (as adjusted after the [REDACTED]) . . .	[REDACTED] Shares	[REDACTED] Series A Preferred Shares	[REDACTED] Series B-1 Preferred Shares ⁽⁴⁾	[REDACTED] Series B-2 Preferred Shares ⁽⁴⁾	[REDACTED] Series B+ Preferred Shares	[REDACTED] Series C Preferred Shares	[REDACTED] Series C+ Preferred Shares
Amount of consideration paid	RMB20,000,000	RMB100,000,000	US\$13,000,000	US\$9,000,000	US\$59,716,000	US\$80,000,000	US\$26,600,000
Date of investment agreement	October 17, 2011	June 17, 2016 and December 19, 2016	September 25, 2018	December 29, 2018	August 28, 2020	October 18, 2021	April 26, 2022 and September 5, 2022
Date of payment of full consideration	November 30, 2011	December 26, 2016	December 6, 2018	April 25, 2019	May 14, 2021	November 16, 2021	December 16, 2022 and November 15, 2022
Post-money valuation ⁽¹⁾	RMB35,000,000	RMB600,000,000 ⁽⁵⁾	US\$187,329,962 ⁽⁶⁾	US\$202,000,003 ⁽⁶⁾	US\$277,263,092 ⁽⁷⁾	US\$499,997,980 ⁽⁸⁾	US\$536,601,641 ⁽⁹⁾
Cost per Share ⁽²⁾	RMB0.19	RMB2.65	US\$0.79	US\$0.79	US\$0.79	US\$1.09	US\$1.12
Discount to the middle point of the indicative [REDACTED] range ⁽³⁾	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%	[REDACTED]%

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

	Angel Round	Series A	Series B-1	Series B-2	Series B+	Series C	Series C+
Use of proceeds and whether they have been fully utilized	We utilize the proceeds to finance our research and development activities and fund our daily operations. As of the Latest Practicable Date, approximately 100.00% of the net proceeds from the Angel Round Investment, Series A Investment, Series B-1 Investment, Series B-2 Investment and Series B+ Investment and approximately 66.1% of net proceeds from the Series C Investment had been utilized by our Group. We had not used any net proceeds from the Series C+ Investment as of the Latest Practicable Date. As of the Latest Practicable Date, approximately RMB381.1 million of the proceeds from the [REDACTED] Investments had not been utilized. We plan to utilize the unutilized proceeds to continue to finance our research and development activities (including conducting the Phase IIb clinical trial of MASH in the United States, Hong Kong, Mexico and Mainland China and the Phase III clinical trial of T2DM in China) and fund our daily operations.						
Lock-up period	The Shares held by the [REDACTED] Investors ⁽¹⁰⁾ will be subject to lock-up for a period of [six] months commencing from the [REDACTED].						
Strategic benefits of the [REDACTED] Investment brought to our Group	Our Group would benefit from the additional capital injected by the [REDACTED] Investors in our Group, their business resources, knowledge and experience, potential business opportunities and benefits that may be provided by them. Our [REDACTED] Investors include a major pharmaceutical company, private equity funds and other professional investment companies, many of which are highly experienced in investing in the healthcare and biopharmaceutical industry. Our Directors believed that our Company could benefit from their industry insights and guidance. For example, we have established a long-term strategic cooperative relationship with Hepalink, one of our [REDACTED] Investors, which is a major pharmaceutical company. On August 29, 2020, we entered into the HTD1801 Agreement with Hepalink. By leveraging Hepalink’s strong sales force established in Europe, its advantageous position in market share in the relevant jurisdictions and its established track record of sales of similar pharmaceutical products in the European pharmaceutical market, the Company believes Hepalink will be able to successfully promote the commercialization of innovative drug formulations containing HTD1801 in Europe. Our Directors were also of the view that the [REDACTED] Investments demonstrate the [REDACTED] Investors’ commitment and confidence in the business performance and operations, strengths and long-term prospects of our Group.						

Notes:

- (1) Equals the total consideration paid by each round of [REDACTED] Investors divided by the shareholding percentage of it immediately following their investments.
- (2) Calculated based on the currency conversion rate of USD1:RMB7.0157.
- (3) Calculated on the basis of the [REDACTED] of HK\$[REDACTED], the mid-point of the proposed range of the [REDACTED], and based on the currency conversion rate of HKD1:RMB0.8971.
- (4) Adjusted by the share transfers to the 2020 ESOP Platform. Please refer to “— Transfer of Shares to 2020 ESOP Platform by Series B Investors”.
- (5) The valuation of our Company increased significantly during the period between our Angel Round Investment and the Series A Investment, primarily because (i) HTD4010 had entered into clinical stage and (ii) HTD1801 was granted Orphan Drug Designation for PSC indication by the FDA.
- (6) The valuation of our Company increased significantly during the period between the Series A Investment and the Series B Investments, primarily due to that the Company completed the Phase Ia trial of HTD1801 for hypercholesterolemia and initiated Phase Ib/IIa clinical trial of HTD1801 for hypercholesterolemia in Australia.
- (7) The valuation of our Company increased during the period between the Series B Investments and the Series B+ Investment, primarily due to that the Company completed the Phase IIa trial of HTD1801 for MASH in the United States.
- (8) The valuation of our Company increased significantly during the period between the Series B+ Investment and the Series C Investment, primarily due to that the Company completed the Phase II trial of HTD1801 for PSC and obtained the approval for clinical trial of T2DM in China.
- (9) The valuation of our Company increased during the period between the Series C Investment and the Series C+ Investment, primarily because the Company completed the Phase I clinical trial of HTD1801 for T2DM in November 2021 and initiated the Phase II clinical trial of HTD1801 for T2DM in China in March 2022. The valuation of our Company is expected to further increase after the Series C+ Investments because our Company initiated the Phase IIb study (HTD1801.PCT014) for MASH in the United States in December 2022 and in Hong Kong in October 2023, initiated the Phase II study (HTD1801.PCT103) for T2DM in China in March 2022, and completed the Phase II study (HTD1801.PCT103) for T2DM in January 2023.
- (10) excluding the Shares held by Hepalink through its indirectly wholly-owned subsidiary Hepalink Biotechnology II Limited.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Special rights granted to the [REDACTED] Investors

Our Company and, among others, the [REDACTED] Investors entered into the shareholders’ agreement dated September 5, 2022 (the “**Sixth Amended and Restated Shareholders Agreement**”), pursuant to which certain shareholder rights were agreed among the parties. Pursuant to the Sixth Amended and Restated Shareholders Agreement and the then existing amended and restated memorandum and articles of association (the “**Existing M&A**”) of our Company, certain [REDACTED] Investors have, among other rights, information rights, registration rights, the right to dividend, the right to preferred liquidation, pre-emptive rights, right of first refusal and right of co-sale, the right to nominate Directors, drag-along and redemption rights that are exercisable if the [REDACTED] does not take place, and conversion rights and anti-dilution rights.

The divestment rights granted to the [REDACTED] Investors, namely, the redemption rights under the Sixth Amended and Restated Shareholders Agreement and the Existing M&A of our Company have been automatically suspended immediately upon the Company’s submission of our [REDACTED] for the [REDACTED]. Such suspended divestment rights will be restored and will become exercisable if the [REDACTED] does not take place or if the [REDACTED] fails to consummate by the relevant redemption restoration date as agreed between the Company and the respective parties (which in any case is not earlier than December 31, 2023).

All other special rights of the [REDACTED] Investors granted under the foregoing documents will be automatically terminated upon the completion of the [REDACTED]. No special rights granted to the [REDACTED] Investors will survive after the [REDACTED].

Compliance with Interim Guidance and Guidance Letters on [REDACTED] Investments

On the basis that (i) the considerations for the [REDACTED] Investments were irrevocably settled more than 28 clear days before the date of our first submission of the [REDACTED] to the Stock Exchange; and (ii) the special rights granted to the [REDACTED] Investors shall cease to be effective and be terminated upon the [REDACTED], the Joint Sponsors confirm that the investments by the [REDACTED] Investors are in compliance with the Guidance Letter HKEX-GL29-12 issued on January 2012 and updated in March 2017 by the Stock Exchange, the Guidance Letter HKEX-GL43-12 issued in October 2012 and updated in July 2013 and in March 2017 by the Stock Exchange, and the Guidance Letter HKEX-GL44-12 issued in October 2012 and updated in March 2017 by the Stock Exchange.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Information regarding the [REDACTED] Investors

Our [REDACTED] Investors include two Sophisticated Investors (i.e., Greater Bay Area Fund and Traditional Chinese Medicine Fund, each as defined below). The background information of our [REDACTED] Investors is set out below.

<u>Name of the [REDACTED] Investors</u>	<u>Background</u>
Hepalink	Hepalink Biotechnology II Limited is indirectly wholly-owned by Hepalink. Hepalink is a joint stock limited company incorporated under the laws of the PRC. Hepalink completed its initial public offering and listing of its A shares on the Shenzhen Stock Exchange (stock code: 002399) on May 6, 2010, and completed its initial public offering and listing of its H shares on the Stock Exchange (stock code: 9989) on July 8, 2020. Hepalink is a leading China-based pharmaceutical company with global pharmaceutical, innovative biotech and CDMO businesses. Hepalink has a track record of operating its business in the pharmaceutical industry for more than 20 years.
Qianhai Haichuang	Qianhai Haichuang is a limited partnership established under the laws of the PRC. Qianhai Haichuang has approximately RMB20 million under its management and is principally engaged in the investment in biopharmaceutical innovation enterprises. The general partner of Qianhai Haichuang is Nanfang Haichuang Funds Management (Shenzhen) Co., Ltd. (南方海創基金管理(深圳)有限公司), which is owned by LUO Feng (羅鋒) and DENG Zhineng (鄧志能), both of whom are Independent Third Parties, as to 55% and 45%, respectively. The limited partners of Qianhai Haichuang are YU Jielin (餘潔琳), LI Hao (李浩), ZHAN Biao (詹表), ZHONG Weizhen (鐘偉珍), YANG Jing (楊靜) and YAN Ming (嚴明), each of whom is an Independent Third Party. Qianhai Haichuang is an Independent Third Party.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
Goldlink	Goldlink Greater China Fund SP V is a segregated portfolio under Goldlink Capital Fund SPC, which is a segregated portfolio company incorporated under the laws of the Cayman Islands. Goldlink Greater China Fund SP V is indirectly wholly owned by CHINA GOLDLINK CAPITAL GROUP LIMITED (中國金聯資本集團有限公司), which is owned by SHAN Miao (單淼) as to 9.47%, Eternal Wealth Investment Limited as to 36%, LUO Yi (羅毅) as to 34%, CHEN Yihong (陳奕宏) as to 4.74%, City Energy Holdings Limited as to 6.60%, and ZHU Jun (朱軍) as to 9.19%. Goldlink Capital Fund SPC - Goldlink Greater China Fund SP V is principally engaged in the investment in the equity of private companies (including companies principally engaged in the biopharmaceutical industry) with assets under management of over HK\$40 million. Each of Goldlink Greater China Fund SP V, SHAN Miao, Eternal Wealth Investment Limited, LUO Yi, CHEN Yihong, City Energy Holdings Limited and ZHU Jun is an Independent Third Party.
Able Holdings	Able Holdings is a limited company incorporated in the BVI with limited liabilities, which is wholly-owned by Taitong Fund L.P. The general partner of Taitong Fund L.P. is Taitong Management Co., Ltd. (" Taitong Management "). Taitong Management is a limited company incorporated in the Cayman Islands and controlled by CHIANG Chen Hsiu-Lien, an Independent Third Party.
Yuexiu Jinchan IV	Yuexiu Jinchan IV is a limited partnership established under the laws of the PRC on November 10, 2020. Yuexiu Jinchan IV focuses on investments in healthcare, equipment manufacturing, information technology and consumption with assets under management of over RMB630 million. Yuexiu Jinchan IV is managed by its general partner, Guangzhou Yuexiu Industrial Investment Fund Management Co., Ltd. (廣州越秀產業投資基金管理股份有限公司). The limited partner with the largest equity of Yuexiu Jinchan IV is Guangzhou Yuexiu Industrial Investment Co., Ltd. (廣州越秀產業投資有限公司) with approximately 97.60% of equity interest in Yuexiu Jinchan IV. Each of Yuexiu Jinchan IV, Guangzhou Yuexiu Industrial Investment Fund Management Co., Ltd. and Guangzhou Yuexiu Industrial Investment Co., Ltd. is an Independent Third Party.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
Pingtan Rongjing and Yuthai Investment	Pingtan Rongjing is a limited partnership established under the laws of the PRC on November 26, 2021. Pingtan Rongjing is managed by its general partner, Yuthai Investment Management Co., Ltd. (昱烽晟泰投資管理有限公司) (“ Yuthai Investment ”), which is owned as to 80% by MA Lixiong, our non-executive Director. The limited partner holding the largest equity interest of Pingtan Rongjing as to 47.72% is LIU Ya (劉亞) who is an Independent Third Party. Yuthai Investment is engaged in investments in areas, including but not limited to, healthcare, automotive electronic, education and recruit services.
MPCAPITAL	MPCAPITAL is a limited company established under the laws of Hong Kong on August 8, 2014 and is wholly-owned by DENG Kaiping (鄧開平), an Independent Third Party. MPCAPITAL is principally engaged in investments in areas, including but limited to, healthcare and technology industries.
Greaty Investment	Greaty Investment is a limited company incorporated under the laws of Hong Kong and is wholly-owned by HAO Yong Kuan (郝永寬), an Independent Third Party. Mr. HAO has more than 30 years of management experience in Viction Group and Lamda Restaurant Group. Greaty Investment principally invests globally in biopharmaceuticals, medical equipment and health industries and international chain catering businesses.
ZT Global Energy	ZT Global Energy is an exempted limited partnership incorporated under the laws of the Cayman Islands that is principally engaged in the investment in healthcare and technology industries. The general partner of ZT Global Energy is ML Investment Management Company which is owned by Amaryllis Forest Limited as to 60% interests and a group of individuals each of whom holding no more than 10% interests therein. Amaryllis Forest Limited is wholly owned by Equity Trustee Limited as trustee of The ML Trust. Each of ZT Global Energy, ML Investment Management Company and Amaryllis Forest Limited is an Independent Third Party.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
Green Pine	Green Pine is an exempted limited partnership incorporated under the laws of the Cayman Islands, with its general partner being Green Pine International Capital Partners (“GPCP”) which is owned by LUO Fei (羅飛) and LI Wei (厲偉). GPCP principally invests in artificial intelligence, healthcare and new material industries. The limited partners of Green Pine are (i) Lilac International Investment Company Limited which is interested in 26.53% of its equity interests; (ii) Mizuho Bank, Ltd which is interested in 13.53% of its equity interests; (iii) Bondwa Enterprise Limited which is interested in 10.61% of its equity interests; (iv) JU Xiongwei who is interested in 10.61% of its equity interests; (v) Avant Sports Industrial Co., Limited which is interested in 5.31% of its equity interests; (vi) Sidereal Group Limited which is interested in 6.37% of its equity interests; (vii) KAV Invest Holding AG which is interested in 3.71% of its equity interests; and (viii) five individuals each of whom is interested in no more than 10% of its equity interests. Each of Green Pine, GPCP, LUO Fei and LI Wei and the aforesaid limited partners is an Independent Third Party.
Orient Champion	Orient Champion is a limited liability company incorporated under the laws of Hong Kong and is wholly-owned by REN Qifeng (任奇峰). Mr. REN is an Independent Third Party. Orient Champion is principally engaged in the investment in biopharmaceutical innovation enterprises.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
Blue Ocean and Shenzhen BioResearch	<p>Shenzhen BioResearch, an investment fund registered in the PRC, is managed by Shenzhen Blue Ocean Investment Fund Management Co., Ltd. (深圳藍海創業投資基金管理有限公司) (“BOCG”), which is owned as to 80% by YANG Feng, a former director of our Company. The other general partner of Shenzhen BioResearch is Wuhan Snowball Asset Management Co., Ltd. (武漢雪球資產管理有限公司), whose largest shareholder is WANG Danli (王丹莉) holding 24% equity interests and other shareholders are YAN Zhi (閻志), WANG Xianyuan (王先遠), WANG Hongbin (王宏斌), SUN Aijun (孫愛軍), ZHANG Zhongyu (張縱予) and WU Jiangan (鄔劍剛), each of whom is an Independent Third Party. The limited partners of Shenzhen BioResearch holding more than 10% equity interests are (i) Shenzhen Yourun Investment Consulting Partnership (Limited Partnership) (深圳市優潤投資諮詢合夥企業(有限合夥)) holding 36.6% which is in turn owned by YANG Feng as a general partner and LIU Guanghui (劉光輝) as a limited partner as to 50% each, (ii) Wuhan Xueqiu Bai Aurisi Equity Investment Partnership (Limited Partnership) (武漢雪球柏奧瑞思股權投資合夥企業(有限合夥)) holding 30.3% whose general partner is Wuhan Snowball Asset Management Co., Ltd. and limited partners are eight individuals, each of Wuhan Snowball Asset Management Co., Ltd. and the said eight individuals being an Independent Third Party, and (iii) YANG Feng holding 20.7%. Each of Blue Ocean and Shenzhen BioResearch is an Independent Third Party.</p> <p>Blue Ocean is a limited liability company incorporated under the laws of the Cayman Islands, where YANG Feng is a director. The investment manager of Blue Ocean is Blue Ocean Management Limited, which holds 10% of the equity interests of Blue Ocean and where YANG Feng acts as a director. Blue Ocean Management Limited is wholly owned by ZHAO Cong Richard. Blue Ocean is directly owned as to 40% by ZHAO Cong Richard, and as to 50% by Alpha Prime Ventures Limited, which is wholly owned by CHI Wenfu (池文富). Each of ZHAO Cong Richard and CHI Wenfu is an Independent Third Party.</p>

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the

[REDACTED] Investors

Background

BOCG focuses on venture capital and private equity investment in the most innovative biotech companies with accumulated US\$300 million asset under management with dual currency funds. Recent investments of Blue Ocean include our Company and Suzhou Life Science Co., Ltd, a leading siRNA drug development company in China, devoted to the development of innovative nucleic acid therapeutic drugs and related products.

Shenzhen Taixun

Shenzhen Taixun is a limited partnership established in the PRC. Nanchang JT New Century Bioventure Partnership ("Nanchang JT") is the limited partner of Shenzhen Taixun holding approximately 99.9% of the interests in Shenzhen Taixun. Nanchang JT is a limited partnership established under the laws of the PRC, which manages Shenzhen Taixun, a special purpose vehicle incorporated under the laws of the PRC. Nanchang JT is dedicated to searching for and supporting innovative entrepreneurships in the healthcare and life science industry. Nanchang JT is currently managing a RMB1 billion venture capital fund with experienced professionals. The team is focused on supporting early to mid-stage entrepreneurships in life science in accomplishing their ambitious vision. Each of Shenzhen Taixun and Nanchang JT is an Independent Third Party.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
Poly Platinum and Greater Bay Area Fund	<p>Poly Platinum is an investment holding company incorporated in the BVI. It is a wholly-controlled subsidiary of Greater Bay Area Homeland Development Fund LP (大灣區共同家園發展基金有限合夥) (“Greater Bay Area Fund”). The Greater Bay Area Fund is a private investment fund controlled by Greater Bay Area Homeland Development Fund (GP) Limited (大灣區共同家園發展基金(GP)有限公司) (“GBAHD GP”) and under discretionary management by Greater Bay Area Development Fund Management Limited (“GBAD Fund Management”), a Type 1, Type 4 and Type 9 licensed corporation under the SFO. The Greater Bay Area Fund covers a range of activities, including venture capital, private equity investments and listed company investments and mergers and acquisitions. Both GBAHD GP and GBAD Fund Management are controlled by Greater Bay Area Homeland Investments Limited (大灣區共同家園投資有限公司) (“GBAHIL”), a company incorporated in Hong Kong with limited liability that was jointly owned by a number of international large-scale industrial institutions, financial institutions and new economic enterprises, each of which holds less than 15% shareholding in GBAHIL. Greater Bay Area Fund has assets under management of more than HK\$1 billion and has a track record in healthcare and biotech sectors for four years. It has invested in a number of healthcare and biotechnology companies including HBM Holdings Limited (和鉑醫藥控股有限公司) whose shares are listed on the Stock Exchange (stock code: 2142) and Elpiscience Biopharmaceuticals, Inc. Greater Bay Area Fund is a Sophisticated Investor and has made meaningful investment in our Company at least six months before the [REDACTED]. Each of Poly Platinum, Greater Bay Area Fund, GBAHD GP, GBAD Fund Management and GBAHIL is an Independent Third Party.</p>

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
HK Tigermed and Hangzhou Tigermed	HK Tigermed a limited liability company incorporated in Hong Kong and its principal activity is investment holding and clinical trial operation. HK Tigermed is a wholly-owned subsidiary of Hangzhou Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司) (“ Hangzhou Tigermed ”), a company whose A shares are listed on the Shenzhen Stock Exchange (stock code: 300347) and H Shares are listed on the Stock Exchange (stock code: 3347). Hangzhou Tigermed is a leading China-based provider of comprehensive biopharmaceutical R&D services, with an expanding global presence. Hangzhou Tigermed was one of our top five suppliers during the Track Record Period. Each of HK Tigermed and Hangzhou Tigermed is an Independent Third Party.
Pluto and CITIC	Pluto is an indirectly wholly-owned subsidiary of CITIC Securities Company Limited (中信証券股份有限公司). CITIC Securities Company Limited is a joint stock company incorporated in the PRC with limited liability, the H shares and A shares of which are listed on the Stock Exchange (stock code: 6030) and the Shanghai Stock Exchange (stock code: 600030), respectively. Each of Pluto and CITIC is an Independent Third Party.
Xinyu Cowin	Xinyu Cowin is a limited partnership established under the laws of the PRC. Xinyu Cowin has approximately RMB695 million under its management and is principally engaged in the investment in the industry of comprehensive health. The general partner of Xinyu Cowin is Cowin Jinxiu Capital Firm (深圳同創錦繡資產管理有限公司), a wholly-owned subsidiary of Shenzhen Cowin Asset Management Co., Ltd. (同創偉業資產管理股份有限公司) whose shares are listed on the National Equities Exchange and Quotations (stock code: 832793). The largest shareholder of Shenzhen Cowin Asset Management Co., Ltd. was Shenzhen Cowin Venture Capital Investment Co., Ltd. (深圳市同創偉業創業投資有限公司) holding approximately 35.01% as of the Latest Practicable Date. Shenzhen Cowin Venture Capital Investment Co., Ltd. is owned by HUANG Li (黃荔) and ZHENG Weihe (鄭偉鶴), both of whom are Independent Third Parties, as to 55% and 45%, respectively.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
Shenzhen Winzac	Shenzhen Winzac is a limited partnership established under the laws of the PRC, which is principally engaged in the investment in venture capital. The general partner of Shenzhen Winzac is Shenzhen Winzac Asset Management Co., Ltd. (深圳市穩正資產管理有限公司) (“ Winzac Asset Management ”), which is controlled by Shenzhen Winzac Investment Co., Ltd. (深圳市穩正投資有限公司). The largest shareholder of Shenzhen Winzac Investment Co., Ltd. is Shenzhen Youhe Consulting Co., Ltd. (深圳友和諮詢有限公司) holding 47.8% equity interests of it, which is wholly owned by HUANG Youcheng (黃友成). Winzac Asset Management principally focuses in investing in advanced manufacturing technology, SIoT (Smart Internet of Things) and bio-pharmaceutical industries. Each of Shenzhen Winzac, Winzac Asset Management, Shenzhen Winzac Investment Co., Ltd., Shenzhen Youhe Consulting Co., Ltd. and HUANG Youcheng is an Independent Third Party.
Sichuan Rongxin	Sichuan Rongxin is a limited liability company established under the laws of the PRC, which is wholly owned by Shannan Jintong Runcheng Industrial Co., Ltd. (山南金通潤成實業有限公司) (“ Shannan Jintong ”). Shannan Jintong is owned by ZENG Qingmin (曾慶敏) and ZHANG Yang (張楊) as 50% and 50%, respectively, both of whom are Independent Third Parties. Shannan Jintong is principally engaged in investment and management of expressway service areas, commerce and trade in tourist areas, development of gas stations and exploration and development of minerals.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
Ningbo Borui	Ningbo Borui is a limited partnership established under the laws of the PRC. The general partner of Ningbo Borui is Ningbo Yanghua Enterprise Management Consulting Partnership (Limited Partnership) (寧波仰華企業管理諮詢有限公司(有限合夥)) (“ Ningbo Yanghua ”). The general partner of Ningbo Yanghua is Ningbo Baobo Investment Management Co., Limited (寧波鮑博投資管理有限公司), which is owned by SUN Peng (孫鵬) as to 90% and LIU Lisha (劉莉莎) as to 10%. The limited partner of Ningbo Yanghua is SUN Kai (孫凱). The limited partners of Ningbo Borui are XIE Jianyong (謝健勇) and Ningbo Borui Andi Equity Investment Partnership (Limited Partnership) (寧波博睿安迪股權投資合夥企業(有限合夥)) (“ Ningbo Andi ”), each of which holds 49.95% of the partnerships in Ningbo Borui. The general partner of Ningbo Andi is Ningbo Yanghua. Each of SUN Peng, SUN Kai, XIE Jianyong and LIU Lisha is an Independent Third Party.
Hongtu Capital	Hongtu Capital is a limited liability company incorporated under the laws of the BVI. Hongtu Capital is principally engaged in the investment in, including but not limited to, emerging business, high-tech, new consumption, healthcare, big data and industrial service industries. Hongtu Capital is owned as to 60% and 40% to LAI Hoi Man (賴海民) and CHAN See Ting (陳思廷), respectively, both of which are Independent Third Parties.
BAIYI Capital	BAIYI Capital is a limited liability company incorporated under the laws of the BVI, which is a wholly-owned investment holding company of AIH Capital L.P. (“ AIH Capital ”). AIH Capital has approximately US\$30 million under its management and is principally engaged in the investment in, including but not limited to, innovative pharmaceutical and healthcare industries. AIH Capital is controlled by MA Lixiong, our non-executive Director.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the [REDACTED] Investors	Background
Traditional Chinese Medicine Fund	<p>Traditional Chinese Medicine Fund is a limited partnership established under the laws of the PRC on June 25, 2021. The investment of Traditional Chinese Medicine Fund is primarily focused on the fields of traditional Chinese medicine manufacturing, traditional Chinese medicine service, traditional Chinese medicinal material processing, and traditional Chinese medicinal material planting. Traditional Chinese Medicine Fund also expands its investment into the field of medical health. Traditional Chinese Medicine Fund is managed by its general partner, Guangdong Kaiheng Private Equity Investment Fund Management Co., Ltd. (廣東開恒私募股權投資基金管理有限公司), which is ultimately owned by China Development Bank (國家開發銀行) and State-owned Assets Supervision and Administration Commission, the People’s Government of Guangdong Province (廣東省人民政府國有資產監督管理委員會) as to 50% and 50%, both of which are state-owned entities in the PRC, respectively. The limited partner with the largest equity of Traditional Chinese Medicine Fund is China Development Bank Capital Co., Ltd. (國開金融有限責任公司) with approximately 49.925% of equity interest in Traditional Chinese Medicine Fund, which is wholly owned by China Development Bank. The other limited partners of Traditional Chinese Medicine Fund are Guangdong Hengjian Investment Holding Co., Ltd. (廣東恆健投資控股有限公司) and Guangzhou Guoju Venture Capital Co., Ltd. (廣州國聚創業投資有限公司), both of which are state-owned companies in the PRC. Traditional Chinese Medicine Fund has assets under management of approximately RMB5.0 billion with a track record in healthcare and biotech sectors for two years. Its portfolio companies include Yichang Shanchengshuidu Cordyceps Co., Ltd. (宜昌山城水都冬蟲夏草有限公司), Hunan Yineng Pharma Co., Ltd. (湖南易能生物醫藥有限公司), etc. Traditional Chinese Medicine Fund is a Sophisticated Investor and has made meaningful investment in our Company at least six months before the [REDACTED]. Each of Traditional Chinese Medicine Fund, Guangdong Kaiheng Private Equity Investment Fund Management Co., Ltd., and China Development Bank Capital Co., Ltd. is an Independent Third Party.</p>

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Public Float

The Shares held by Hepalink and Hepalink Biotechnology II Limited will not be considered as part of the public float because they will be the Substantial Shareholders and therefore core connected persons of our Company upon the [REDACTED].

The Shares held by Dr. Liu together with the AIC Group will not be considered as part of the public float because they will be the Substantial Shareholders and therefore core connected persons of our Company upon the [REDACTED]. As such, approximately [REDACTED]% of the total issued Shares held or controlled by Dr. Liu, Greaty Investment, ZT Global Energy and Orient Champion will not count towards public float after the [REDACTED] without taking into account the Shares which may be allotted and issued under the [REDACTED].

The Shares held by BAIYI Capital and Pingtan Rongjing will not be considered as part of the public float because each of them is indirectly wholly-controlled by, and therefore a close associate of, Mr. MA Lixiong, our non-executive Director. As a result, each of BAIYI Capital and Pingtan Rongjing is a core connected person of our Company upon the [REDACTED].

As disclosed above, a total of [REDACTED] Shares, representing approximately [REDACTED]% of our Company's total issued Shares immediately following the completion of the [REDACTED] and the [REDACTED], will not be considered as part of the public float upon the [REDACTED] (assuming the [REDACTED] is not exercised).

To our Director's best knowledge, each of the other [REDACTED] Investors is an Independent Third Party. Accordingly, Shares held by them will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules after the [REDACTED].

Save as disclosed above, to the best of our Directors' knowledge, all other Shareholders of our Company are not core connected persons of our Company. As a result, over 25% of our Company's total issued Shares will be held by the public upon completion of the [REDACTED] as required under Rule 8.08(1)(a) of the Listing Rules. In addition, the market capitalization of the portion of the total number of the Company's issued Shares held by the public pursuant to the requirements under Rule 18A.07 of the Listing Rules (based on the [REDACTED] of HK\$[REDACTED], being the low-point of the indicative [REDACTED] range) would be over HK\$375 million at the time of the [REDACTED].

Shares Subject to Lock-up after the [REDACTED]

As of the Latest Practicable Date, the Shares held by the [REDACTED] Investors⁽¹⁾ and the Founder BVI, being [53,313,484] ([REDACTED] as adjusted after the [REDACTED]) Shares, will be subject to lock-up for a period of [six] months commencing from the [REDACTED]. As of the Latest Practicable Date, up to [5,744,288] ([REDACTED] as adjusted after the [REDACTED]) Shares underlying the granted Awards under the 2020 Share Incentive Plan will be subject to lock-up of six months commencing from the [REDACTED] and up to [1,612,372]

Notes:

- (1) including the Shares held by Greaty Investment, ZT Global Energy, Orient Champion and all other [REDACTED] Investors, but excluding the [18,000,000] ([REDACTED] as adjusted after the [REDACTED]) ordinary Shares held by Hepalink through its indirectly wholly-owned subsidiary Hepalink Biotechnology II Limited
- (2) including the underlying Shares that were granted to Dr. Liu

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

([REDACTED]) as adjusted after the ([REDACTED]) Shares⁽²⁾ underlying the granted Awards under the 2020 Share Incentive Plan will be subject to lock-up of 180 days commencing from the [REDACTED]. As of the Latest Practicable Date, up to [4,000,000] ([REDACTED]) as adjusted after the ([REDACTED]) Shares underlying the granted Awards under the 2023 Share Incentive Plan will be subject to lock-up of 12 months commencing from the [REDACTED]. Therefore, as of the Latest Practicable Date, an aggregate of up to 64,670,144 ([REDACTED]) as adjusted after the ([REDACTED]) Shares, including certain Shares held by the [REDACTED] Investors and the 2020 ESOP Platform, and all Shares held by the AIC Group and the 2023 ESOP Platform, representing approximately [REDACTED]% of our Company’s total issued Shares immediately following the completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised), will be subject to lock-up of no less than 180 days commencing from the [REDACTED]. For further details, see the paragraph headed “— 2023 ESOP Platform”.

CONCERT PARTY AGREEMENT

To ensure maximum control of voting power at general meetings of our Company and thereby enhance the stability of our Company in terms of ownership and management prior to the [REDACTED], Dr. Liu, the Founder BVI, Greaty Investment, ZT Global Energy and Orient Champion have entered into a concert party agreement (the “**Concert Party Agreement**”) on September 30, 2021, pursuant to which the Founder BVI (the voting rights attached to the Shares held by whom are to be exercised by Dr. Liu), Greaty Investment, ZT Global Energy and Orient Champion confirmed and ratified that, since September 1, 2019, (i) they had acted and would continue to act in concert and collectively for all matters relating to the operation and development of our Group that need to be approved by the Shareholders pursuant to applicable laws and the constitutional documents of our Company; and (ii) when and if they could not reach unanimous consent, the decision of Dr. Liu shall prevail. None of the party to the Concert Party Agreement is entitled to terminate the Concert Party Agreement unilaterally. Each of Greaty Investment, ZT Global Energy and Orient Champion was Independent Third Parties prior to becoming a [REDACTED] investor of our Company. The funds of Greaty Investment, ZT Global Energy and Orient Champion used to invest in our Company are sourced with proceeds from their respective investment operations. For detailed information of Greaty Investment, ZT Global Energy and Orient Champion, see “[REDACTED] Investments — Information regarding the [REDACTED] Investors” in this section.

As at the Latest Practicable Date, each of the Founder BVI, Greaty Investment, ZT Global Energy and Orient Champion was entitled to exercise the voting rights attached to approximately 16.04%, 1.26%, 1.26% and 1.77% of the total issued Shares, respectively. The Founder BVI, which forms part of the asset that comprises the Family Trust, is wholly owned by the Family Trust. Dr. Liu, as the investment advisor of the Family Trust, is entitled to exercise the voting rights attached to the 13,500,000 Shares held by the Founder BVI.

Together with the voting rights attached to the 8,849,294 Shares held by the 2020 ESOP Platform and controlled by Dr. Liu (as further detailed below), as of the Latest Practicable Date, Dr. Liu, the Founder BVI, Greaty Investment, ZT Global Energy and Orient Champion, (collectively, the “**AIC Group**”), were entitled to exercise the voting rights attached to approximately 30.84% of the total issued Shares in aggregate and are considered our single largest group of Shareholders prior to the [REDACTED].

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

ADOPTION OF THE INCENTIVE PLANS

For the purpose to attract and retain the best available personnel, to provide additional incentives to employees, Directors and consultants of our Company and to promote the success of our Company’s business, we have adopted the Incentive Plans, including the 2020 Share Incentive Plan and the 2023 Share Incentive Plan. For further details, please see “Statutory and General Information — D. Incentive Plans” in Appendix IV to this document.

2020 ESOP PLATFORM

We incorporated the 2020 ESOP Platform on March 8, 2019 for the purpose of facilitating the administration of the 2020 Share Incentive Plan and holding the Shares underlying the awards granted and to be granted under the 2020 Share Incentive Plan. On March 25, 2019, we allotted and issued 4,200,000 ordinary Shares to the 2020 ESOP Platform. On August 12, 2019, the Series B Investors transferred 462,462 Series B Preferred Shares to the 2020 ESOP Platform due to valuation adjustment, all of which were reclassified into ordinary Shares on a one-to-one basis. For further details, please refer to the paragraph headed “— Transfer of Shares to 2020 ESOP Platform by Series B Investors”. On April 29, 2022, we allotted and issued another 4,186,832 ordinary Shares to 2020 ESOP Platform. As of the Latest Practicable Date, the 2020 ESOP Platform held 8,849,294 ordinary Shares in total, which accounted for approximately 10.51% of the total issued Shares of our Company. As of the Latest Practicable Date, all 8,849,294 ([REDACTED]) as adjusted after the ([REDACTED]) underlying Shares held by the 2020 ESOP Platform had been granted to specified participants under the 2020 Share Incentive Plan, representing approximately ([REDACTED])% of the issued Shares immediately following the completion of the ([REDACTED]), the repurchase of Shares from the 2023 ESOP Platform and the ([REDACTED]).

In addition, pursuant to the 2020 Share Incentive Plan and the terms of the relevant grant agreements, the vesting of all Awards under 2020 Share Incentive Plan will be subject to the ([REDACTED]), irrespective of the vesting commencement date or the vesting schedule of the relevant grants. Accordingly, no Award has been vested as at the date of this document and no Award will be vested unless and until ([REDACTED]) has occurred. In other words, the Awards which are ready to be vested in accordance with the vesting schedule specified the relevant grant agreements will only be effectively vested after the ([REDACTED]). For details of the outstanding Awards under the 2020 Share Incentive Plan, please see section “Appendix IV — Statutory and General Information — D. Incentive Plans — 1. 2020 Share Incentive Plan — Outstanding Awards” in this document.

SHAREHOLDING AND VOTING RIGHTS OF AIC GROUP AND HEPALINK ENTITIES

Pursuant to a deed executed by Core Trust Company Limited, being the trustee and the nominee of the 2020 ESOP Platform, and our Company on November 28, 2019, Dr. Liu was granted power of attorney to, prior to the ([REDACTED]), exercise the voting rights attached to the Shares held by the 2020 ESOP Platform. Pursuant to such power of attorney and considering that no Awards shall be vested prior to the ([REDACTED]), Dr. Liu was entitled to exercise the voting rights attached to the 8,849,294 Shares held by the 2020 ESOP Platform, which represented approximately 10.51% of the total voting power at general meetings as of the Latest Practicable Date and prior to the ([REDACTED]). As a result of such arrangement, Dr. Liu was entitled to exercise the voting rights attached to an aggregate of 22,349,294 Shares, which represented approximately 26.55% of the total voting power at general meetings as of the Latest Practicable Date and prior to the ([REDACTED]). Together with the voting rights controlled by Dr. Liu through

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

the 2020 ESOP Platform, as of the Latest Practicable Date, the AIC Group were collectively entitled to exercise the voting rights attached to approximately 30.84% of the total issued Shares in aggregate and are considered our single largest group of Shareholders prior to the [REDACTED].

Our Directors are of the view that the aforesaid power of attorney allows Dr. Liu, as our founder, executive Director and chief executive officer, to control additional voting rights and remain, together with the parties to the Concert Party Agreement, as the single largest group of Shareholders to ensure maximum control of voting power at general meetings and thereby enhance the stability of the Company in terms of ownership and management prior to [REDACTED]. For the avoidance of doubt, Dr. Liu will abstain from voting on unvested Shares held in the 2020 ESOP Platform only upon [REDACTED] for the purpose of compliance with Rule 17.05A of the Listing Rules.

Upon [REDACTED], the shareholdings of AIC Group and Hepalink entities in our Company are approximately [REDACTED]% and [REDACTED]%, respectively. Immediately after the [REDACTED], Dr. Liu will abstain from voting on the [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) unvested Shares held in the 2020 ESOP Platform for the purpose of compliance with Rule 17.05A of the Listing Rules. In addition, pursuant to the voting agreements entered into by certain Grantees and the Company, Dr. Liu was entitled to the voting rights attached to the [1,290,139] ([REDACTED] as adjusted after the [REDACTED]) [REDACTED] Vesting Shares. As a result, the exercisable voting rights of the AIC Group and the Hepalink Entities in our Company will not be equal to their respective shareholding in our Company upon [REDACTED]. The voting rights in the Company to be exercisable by Dr. Liu immediately after the [REDACTED] will be reduced to approximately [REDACTED]%, and the voting rights in the Company exercisable by the AIC Group shall become approximately [REDACTED]% (assuming the [REDACTED] is not exercised) immediately after the [REDACTED]. While the Hepalink Entities will become the single largest group of Shareholders of our Company upon [REDACTED] with approximately [REDACTED]% exercisable voting rights, the AIC Group will continue to have day-to-day control over the management and operation of our Group.

DAY-TO-DAY CONTROL OVER MANAGEMENT AND OPERATION OF THE GROUP BEFORE AND AFTER THE [REDACTED]

Notwithstanding the aforesaid reduction of voting rights exercisable by the AIC Group after [REDACTED] mainly as a result of Dr. Liu abstaining from voting on the unvested Shares held in the 2020 ESOP Platform in accordance with Rule 17.05A of the Listing Rules, the [REDACTED] would not result in any material change in the influence on the management of our Company and would not affect the actual dynamics between the AIC Group and our management for the following reasons:

- (i) Our Group was founded by Dr. Liu in November 2011. Since then, our operations had been managed by Dr. Liu with the assistance of other members of the senior management who had been recruited and assembled under the direction of Dr. Liu.
- (ii) Noting that Dr. Liu is a pioneer in the field of metabolic and digestive diseases with over 20 years of drug development experience and has led eight IND approvals in the United States, China, Canada and Australia for two drugs, and having over 100 patents and patent applications to her credit, Dr. Liu has led and spearheaded the Company's discovery development of multifunctional and multi-targeted therapies for the treatment of metabolic and digestive diseases with the assistance of our R&D team since the founding of our Group's business.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

- (iii) Under the aforesaid shareholding structure, major decisions of our Group, including operational strategies, financing and investment, appointment of management and members of the Board, had (with the exception of Hepalink's right to nominate one Director prior to the [REDACTED]) been driven by the executive Directors and the senior management under the leadership and control of Dr. Liu.
- (iv) Hepalink and other [REDACTED] Investors who are not members of the AIC Group had acted as financial investors and did not involve in the day-to-day management of our Company during the Track Record Period.

Based on the above, the AIC Group had, and will continue to have day-to-day control over the management and operation of our Group before the [REDACTED] completes.

- (v) Despite that the percentage of the voting power exercisable by the AIC Group will no longer be the highest among all Shareholders after the [REDACTED], the Company will continue to have no controlling shareholder upon [REDACTED].
- (vi) In addition, while the Board will establish the Nomination Committee which will be chaired by Dr. Liu, and candidates for directorship shall be subject to the recommendation by the Nomination Committee under the leadership of Dr. Liu before they are appointed by the Board or at the general meetings.
- (vii) As such, major decisions of the Group, including but not limited to the strategy and direction of its research and development of drugs for metabolic and digestive diseases, will remain to be driven by the executive Directors and the senior management under the leadership of Dr. Liu as the founder, chief executive officer, executive Director and chairwoman of the Board upon [REDACTED].

Based on the foregoing, the drop in the voting rights exercisable by the AIC Group, mainly for the purpose of compliance with Rule 17.05A of the Listing Rules, does not give rise to any material change to Dr. Liu's influence over the day-to-day management of the Group, the decision-making process at the level of the Board or at the general meetings of the Company, nor does it result in any change in the actual dynamics between the AIC Group and the management of the Group. It follows that the AIC Group will continue to have day-to-day control over the management and operation of our Group upon [REDACTED], while the designated director from Hepalink Entities remains a non-executive Director of the Company who will not involve in the day-to-day management of our Company.

2023 ESOP PLATFORM

We established the 2023 ESOP Platform on May 26, 2023 for the purpose of facilitating the administration of the 2023 Share Incentive Plan and holding the Shares underlying the awards under the 2023 Share Incentive Plan. On May 29, 2023, we allotted and issued 4,000,000 ordinary Shares to the 2023 ESOP Platform. As of the date of this document, the 2023 ESOP Platform held 4,000,000 ordinary Shares in total, which accounted for approximately 4.75% of the total issued Shares of our Company. As of the Latest Practicable Date, all of the underlying Shares held by the 2023 ESOP Platform had been granted to specified participants under the 2023 Share Incentive

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Plan, subject to the repurchase of [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares before [REDACTED]. For details of the outstanding Awards under the 2023 Share Incentive Plan, please see section “Appendix IV — Statutory and General Information — D. Incentive Plans — 2. 2023 Share Incentive Plan — Outstanding Awards” in this document. Futu Trust Limited serves as the trustee of the 2023 ESOP Platform.

The shareholding and voting right structure of our Company as of the date of the document and immediately upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised) is set forth below:

Name of Shareholder	Series of Shares	Number of Shares	Shareholding percentage as of the date of the document	Percentage of voting rights as of the date of the document	Number of Shares held immediately upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised)	Shareholding percentage of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised)	Percentage of exercisable voting rights immediately upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised) ⁽⁶⁾
The AIC Group							
Dr. Liu ⁽¹⁾⁽²⁾	Ordinary Shares	13,500,000	16.04%	26.55%	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Greaty Investment ⁽²⁾	Series B-1 Preferred Shares	1,061,562	1.26%	1.26%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
ZT Global Energy ⁽²⁾	Series B-1 Preferred Shares	1,061,562	1.26%	1.26%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Orient Champion ⁽²⁾	Series B-2 Preferred Shares	1,486,186	1.77%	1.77%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Subtotal of the AIC Group		17,109,310	20.33%	30.84%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
2020 ESOP Platform ⁽¹⁾	Ordinary Shares	8,849,294	10.51%	nil	[REDACTED] ⁽⁵⁾	[REDACTED] ⁽⁵⁾	[REDACTED] ⁽⁵⁾
2023 ESOP Platform ⁽⁸⁾	Ordinary Shares	4,000,000	4.75%	4.75%	[REDACTED] ⁽⁷⁾	[REDACTED] ⁽⁷⁾	[REDACTED] ⁽⁷⁾
Hepalink Biotechnology II Limited ⁽³⁾	Ordinary Shares	18,000,000	21.39%	21.39%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Hepalink ⁽²⁾⁽³⁾	Series A Preferred Shares	2,252,535	2.68%	2.68%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Qianhai Haichuang ⁽²⁾	Series A Preferred Shares	1,260,000	1.50%	1.50%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Goldlink ⁽²⁾	Series A Preferred Shares	945,000	1.12%	1.12%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Able Holdings ⁽²⁾	Series A Preferred Shares	378,000	0.45%	0.45%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Yuexiu Jinchan IV ⁽²⁾	Series A Preferred Shares	631,811	0.75%	0.75%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Pingtian Rongjing ⁽²⁾	Series A Preferred Shares	461,000	0.55%	0.55%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
MPCAPITAL ⁽²⁾	Series A Preferred Shares	371,654	0.44%	0.44%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Green Pine ⁽²⁾	Series B-1 Preferred Shares	636,937	0.76%	0.76%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Blue Ocean ⁽²⁾	Series B-2 Preferred Shares	424,625	0.50%	0.50%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Shenzhen Taixun ⁽²⁾	Series B+ Preferred Shares	3,184,713	3.78%	3.78%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾
Poly Platinum ⁽²⁾	Series B+ Preferred Shares	3,184,713	3.78%	3.78%	[REDACTED]	[REDACTED] ⁽⁴⁾	[REDACTED] ⁽⁴⁾

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of Shareholder	Series of Shares	Number of Shares	Shareholding percentage as of the date of the document	Percentage of voting rights as of the date of the document	Number of Shares held immediately upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised)	Shareholding percentage of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised)	Percentage of exercisable voting rights immediately upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised) ⁽⁶⁾
HK Tigermed ⁽²⁾	Series B+ Preferred Shares	2,123,142	2.52%	2.52%	[REDACTED]	[REDACTED]%	[REDACTED]%
Pluto ⁽²⁾	Series B+ Preferred Shares	1,507,431	1.79%	1.79%	[REDACTED]	[REDACTED]%	[REDACTED]%
Xinyu Cowin ⁽²⁾	Series B+ Preferred Shares	1,061,571	1.26%	1.26%	[REDACTED]	[REDACTED]%	[REDACTED]%
Shenzhen Winzac ⁽²⁾	Series B+ Preferred Shares	520,594	0.62%	0.62%	[REDACTED]	[REDACTED]%	[REDACTED]%
Sichuan Rongxin ⁽²⁾	Series B+ Preferred Shares	459,448	0.55%	0.55%	[REDACTED]	[REDACTED]%	[REDACTED]%
Ningbo Borui ⁽²⁾	Series B+ Preferred Shares	424,628	0.50%	0.50%	[REDACTED]	[REDACTED]%	[REDACTED]%
Shenzhen BioResearch ⁽²⁾	Series B+ Preferred Shares	212,314	0.25%	0.25%	[REDACTED]	[REDACTED]%	[REDACTED]%
Hongtu Capital ⁽²⁾	Series C Preferred Shares	7,618,932	9.05%	9.05%	[REDACTED]	[REDACTED]%	[REDACTED]%
BAIYI Capital ⁽²⁾	Series C Preferred Shares	4,571,359	5.43%	5.43%	[REDACTED]	[REDACTED]%	[REDACTED]%
Traditional Chinese Medicine ⁽²⁾	Series C+ Preferred Shares						
Fund		2,987,795	3.55%	3.55%	[REDACTED]	[REDACTED]%	[REDACTED]%
Yuexiu Jinchuan IV ⁽²⁾	Series C+ Preferred Shares	985,972	1.17%	1.17%	[REDACTED]	[REDACTED]%	[REDACTED]%
Grantees with [REDACTED] Vesting Shares ⁽⁵⁾	Ordinary Shares	nil	nil	nil	[REDACTED]	[REDACTED]%	[REDACTED]%(5)
Total		84,162,778	100%	100%	[REDACTED]	[REDACTED]%	[REDACTED]%

Notes:

- (1) Dr. Liu, being the investment advisor of the Family Trust, is entitled to exercise the voting rights attached to the 13,500,000 Shares held by the Founder BVI. Dr. Liu was also granted power of attorney to exercise the voting rights attached to the Shares held by the 2020 ESOP Platform. For details, please refer to the paragraph headed “—2020 ESOP Platform”. As of the Latest Practicable Date, up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) Shares underlying the Awards granted to the PRC Grantees under the 2020 Share Incentive Plan will be subject to lock-up of six months commencing from the [REDACTED] and up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) Shares underlying the Awards granted to the Grantees who are U.S. citizens (the “U.S. Grantee(s)”) under the 2020 Share Incentive Plan will be subject to lock-up of 180 days commencing from the [REDACTED]. The difference (of approximately three days) between the lock-up periods of the Shares underlying the Awards granted to the PRC Grantees and the U.S. Grantees is due to different local practices.
- (2) The Shares held will be subject to lock-up for a period of [six] months commencing from the [REDACTED].
- (3) Immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), Hepalink and Hepalink Biotechnology II Limited will be entitled to exercise the voting rights attached to approximately [REDACTED]% of the total issued Shares of our Company.

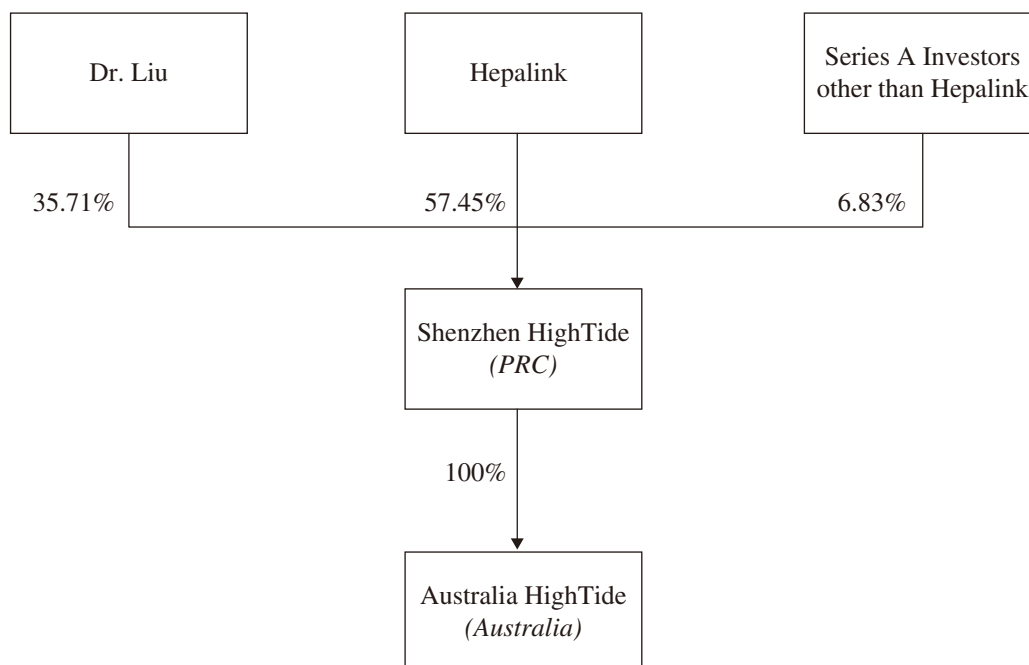
HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

- (4) Immediately after the [REDACTED], Awards with up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares shall be vested (comprising [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) [REDACTED] Vesting Shares and [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares that were granted to Dr. Liu under the 2020 Share Incentive Plan). Pursuant to the voting agreements entered into by certain Grantees and the Company, Dr. Liu was entitled to the voting rights attached to the [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) [REDACTED] Vesting Shares. Immediately after the [REDACTED], Dr. Liu will abstain from voting on the [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) unvested Shares held in the 2020 ESOP Platform for the purpose of compliance with Rule 17.05A of the Listing Rules. As a result, The voting rights in the Company to be exercisable by Dr. Liu immediately after the [REDACTED] will be approximately [REDACTED]%, and the voting rights in the Company exercisable by the AIC Group shall become approximately [REDACTED]% (assuming the [REDACTED] is not exercised) immediately after the [REDACTED]. While the Hepalink Entities will become the single largest group of Shareholders of our Company upon [REDACTED] with approximately [REDACTED]% exercisable voting rights, the AIC Group will continue to have day-to-day control over the management and operation of our Group.
- (5) Immediately after the [REDACTED], Awards with up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED] underlying Shares) shall be vested (comprising [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) [REDACTED] Vesting Shares and [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares that were granted to Dr. Liu under the 2020 Share Incentive Plan). Based on the assumptions in note (4), the Shares held in the 2020 ESOP Platform will be decreased from 8,849,294 to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) unvested Shares immediately after the [REDACTED], which will represent approximately [REDACTED]% of the issued Shares in the Company immediately after the [REDACTED] but shall abstain from voting after the [REDACTED] for the purpose of compliance with Rule 17.05A of the Listing Rules.
- (6) The unvested Shares held in the 2020 ESOP Platform and the 2023 ESOP Platform and the Shares to be repurchased from the 2023 ESOP Platform have been excluded from both the denominator and the numerator when calculating the percentage of the exercisable voting rights immediately upon [REDACTED].
- (7) [As of the Latest Practicable Date, all of the underlying Shares held by the 2023 ESOP Platform had been granted to specified participants under the 2023 Share Incentive Plan, which will remain unvested upon [REDACTED]. Pursuant to the terms of the 2023 Share Incentive Plan, to the extent the final [REDACTED] size of the [REDACTED] falls below US\$130 million, a portion of the Awards granted under the 2023 Share Incentive Plan shall lapse and be cancelled automatically. With respect to the Awards granted but automatically lapsed in accordance with such condition, the underlying Shares shall be repurchased and cancelled before the [REDACTED]. [Based on the mid-point of the indicative [REDACTED] and the exchange rate between U.S. dollars and Hong Kong dollars as of the Latest Practicable Date], the expected final [REDACTED] size of the [REDACTED] was expected to be approximately US\$[REDACTED]. Accordingly, [REDACTED]% of the Awards granted under the 2023 Share Incentive Plan shall lapse and be cancelled automatically and [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) Shares held by the 2023 ESOP Platform shall be repurchased and cancelled before the [REDACTED]. As a result, the Shares held by the 2023 ESOP Platform will be decreased from 4,000,000 ([REDACTED] as adjusted after the [REDACTED]) Shares to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) Shares upon the completion of the repurchase of Shares from the 2023 ESOP Platform. The Shares held by the 2023 ESOP Platform will remain unvested and shall abstain from voting after the [REDACTED] for the purpose of compliance with Rule 17.05A of the Listing Rules.]
- (8) As of the Latest Practicable Date, up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) Shares underlying the Awards granted to the Grantees under the 2023 Share Incentive Plan will be subject to lock-up of 12 months commencing from the [REDACTED].

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

REORGANIZATION

The following chart sets forth the corporate structure of our Group with principal operating entities immediately prior to our Reorganization:



We have carried out the following Reorganization steps in preparation for the [REDACTED]:

Step 1. Incorporation of Our Company and Our Offshore Subsidiaries

On February 28, 2018, our Company was incorporated in the Cayman Islands as an exempted company with limited liability and has an authorized share capital of US\$50,000 divided into 50,000 Shares with a nominal value of US\$1 each. Upon incorporation, one Share, representing the then issued share capital of our Company, was issued and transferred to the Founder BVI at nominal value.

BVI HighTide was incorporated in the BVI on March 16, 2018 as a direct wholly-owned subsidiary of our Company.

HK HighTide was incorporated in Hong Kong on April 9, 2018 as a direct wholly-owned subsidiary of BVI HighTide.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Step 2. Equity Transfer by Certain Shareholders, Share Subdivision and Allotment and Issue of Shares to Certain Shareholders

During the period from June 2018 to September 2018, each of Dr. Liu, Hepalink, and Qianhai Haichuang entered into an equity transfer agreement with HK HighTide pursuant to which they agreed to transfer the entire equity interests they held in Shenzhen HighTide to HK HighTide.

On October 16, 2018, our Company conducted a share subdivision (the “**Share Subdivision**”), pursuant to which each issued and unissued Share of US\$1 par value be subdivided into 10,000 Shares, each with a nominal value of US\$0.0001. Immediately after the completion of the Share Subdivision, our Company reclassified a total of 7,590,334 unissued Shares as 4,977,000 Series A Preferred Shares and 2,613,334 Series B-1 Preferred Shares respectively. Immediately after such reclassification and re-designation, our Company had an authorized share capital of US\$50,000 divided into 500,000,000 shares of US\$0.0001 each comprising of (i) 492,409,666 ordinary Shares, (ii) 4,977,000 Series A Preferred Shares and (iii) 2,613,334 Series B-1 Preferred Shares. On the same day, our Company allotted and issued 280,000 Series B Preferred Shares to Green Pine; 13,490,000 Ordinary Shares to Founder BVI; 18,000,000 Ordinary Shares and 3,717,000 Series A Preferred Shares to Hepalink; 1,260,000 Series A Preferred Shares to Qianhai Haichuang; 1,166,667 Series B-1 Preferred Shares to Greaty Investment; and 1,166,667 Series B-1 Preferred Shares to ZT Global Energy, respectively.

Step 3. Transfer of Interests in Our Group by Certain Shareholders

Xinjiang Taitong and Tibet Ningfeng transferred their interests in our Group to Able Holdings and Goldlink on March 14, 2019 and June 10, 2021, respectively. Please refer to the paragraphs headed “— Transfer of Interest in Our Group by Xinjiang Taitong to Able Holdings” and “— Transfer of Interest in Our Group by Tibet Ningfeng to Goldlink”, respectively, for further details.

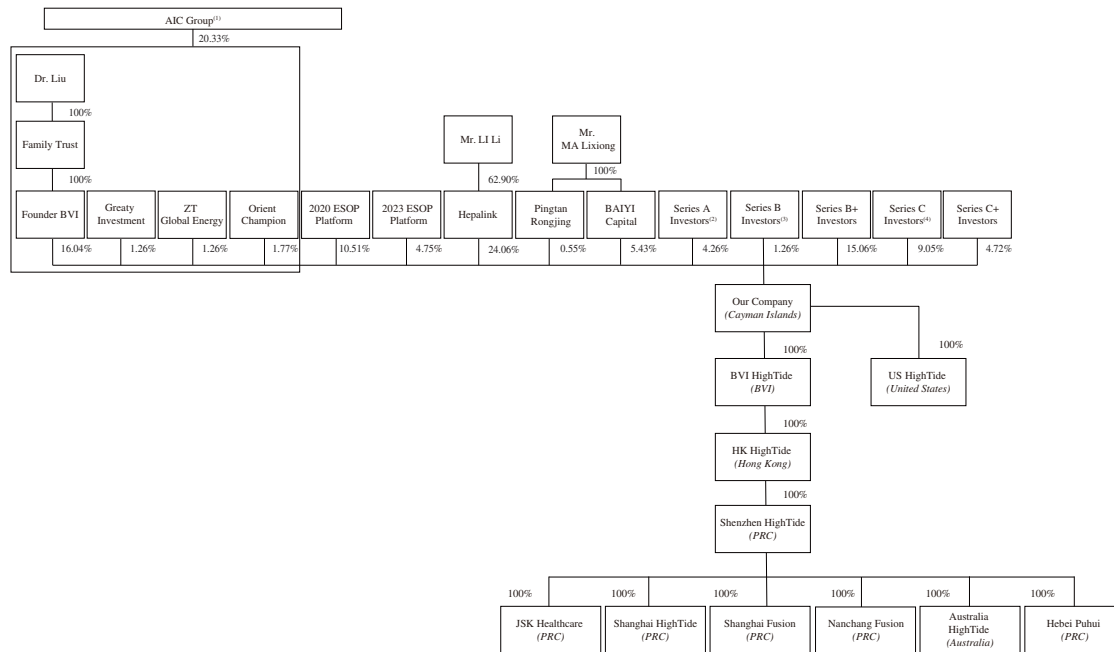
[REDACTED]

Subject to the share premium account of our Company being credited as a result of the issue of the [REDACTED] pursuant to the [REDACTED], our Company will, on the [REDACTED], allot and issue a total of [REDACTED] Shares credited as fully paid at par to the holders of Shares whose names appear on the register of members of our Company at the close of business on the business day preceding the [REDACTED] in proportion to their then-existing respective shareholdings in our Company (on the basis that each Preferred Share is converted into one Share and no holder of Shares shall be entitled to be allotted or issued any fraction of a Share) by capitalizing the relevant sum from the share premium account of our Company. The Shares allotted and issued pursuant to the [REDACTED] will rank *pari passu* in all respects with the then-existing issued Shares.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

CORPORATE STRUCTURE AFTER THE REORGANIZATION AND IMMEDIATELY PRIOR TO THE [REDACTED], THE REPURCHASE OF SHARES FROM THE 2023 ESOP PLATFORM AND THE [REDACTED]

Our corporate and shareholding structure after the Reorganization and the changes as described above and immediately prior to the completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] is as follows:



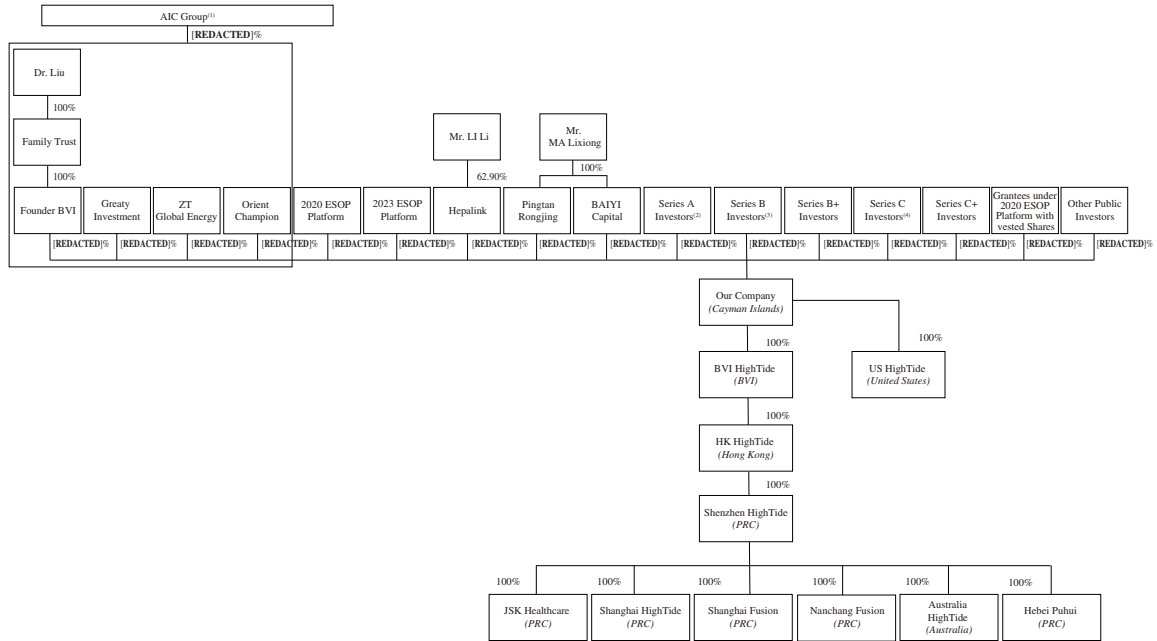
Notes:

- (1) Each of the member of the AIC Group is a party to the Concert Party Agreement. Please see “Concert Party Agreement” and “2020 ESOP Platform” in this section.
- (2) Excluding Hepalink and Pingtan Rongjing, the shareholding percentages of which are separately shown
- (3) Excluding Greaty Investment, ZT Global Energy and Orient Champion, the shareholding percentages of which are separately shown
- (4) Excluding BAIYI Capital, the shareholding percentage of which is separately shown

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

CORPORATE STRUCTURE IMMEDIATELY AFTER THE [REDACTED], THE REPURCHASE OF SHARES FROM THE 2023 ESOP PLATFORM AND THE [REDACTED]

Our corporate and shareholding structure immediately after the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming that the [REDACTED] is not exercised) is as follows:



Notes:

- (1) Each of the member of the AIC Group is a party to the Concert Party Agreement. Please see “Concert Party Agreement” and “2020 ESOP Platform” in this section.
- (2) Excluding Hepalink and Pingtan Rongjing, the shareholding percentages of which are separately shown
- (3) Excluding Greaty Investment, ZT Global Energy and Orient Champion, the shareholding percentage of which are separately shown
- (4) Excluding BAIYI Capital, the shareholding percentage of which is separately shown

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Together with the voting rights attached to the Shares held by the 2020 ESOP Platform and controlled by Dr. Liu (as further detailed below), as of the Latest Practicable Date, Dr. Liu, the Founder BVI, Grealy Investment, ZT Global Energy and Orient Champion were entitled to exercise the voting rights attached to approximately 30.84% of the total issued Shares in aggregate and are considered our single largest group of Shareholders prior to the [REDACTED].

PRC LEGAL COMPLIANCE

Our PRC Legal Advisor has confirmed that the establishment of Shenzhen HighTide and Shanghai HighTide and the increase or transfer of equity interests in respect of Shenzhen HighTide as described above in this section have been legally completed and the requisite government approvals or filings in all material respects, as applicable, have been obtained in accordance with PRC laws and regulations.

ODI Registration

Pursuant to the Administrative Measures for the Overseas Investment of Enterprises (《企業境外投資管理辦法》) promulgated by the NDRC and Administrative Measures for Overseas Investment Management (《境外投資管理辦法》) promulgated by the MOFCOM (the “**ODI Rules**”), a domestic institution shall undergo registration procedure for foreign investment in accordance with the provisions of the ODI Rules, which require the domestic institution to undergo relevant procedures for offshore investment prior to its overseas direct investment and obtain relevant recordation, approval, certificate or permit.

As advised by our PRC Legal Advisor, each of Hepalink and Qianhai Haichuang has completed the overseas direct investment registration with the local MOFCOM and NDRC on October 9, 2018 and September 21, 2018, each of Shenzhen Taixun, Xinyu Cowin, Shenzhen Winzac, Sichuan Rongxin, Ningbo Borui and Shenzhen BioResearch has completed the overseas direct investment registration with the local MOFCOM and NDRC on January 4, 2021 and February 2, 2021 and each of Yuexiu Jinchan IV, Traditional Chinese Medicine Fund and Pingtan Rongjing has completed the overseas direct investment registration with the local MOFCOM and NDRC on October 24, 2022 pursuant to the ODI Rules in relation to their overseas direct investments in our Company as domestic institutions.

M&A Rules

The M&A Rules require that foreign investors acquiring domestic companies by means of asset acquisition or equity acquisition shall comply with relevant foreign investment industry policies and shall be subject to approval by the relevant commerce authorities. Article 11 of the M&A Rules stipulates that an offshore special purpose vehicle, or a SPV, established or controlled by a PRC company or individual shall obtain approval from MOFCOM prior to the acquisition of any domestic enterprise related to such company or individual. The M&A Rules, among others, also require that an offshore SPV formed for [REDACTED] purposes and controlled directly or indirectly by PRC companies or individuals, shall obtain the approval of the CSRC prior to the [REDACTED] and trading of such SPV’s securities on an overseas stock exchange.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

As advised by our PRC Legal Advisor, the MOFCOM approvals or CSRC approvals under the M&A Rules are not required because Shenzhen HighTide was established at the beginning as a foreign-invested enterprise in the PRC, rather than become foreign-invested enterprises through merger or acquisition under the M&A Rules. However, there is uncertainty as to how the M&A Rules will be interpreted or implemented and whether the MOFCOM and other related government authorities would promulgate future PRC laws, regulations or rules contrary to the M&A Rules.

As advised by our legal advisers, all historical share transfers and restructuring steps as described above were compliant with applicable laws and regulations in all material aspects.

BUSINESS

OVERVIEW

We are a biopharmaceutical company specializing in the discovery, development and commercialization of multifunctional, multi-targeted therapies for the treatment of metabolic and digestive diseases. We have developed a product pipeline of five product candidates in-house, covering nine indications in metabolic and digestive diseases among which, five are at clinical-stage. Our Core Product, HTD1801 (berberine ursodeoxycholate), a new molecular entity, is a gut-liver anti-inflammatory metabolic modulator which targets multiple pathways pivotal to metabolic regulation, including those associated with metabolic and digestive diseases. It is created by forming a novel salt between two active moieties, berberine (“**BBR**”) and ursodeoxycholic acid (“**UDCA**”). HTD1801 has demonstrated good safety and efficacy across multiple clinical trials, including: a Phase IIa study in metabolic dysfunction-associated steatohepatitis (“**MASH**”, formerly known as nonalcoholic steatohepatitis or NASH) in the United States, a Phase II study in type 2 diabetes mellitus (“**T2DM**”) in China, a Phase Ib study in T2DM in China, a Phase II study in primary sclerosing cholangitis (“**PSC**”) in the United States and Canada, a Phase II study in primary biliary cholangitis (“**PBC**”) in the United States, and a Phase Ib/IIa study in hypercholesterolemia in Australia. We believe the good safety and efficacy profile strongly supports the “pipeline-in-a-product” potential of HTD1801 for selected metabolic and digestive diseases with suboptimal or no approved therapies.

Metabolic and digestive diseases are multifactorial diseases associated with comorbidities across various organs, which greatly complicate disease management. We strategically focus our efforts on developing innovative multifunctional and multi-target therapies for complex metabolic and digestive diseases, which are prevalent worldwide and expected to increase in cases and market size. According to CIC, the prevalence of major metabolic and digestive diseases was 4.9 billion as of the end of 2022 and is expected to reach 5.7 billion as of the end of 2032, with a market size growing from US\$330 billion in 2022 to US\$687 billion in 2032 at a CAGR of 7.6%.

One important feature of metabolic and digestive disease which gives rise to unmet medical needs is the coexistence of highly interrelated morbidities in patients. Current treatments of single-target drugs or their combinations do not fully address the complications of the interrelated comorbidities. Our goal is to offer multifunctional and multi-target therapies that treat complex metabolic and digestive diseases with a systemic approach, providing effective and safe options to improve overall clinical benefits of patients.

Achieving good balances of efficacy and safety is the key to develop multifunctional and multi-target therapies. The successful development of HTD1801 enabled us to establish the FUSIONTX™ drug discovery approach. Through FUSIONTX™, we integrate real-world clinical data, network pharmacology, known and established molecules with desired therapeutic benefits to design novel, multifunctional drug candidates to treat complex diseases with a systemic approach. We believe our approach in creating multifunctional products are paradigm-shifting which could lead to discovery and development of the next-generation therapies.

The two active moieties, BBR and UDCA, in our Core Product HTD1801 have a long history of medicinal applications as remedies for gut and liver diseases in traditional Chinese medicine. In HTD1801, BBR and UDCA work in tandem in the salt form with unique microstructure to produce distinct and improved properties of HTD1801. The improved properties are not observed with either of the individual active moieties or their physical mixture. We have successfully obtained





















BUSINESS


composition of matter patent for HTD1801 in many countries and regions, including the United States, China, the European Union and Japan, as well as crystalline form patent in the United States and China. Our clinical results show that HTD1801 delivers a therapeutic effect for patients including metabolic improvement, liver protection, anti-inflammation and antioxidative stress. However, therapeutic effect of the Core Product is based on preliminary clinical data only which is yet to be validated in later clinical trials, and the Core Product may fail to meet the primary and secondary endpoints at the late-stage clinical trials due to higher clinical development risks. For details, see “Risk Factors — Risks relating to the development, clinical trials and regulatory approval of our drug candidates — the Core Product may fail to meet the primary and secondary endpoints at the late-stage clinical trials due to higher clinical development risks resulted from HTD1801 being a new molecular entity and potential rejection from competent authorities” in this Document. HTD1801 is currently being developed for indications across MASH, T2DM, severe hypertriglyceridemia (“**SHTG**”), PSC and PBC, with a focus on comorbidities and a potential for indication expansion. In China, we received government support from “Major National Science and Technology Projects for New Drug Development” under the “National 13th Five-Year Plan”, which may further accelerate the speed of domestic market approval for HTD1801. In the United States, HTD1801 received FTD from FDA for MASH, and for PSC indications, as well as an ODD for the PSC indication. For more details, please see “Regulatory Overview — Laws and Regulations in the United States and EU — Orphan Drugs.” According to CIC, HTD1801 is the first PSC drug candidate to receive a FTD from the FDA. The FTD designation is based on available preclinical and clinical data that demonstrate the potential to address an unmet medical need and is intended to facilitate an expedited regulatory review process.

Building on our expertise in the development of HTD1801, we have also invested in and developed our pipeline to cover alcoholic hepatitis (“**AH**”), obesity, inflammatory bowel disease (“**IBD**”) and other metabolic diseases to address large unmet medical needs of other patient populations. For the treatment of AH, we are advancing the early clinical development of HTD4010. AH is one of the manifestations from alcohol-associated liver disease (“**ALD**”) characterized by acute liver inflammation. There are currently no approved drug treatments specifically targeting AH. The use of corticosteroids is recommended for patients with severe AH, but it has not shown meaningful long-term survival benefit and usually carries serious side effects. HTD4010 is a TLR4 inhibitor potentially capable of modulating the innate immune response and the resulting liver inflammation, a major contributor to AH pathogenesis. In animal studies, HTD4010 demonstrated potent beneficial effects for AH, alleviating signs of severe liver injury and reducing systemic inflammation. Our completed Phase I clinical result demonstrated its favorable safety profile in healthy humans.

An additional drug candidate, HTD1804, is under evaluation for the treatment of obesity, which is a growing global health risk associated with a wide range of comorbidities, most notably cardiovascular diseases (“**CVDs**”) and T2DM. Preclinical studies show that HTD1804 may be an important modulator of energy metabolism as well as offer cardiovascular protection. HTD1805, another drug candidate in our pipeline, is a multifunctional small molecule drug for the treatment of metabolic diseases. HTD2802 is a preclinical stage multifunctional drug for the treatment of IBD. In preclinical studies, HTD2802 has shown positive effects on stool formation and the occurrence of fecal occult blood, as well as reducing inflammatory cytokine levels and preventing pathological injury. We have researched and developed all drug candidates in-house. The following chart summarizes the development status of our drug candidates as of the Latest Practicable Date.

BUSINESS

Candidate	Mechanism/Target	Indication	Right	Designations	Pre-Clinical	Phase I	Phase II	Phase III	Competent or regulatory authorities	Upcoming Milestone
HTD1801 	Berberine ursodeoxycholate (BUDC)	MASH	 Global ^(b)	FTD	Ph I is completed in US; Ph I is initiated in US and Hong Kong and to be initiated in Mexico and Mainland China				FDA, NMPA, The Federal Commission for Protection against Sanitary Risks, Department of Health	Ph I in Mexico and Mainland China initiated in late 2023 and studies in all clinical sites expected to be completed in 2025
		T2DM	 Global		Ph II completed in Mainland China, Ph III initiated in Mainland China ^(c)				NMPA	Ph III to be completed in 2025
		SHTG	 Global		Ph II to be initiated in US ^(e)				FDA	Ph II to be initiated in H1 2024
		PSC	 Global ^(b)	FTD, ODD	Ph II completed in US and Canada; IND approval obtained in China ^(d)				FDA, Health Canada, NMPA	Joint collaboration strategy
		PBC	 Global		Ph II completed in US				FDA	Joint collaboration strategy
HTD4010	Polypeptide drug	AH	 Global		Ph I completed in Australia				TGA	Ph II to be initiated in late 2024 or beyond
HTD1804	Undisclosed	Obesity	 Global						N/A	IND-enabling
HTD1805	Undisclosed	Metabolic disease	 Global						N/A	IND-enabling
HTD2802	Undisclosed	IBD	 Global						N/A	IND-enabling

 Core Product

Abbreviations: MASH: metabolic dysfunction-associated steatohepatitis formerly known as nonalcoholic steatohepatitis or NASH; T2DM: type 2 diabetes mellitus; SHTG: severe hyperriglyceridemia; PSC: primary sclerosing cholangitis; PBC: primary biliary cholangitis; AH: alcoholic hepatitis; IBD: inflammatory bowel disease; FTD: Fast Track Designation; ODD: Orphan Drug Designation; Ph: Phase.

Notes:

1. Researched and developed in-house. We have granted Hepalink an exclusive, sublicensable (solely to Hepalink's designated wholly-owned subsidiaries), non-transferable license for the commercialization of HTD1801 for MASH and PSC in Europe. The Company reserved the rights to (i) research, develop and manufacturing HTD1801 globally; (ii) commercialize HTD1801 for any indications outside Europe; (iii) commercialize HTD1801 in Europe for any indications other than MASH and PSC; and (iv) import and export HTD1801. For details, see "Business — Collaboration Agreement — HTD1801 License-Out Agreement" and "Connected Transaction".
2. In November 2023, we initiated the two Phase III clinical trials (i.e. one with HTD1801 as a standalone treatment and one with HTD1801 as an add-on therapy with metformin) for the T2DM indication of our self-developed HTD1801 in China. We expect to complete those two Phase III studies in 2025. For details, see "Business — Clinical Stage Candidate — Core Product HTD1801 — Summary of Clinical Trials of HTD1801".
3. We have completed a Phase Ib/IIa trial for hypercholesterolemia in Australia and a Phase IIa trial for MASH in the United States. Based on FDA's written responses to the pre-IND meeting, the FDA concluded that the available preclinical and clinical data of the above trials was adequate to support the initiation of Phase II trial for SHTG.
4. We have obtained the IND approval from the NMPA to conduct the China part in the Phase II MRCT of PSC. However, due to COVID-19 pandemic, we did not initiate the China part of the Phase II clinical trial. After the completion of Phase II trials in the United States and Canada, the China part of the Phase II trial is not required because the Phase II trials had met the endpoints in the United States and Canada.
5. Competent authority in respective jurisdictions: US — FDA; Mainland China — NMPA; Canada — Health Canada; Australia — TGA; Hong Kong — The Department of Health; Mexico — The Federal Commission for Protection against Sanitary Risks.

BUSINESS

We have developed a strong patent portfolio, which forms an effective entry barrier against competition. As of the Latest Practicable Date, we held 132 patents and patent applications, which provide us with protection in all of our major markets, including the United States, China and Europe.

We are an integrated company with operations in the United States, Mainland China, Hong Kong and Australia. Our global presence, experience and knowledge allow us to conduct high-quality multi-center clinical trials with sites in the United States, China, Canada, and Australia in a cost-effective and time-efficient manner. With our accumulated extensive successful experience in building and developing a broad pipeline of innovative therapies for metabolic and digestive diseases, we expect to provide the market with a steady roll-out of competitive products that aim to address unmet clinical needs in complex metabolic and digestive diseases.

STRENGTHS

Develop novel multifunctional, multi-target therapies for metabolic and digestive diseases to treat the patients as a whole

We are a biopharmaceutical company focused on the discovery, development and commercialization of multifunctional and multi-target therapies for the treatment of metabolic and digestive diseases. Metabolic and digestive diseases' pathogenesis and progress are commonly impacted by multiple factors through a complex network of interactions, associated with various comorbidities. The prevalence of these diseases has increased significantly in recent years due to changing lifestyles, rising obesity rates and aging populations. The high prevalence and the complicated disease management lead to significant unmet medical need and great market potential. According to CIC, the prevalence of major metabolic and digestive diseases was 4.9 billion as of the end of 2022 and is expected to reach 5.7 billion as of the end of 2032, with a market size of US\$330 billion in 2022 to US\$687 billion in 2032 at a CAGR of 7.6%.

Treat the patient as a whole. One important feature of metabolic and digestive disease which gives rise to significant unmet medical needs is the co-existence of highly interrelated morbidities in patients. Current treatments of single-target drugs or their combinations do not fully address the complications of the interrelated comorbidities. We believe that the next-generation therapeutics for metabolic and digestive diseases should strive to treat the patients as a whole to provide comprehensive clinical benefits. Our goal is to offer multifunctional and multi-target therapies that treat complex metabolic and digestive diseases with a systemic approach, providing effective and safe options to improve overall clinical benefits to patients.

A drug discovery approach potentially facilitates higher probability of success in disruptive innovation. Achieving good balances of efficacy and safety is the major challenge in developing multifunctional and multi-target therapies. The successful development of HTD1801 enabled us to establish the FUSIONTX™ drug discovery approach for the design of multifunctional and multi-target drug candidates. Through FUSIONTX™, we integrate real-world clinical data, network pharmacology, known and established molecules with desired therapeutic benefits and known safety profiles to design novel, multifunctional drug candidates to treat complex diseases with a systemic approach. Drug discovery and design through this approach enables systematic, precise, and efficient early-stage drug development that potentially facilitates a higher rate of clinical success at an accelerated pace and lowers development risks, fueling our

BUSINESS

sustained pipeline expansion. We believe our approach in creating multifunctional drug candidates is paradigm-shifting and could lead to disruptive discovery and development of next-generation therapies in many diseases.

Global development strategies. With solid global IP protection, we implement global development strategies for our drug candidates. Global regulatory and clinical plans are a strong focus in that we plan and execute clinical trials with a global perspective to ensure that trials are designed to meet the regulatory requirements of multiple jurisdictions. By harmonizing protocols, endpoints, and data collection to the extent possible across different regions, we optimize global regulatory submissions and approvals. Our exceptional regulatory capabilities are demonstrated by many successful interactions with regulatory agencies. The superiority and innovation of our assets have been recognized by regulatory agencies and international academic communities. HTD1801 has been granted the FTD by the FDA for MASH and PSC, respectively. FTD is granted by FDA for new drugs or biologics that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. In addition, we submit data from completed clinical studies to major scientific conferences with presentations at the Liver Meeting organized by the American Association for the Study of Liver Disease ("AASLD") and the International Liver Conference organized by the European Association for the Study of the Liver ("EASL"). Among abstracts presented, one was selected for inclusion in the "Best of The Liver Meeting 2021" program created by AASLD to highlight key scientific achievements presented in the annual conference. Further, key findings of studies have been published in prestigious peer-reviewed journals including Nature Communications and the American Journal of Gastroenterology.

HTD1801, a "pipeline-in-a-product," new molecular entity with the potential to become a therapy for MASH, T2DM and other metabolic and digestive diseases

Our Core Product HTD1801, a new molecular entity, is a gut-liver anti-inflammatory metabolic modulator which targets multiple pathways pivotal to metabolic regulation, including those associated with metabolic and digestive diseases. We believe HTD1801 has the potential to be a therapy for multiple metabolic and digestive diseases based on its safety and efficacy profile as well as ease of administration.

1+1 >2. HTD1801 is a salt formed from two active moieties, BBR and UDCA. The two active moieties work in tandem in the salt form with unique microstructure to produce distinct and improved properties of HTD1801. HTD1801 has different physico-chemical characteristics compared to each of the BBR and UDCA active moieties or their physical mixture, including distinct X-ray powder diffraction, melting point, infrared spectrum, solubility or dissolution and LogD. Further, HTD1801 exhibits good pharmacokinetics ("PK"), efficacy and safety profiles, which are believed to owe to the unique interaction of BBR:UDCA in the ionized salt form. Those improved properties are not observed with either of the individual active moieties or their physical mixture. Given these unique attributes of HTD1801, the FDA has recognized HTD1801 as distinctive from its individual constituent components or their physical mixture with therapeutic potential across multiple indications.

BUSINESS

“Pipeline-in-a-product” with significant potential. HTD1801 has demonstrated good safety and efficacy in clinical trials across MASH, T2DM, SHTG, PSC and PBC, yielding therapeutic benefits in patients across multiple indications. We believe the demonstrated good safety and efficacy strongly supports the “pipeline-in-a-product” potential of HTD1801 for additional metabolic and digestive diseases with suboptimal or no approved therapies. Development costs can be allocated more efficiently, creating discrete commercial opportunities without additional discovery, preclinical, CMC development and early clinical development.

For MASH, we have completed a randomized, double-blind Phase I study of HTD1801 in healthy subjects in Australia and a randomized, double-blind, placebo-controlled Phase IIa study of HTD1801 in patients with MASH and T2DM in the United States. The Phase IIa study met the primary endpoint, which showed that HTD1801 resulted in statistically significant, meaningful improvements in liver fat content, as assessed by MRI-PDFF, compared to a placebo. MRI-PDFF is commonly used to assess treatment response in early-phase, proof-of-concept clinical studies in MASH and has been shown to be closely correlated with liver steatosis grades from histology. The beneficial effect of HTD1801 on liver fat was accompanied by additional improvements in liver health including liver biochemistry (ALT, AST, GGT), and non-invasive markers of fibrosis and inflammation (cT1 and FIB-4). Treatment with HTD1801 also resulted in weight loss and improvements in LDL cholesterol and triglycerides, both of which are independent risk factors for cardiovascular disease. A positive effect of HTD1801 on glucose metabolism was also evident based on meaningful reductions in fasting glucose and HbA1c. Effects were even more pronounced in a subgroup of patients with insulin resistance (hyperinsulinemia). HTD1801 has been granted a FTD for the treatment of MASH, which allows us to communicate with the FDA more frequently and gives us a competitive advantage in the regulatory approval process. We are currently conducting a Phase IIb study of HTD1801 for the treatment of MASH with T2DM or pre-diabetes. The study has initiated in the United States and Hong Kong and we plan to initiate additional study sites in Mexico and Mainland China in December 2023.

For T2DM, our completed Phase Ib and Phase II clinical trials in China have demonstrated a strong therapeutic effect in improving glucose metabolism, including statistically significant decreases in HbA1c and fasting glucose levels, which may be the result of decreased insulin resistance based on observed reductions in HOMA-IR with HTD1801. In the clinical trials, improvements in other disease-relevant parameters were also observed. With HTD1801 treatment, liver biomarkers (ALT, AST, GGT) were reduced despite being within the normal range at baseline, on average. HTD1801 also led to improvement of lipid profiles, such as reduction of LDL-c and non-HDL-c levels. Collective results from our Phase Ib T2DM trial, Phase II T2DM trial and Phase IIa MASH and T2DM trial suggest that HTD1801 has broad efficacy on glucose homeostasis, other cardiometabolic markers and liver health, supporting a differentiated profile compared to other anti-diabetic agents. We initiated Phase III registrational trials of HTD1801 for the treatment of T2DM in China in November 2023. Based on the comprehensive benefits observed for HTD1801 treatment, coupled with its safety profile and ease of administration, we believe that HTD1801 has the potential to become a therapy for T2DM patients who also suffer from metabolic comorbidities such as metabolic dysfunction-associated steatotic liver disease (“MASLD”, formerly known as nonalcoholic fatty liver disease or NAFLD), and dyslipidemia.

BUSINESS

For SHTG, preclinical studies demonstrated that HTD1801 could improve lipids in hamster models of dyslipidemia and MASLD. In addition, in a pooled analysis of clinical studies of MASH and hypercholesterolemia, focusing on subjects with baseline TGs above 200 mg/dL (hypertriglyceridemia), treatment with HTD1801 was associated with clinically meaningful reductions in TG levels. The effect on TG levels in the HTG population was paralleled by improvement of key cardiometabolic parameters including a decrease in LDL-C, an increase in HDL-C, improved glucose levels and marked weight loss. Efficacy beyond TG lowering differentiates HTD1801 from currently approved therapies. While the existing therapies for SHTG offer a benefit in treating high TGs, they offer limited benefits in the treatment of the constellation of metabolic issues in orbit around or underlying the TG levels (e.g. T2DM, MASH, obesity). This clinical evidence supports the therapeutic potential of HTD1801 in SHTG. We have completed Phase I clinical trial in healthy subjects in Australia and plan to initiate a Phase II clinical trial of HTD1801 for the treatment of SHTG in the United States in first half of 2024.

For PSC, HTD1801 provides a unique and comprehensive treatment of the gut-liver-biliary system, acting through multiple mechanisms to address the complex pathogenesis of PSC, including a choleric effect achieved by displacing toxic bile acids from the bile acid pool and a variety of anti-inflammatory effects. In addition, HTD1801 treatment has demonstrated positive changes in the gut microbiome, an important contributor to the pathogenesis of PSC. A Phase II clinical trial of HTD1801 for PSC in the United States and Canada met its primary endpoint, with the HTD1801 treatment group demonstrating a statistically significant reduction in serum alkaline phosphatase, a key biomarker indicating the presence of cholestatic liver disease, compared to the placebo group. HTD1801 treatment was also associated with improvements in markers of liver injury and inflammation. In addition to its efficacy profile, HTD1801 demonstrated a good safety profile in this patient population including liver-related safety. HTD1801 has been granted FTD and ODD from FDA for the treatment of PSC, which allows for expedited regulatory review.

A completed Phase II open-label study in the United States demonstrated proof of concept of HTD1801 for the treatment of PBC patients with an incomplete response to UDCA treatment. Upon transition from UDCA to HTD1801, efficacy across multiple endpoints was observed with HTD1801 therapy, including a reduction in ALP and GGT, markers of cholestatic injury, as well as a reduction in total bilirubin levels, indicative of improved liver function. Markers of inflammation and blood lipids generally improved with HTD1801. Our Phase II clinical results suggest that additional benefits are obtained with HTD1801 monotherapy over UDCA alone, potentially in part driven by the BBR moiety of HTD1801 and the improved physicochemical characteristics of HTD1801. In addition to the efficacy profile, HTD1801 demonstrated a good safety profile in this patient population including liver-related safety. In particular, pruritus, a common symptom of PBC, showed improvement with HTD1801 treatment.

Late stage global commercial potential. As of the Latest Practicable Date, 13 clinical trials for HTD1801 have been initiated or completed with more than 500 subjects enrolled in the aggregate, and the efficacy and safety have been well evidenced in different populations in these trials. As described above, HTD1801 has entered the late development stage for various indications with a good expectation of success. According to the current development progress and timeline, we expect to submit the first NDA for HTD1801 for T2DM in 2025 in China.

BUSINESS

Pipeline of new molecular entities with therapeutic profile to address unmet needs in metabolic and digestive diseases

Leveraging the patient-centric strategy, we have developed a pipeline of multifunctional, multi-target therapeutics to treat metabolic and digestive diseases with unmet medical needs. In addition to HTD1801, our pipeline comprises clinical and preclinical assets to address a wide range of indications, including AH, obesity, IBD and other metabolism disorders.

Our HTD4010 is a Phase I clinical-stage, polypeptide drug for the treatment of complex, life-threatening diseases such as AH, which is caused by chronic heavy alcohol abuse or a sudden, drastic increase in alcohol consumption. It is characterized by severe inflammation and, ultimately, liver failure and death. There is currently no approved treatment for AH and only a few drug candidates are in clinical development. The current standard of care focuses on symptom management, including abstinence, treating inflammation and providing nutrition. Our HTD4010, however, has the potential to address the underlying disease mechanism. In animal studies, for example, HTD4010 demonstrated potent beneficial effects for AH, alleviating characteristic signs of severe liver injury and reducing systemic inflammation. Our completed Phase I clinical trial of HTD4010 in healthy subjects demonstrated its favorable safety profile.

Our HTD1804 is a preclinical-stage, small molecule multifunctional therapy for the treatment of obesity, a growing global health risk associated with a wide range of comorbidities, most notably CVDs and T2DM. Preclinical studies have shown that HTD1804 may be an important modulator of energy metabolism to provide cardiovascular protection, and can effectively reduce the body weight of animals with obesity as well as lipid- and glucose-lowering effects. HTD1805, another drug candidate in our pipeline, is a multifunctional small molecule drug for the treatment of metabolic diseases. Our HTD2802 is a preclinical-stage, multifunctional drug for the treatment of IBD, a common GI tract disorder. The existing IBD drugs fail to adequately control the symptoms and complications in many patients. In preclinical studies, HTD2802 has shown positive effects on improving stool formation, relieving abnormal weight loss and reducing the occurrence of fecal occult blood, as well as reducing inflammatory cytokine levels and preventing pathological injury.

Commercial opportunity in metabolic and digestive diseases for HTD1801 and our pipeline of other highly differentiated therapeutic candidates

There has been an increasing industry focus on metabolic and digestive diseases in recent years, which has driven our continued investment in the development of new and more effective treatments for the following indications: MASH, T2DM, SHTG, PSC and PBC. Notably, demographic trends support continued market growth. With our innovative pipeline, we believe that we are well positioned to address these growing therapeutic areas which represent unmet medical need.

MASH is a growing health issue, particularly in developed countries, due to the rising rates of obesity and metabolic syndrome. As of the end of 2022, the prevalence of MASH reached 40.4 million, 20.7 million and 35.0 million in China, the United States and Europe, respectively, according to CIC. There are currently no approved therapies for the treatment of MASH. While lifestyle modifications and management of underlying conditions can help slow or stop the progression of MASH, there are currently no approved pharmacologic therapies that

BUSINESS

comprehensively ameliorate the full spectrum of MASH, from inflammation and liver cell damage to fibrosis and cirrhosis. Effects on cardiometabolic parameters such as lipid metabolism, glycemic control, and body weight are also important considerations given the prevalence of such comorbidities in patients with MASH. Given the pathogenetic complexity and heterogeneity of the disease, there is growing interest in developing therapies that target multiple pathways involved in the development and progression of MASH.

T2DM is one of the most common metabolic disorders worldwide. According to CIC, China has the largest number of T2DM patients, with approximately 123.2 million patients in 2022, which is expected to increase to 141.8 million by 2032. T2DM and MASLD are closely interrelated metabolic diseases. A key function of the liver is the storage and management of energy (e.g., sugars and lipids) in the body. As such, a dysregulation in energy management or sensitivity (e.g., insulin resistance in T2DM) may have a substantial impact in that function. T2DM aggravates MASLD and results in a higher risk of disease progression and outcomes including MASH, cirrhosis and hepatocellular carcinoma. Similarly, MASLD compounds the severity of T2DM and correlates with an increase in comorbidities such as cardiovascular disease and liver-related outcomes. The worldwide prevalence of MASLD among people with T2DM is 55.5% and in China the prevalence of T2DM with MASLD was 64.1 million as of the end of 2022. The goal in treating these patients is to halt or reverse the progression of T2DM and MASLD thereby reducing the risk of clinical outcomes associated with advanced disease. Therefore, an ideal therapy for patients with T2DM and MASLD should provide comprehensive benefits across a wide variety of parameters which encapsulate the spectrum of these diseases.

SHTG is the presence of high levels of triglycerides. The diagnosis of hypertriglyceridemia ("**HTG**") is defined by the presence of serum triglycerides ("**TGs**") greater than 150 mg/dL with SHTG being defined by TGs greater than or equal to 500 mg/dL. As of the end of 2022, the prevalence of SHTG reached 1,586.4 thousand, 339.8 thousand and 813.0 thousand in China, the United States and Europe, respectively, according to CIC. Nearly all patients with SHTG have a genetic predisposition plus an additional condition or factor known to raise serum TGs (e.g., diabetes mellitus, alcohol abuse, or oral estrogen therapy). Lifestyle changes and dietary modifications are the current standard treatment for patients with SHTG. The most commonly utilized classes of therapeutics utilized for treatment of SHTG include omega-3 fatty acids, fibrates, and statins, which have all demonstrated the ability to reduce TG levels. Unfortunately, while each of these classes of therapeutics offers benefit in the treatment of SHTG, each of them still leaves a large fraction of patients with an incomplete response to treatment or presents with additional risks or adverse reactions. Furthermore, while the existing therapies for SHTG offer a benefit in treating high TGs, they offer limited benefit in the treatment of the constellation of metabolic issues in orbit around or underlying the TG levels (e.g., T2DM, MASLD/MASH, obesity). For example, fenofibrate and gemfibrozil may result in elevated LDL-c and are contraindicated for subjects with active liver disease (e.g., MASLD/MASH).

PSC is a rare, chronic cholestatic liver disease characterized by intrahepatic or extrahepatic bile duct injury, or both. As of the end of 2022, the prevalence of PSC reached 171.9 thousand, 48.4 thousand and 60.7 thousand in China, the United States and Europe, respectively, according to CIC. Despite the seriousness of the disease, there is no available therapy for patients with PSC, and standard of care consists of supportive therapies to manage symptoms and prevent complications. Given that the pathogenesis of PSC is complex and multifactorial, an effective treatment should target multiple underlying mechanisms that contribute to the development and progression of PSC.

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PBC is a chronic, slowly progressive autoimmune, cholestatic liver disease characterized by female predominance. As of the end of 2022, the prevalence of PBC reached 789.8 thousand, 135.4 thousand and 175.6 thousand in China, the United States and Europe, respectively, according to CIC. There are only two approved treatments for PBC to date, each with its own limitations. While UDCA is prescribed for patients with PBC as the current first-line therapy, up to 40% of PBC patients do not achieve an adequate response to UDCA as a monotherapy. In the United States and Europe, obeticholic acid (“**OCA**”) is approved as second-line therapy for the treatment of patients with PBC patients who have had an inadequate response to or are intolerant of UDCA. Approximately 40% of patients with PBC who are incomplete responders to UDCA alone also do not achieve a complete response with the addition of OCA. Further, OCA is contraindicated for patients with PBC who have compensated cirrhosis with evidence of portal hypertension or patients with decompensated cirrhosis. Tolerability concerns related to the use of OCA includes an exacerbation of pruritus — a common symptom of PBC.

R&D capabilities bolstered by visionary management team and world-renowned key opinion leaders with deep expertise in metabolic and digestive diseases

Our R&D team has strong expertise, deep understanding, and broad development experience in metabolic and digestive diseases. Our R&D team pioneered the identification of compounds designed to modulate multiple pathways underlying chronic diseases, providing a unique advantage in addressing the unmet clinical needs across complex pathologies. Our R&D team is led by a team of world-class scientists with years of drug development experience on average. As of the Latest Practicable Date, our R&D team consisted of 45 members including nine members holding PhDs and 22 members holding masters covering the fields of chemistry, biology, pharmacology and medicine. Our global clinical development team, in particular, is comprised of a team of industry veterans with extensive experience in the Company’s target therapeutic areas and a track record of conducting registrational clinical trials to achieve marketing approvals in major markets such as the United States and Europe. Some team members have experience leading successful programs at domestic or global biopharmaceutical companies.

Our management team is led by our founder, executive Director and chief executive officer, Dr. Liping Liu, a pioneer in the field of metabolic and digestive diseases with extensive industry experience across the drug development cycle and a track record of leading clinical development of highly innovative drugs internationally. Dr. Liu has over 20 years of drug development experience and has led eight IND approvals in the United States, China, Canada and Australia for two drugs. Dr. Liu is a prolific scientist with over 100 patents and patent applications to her credit. Dr. Liu previously served as the senior director of R&D of Stealth Peptide Inc., worked in the translational research department of the American Type Culture Collection and the group leader in chemistry department of MannKind Corporation.

Our chief development officer, Dr. Leigh Anne MacConell, has more than 20 years of global drug discovery and development experience in MASH, T2DM, PSC and PBC. She has participated in submission of a number of NDAs and INDs and has overseen more than 20 clinical trials worldwide. Dr. MacConell previously served as senior vice president at Intercept Pharmaceuticals and worked at Amylin Pharmaceuticals Inc.

BUSINESS

Our vice president of discovery research, Dr. Tianwei Ma, has over 20 years of experiences in drug discovery. Dr. Ma participated in the early discovery of Clevudine (Levovir), an anti-HBV agent that was later approved in Korea and several other Asian countries. During his professional career, Dr. Ma has led many discovery programs to achieve PCC or IND stages and he is listed as an inventor or co-inventor for approximately 30 granted patents or applications. Dr. Ma previously served as a director of chemistry at Eli Lilly & Company, vice president of drug discovery at PegBio Inc. (Suzhou) and vice president and head of chemistry at BioFront Therapeutics (Beijing).

Our deputy general manager, Ms. Meng Yu, has over 15 years of experience in business strategy management, corporate development and research and R&D operations management. Ms. Meng Yu worked at Asymchem Laboratories (Tianjin) Co., Ltd. (凱萊英醫藥集團(天津)股份有限公司), a pharmaceutical company listed on the Shenzhen Stock Exchange (stock code: 002821) and a scientific liaison manager of Huya Biological Medicine Technology (Shanghai) Co., Ltd. (滬亞生物醫藥技術(上海)有限公司).

Our chief financial officer, Mr. Koon Yin Edmund Sim, has over 18 years of experience in the financial sector in the United States and China. Mr. Sim holds a Bachelor of Business Degree from the Queensland University of Technology, a Master of Science in Financial Management from the University of London and a CPA qualification from Hong Kong. Mr. Sim previously served as vice president of Vitasky Research Holdings Co. Limited and held key positions at China Merchants Securities International Company Limited, Merrill Lynch (Asia Pacific) Limited, Goldman Sachs (Asia) L.L.C., Goldman Sachs Gao Hua Securities Company Limited and Citigroup Global Markets Asia Limited.

We engage a world-renowned expert team of clinical and regulatory advisors, including key opinion leaders in liver and metabolic disease, to advise our development strategies to maximize our probability of success. We have consistently been able to attract industry-leading experts and renowned KOLs to participate in our drug discovery and development projects, which speaks to the solid foundation of our research and development process and reflects the cutting-edge nature and clinical potential of our drug candidates. In addition to the world-renowned KOLs, we are also a leader in global drug development with deep expertise in navigating the drug approval process. Our multi-jurisdictional regulatory expertise is particularly strong in our key markets such as the United States and China. We have used this expertise to strategically form our drug development plan, making strategic decisions regarding the direction of our drug development focus to take full advantage of the local regulatory environment. Part of our clinical strategy is to focus on therapeutic indications that are interrelated (i.e., T2DM, MASH and SHTG) allowing the company to design clinical programs in a way that enables databases from multiple programs to be leveraged across indications and regions (i.e., United States and China), further streamlining development. We utilize consistent trial designs, statistical approaches, and bridging where possible, to allow clinical data from each regional trial to support registrations globally (i.e., the United States and China). Our exceptional regulatory capabilities are demonstrated thus far by many successful interactions with the FDA including two FTD for HTD1801 (for the treatment of MASH and PSC), and a successful end-of-Phase II meeting for PSC, among others.

BUSINESS

STRATEGIES

Rapidly advance our current pipeline of drug candidates through clinical development, and continue to expand indication coverage to maximize the therapeutic and economic value of our assets

Leveraging our in-house development and clinical capabilities, we intend to continue to advance our clinical programs to achieve rapid time-to-market and successful commercialization. We plan to advance our clinical assets through the clinical developments and shorten trial timelines with regulatory designations where appropriate. To maximize the global value of our pipeline, we have implemented, and plan to further expand, our clinical development approach internationally. We select the sites of our clinical trials primarily based on the experience and expertise of the principal investigators, the reputation of our partner institutions in the relevant fields, our multi-jurisdictional regulatory expertise and the enrollment projections. In particular, we have formulated the following plans with respect to our drug candidates.

- **HTD1801.** We will continue to advance the global development of Core Product HTD1801 for metabolic and digestive diseases. For the T2DM program, we have successfully completed our Phase II trial in China and we initiated two Phase III registrational trials in China in November 2023. For the MASH program, a Phase IIb study for the treatment of MASH with T2DM or pre-diabetes is currently ongoing. Sites have been initiated in the United States and Hong Kong with plans to initiate sites in Mexico and Mainland China in December 2023. For the SHTG program, we plan to initiate a Phase II clinical trial in the United States in first half of 2024. For the PSC program, we have completed the Phase II clinical trial in the United States and Canada and held a successful end of Phase II (EOP2) meeting with FDA and it has no objection for us to commence Phase III clinical trial.

In addition to HTD1801, we also plan to leverage our in-house R&D capabilities to advance our clinical-stage candidate HTD4010's development in treating AH and various preclinical programs, such as HTD1804, HTD1805 and HTD2802 into clinical development in the near future.

Leverage our drug discovery capabilities and team expertise to build an innovative pipeline based on the multi-mechanism approach

We will leverage our global leadership to optimize and enhance our FUSIONTX™ development approach. We will upgrade and optimize our discovery, design and development of potential drug candidates to maximize the potential of our novel development approach.

We will continue to build on our extensive R&D experience and strict adherence to clinical and manufacturing protocols to ensure the efficacy, safety and commercial viability of our innovative drug candidates. In particular, we will strictly adhere to our clinical protocols, and maintain high standards in manufacturing consistency and quality control.

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We will continue to focus on deepening our understanding of complex disease pathogenesis by leveraging internal and external expertise, to identify opportunities addressing unmet medical needs. From time to time, we actively evaluate collaboration opportunities globally, such as collaboration for artificial intelligence, to improve the probability of success for our discovery efforts.

Expanding our R&D team and capabilities

We are committed to expanding our R&D capabilities by continuing to identify potential new indications for our existing drug candidates and expand our pipeline into new therapeutic areas to address unmet medical needs. With respect to our development pipeline, our strategy is to continue to focus on innovative therapies for metabolic and digestive diseases and to advance them from preclinical research to clinical development, which we believe will support our long-term growth. We plan to deliver one to two preclinical candidates each year and aim to advance them into preclinical and clinical development.

To sustain our growth, we are also focused on building a global talent pool and enhancing our capabilities across research, clinical development and commercialization. We aim to grow our R&D team by actively recruiting talents with strong academic background and industry experience. We believe that an expanded high-quality R&D team will enable us to accelerate our drug discovery, development and commercialization processes. We also plan to partner with world-leading academic institutions to conduct research on diseases, targets and mechanisms of actions that may fit our pipeline expansion strategy.

Pursue strategic collaborations in drug development and commercialization in the global market

We currently outsource manufacturing activities of our drug candidates to CDMOs to enhance operational efficiency and cost control. We plan to continue to outsource our commercial-scale manufacturing to globally recognized CDMOs. We have implemented and will continue to implement stringent protocols to ensure that our CDMOs are in full compliance with our internal quality control polices and external regulatory requirements. We will select additional qualified CDMOs to ensure a sufficient supply of our drug candidates. Our selection of CDMOs is based on a number of factors, including qualifications, experience, expertise, manufacturing capacity, geographic proximity, reputation, track record and product quality, among others.

We will pursue the commercialization strategy of win-win cooperation for future assets to maximize the value of our drug candidates globally. We plan to partner with pharmaceutical companies who have strong commercialization capability and rich experience in the therapeutical fields we are focusing on, to utilize their well-established sales networks and other resources to achieve mutually beneficial results and maximize the commercial value of our drug candidates.

BUSINESS

Strategically seek partnerships to drive long-term growth

We intend to further expand our drug portfolio through a combination of internal discovery and external business development efforts. We will continue to focus our in-house discovery efforts on the development of novel metabolic and digestive diseases therapies. We will actively seek strategic collaborations to drive our growth, including in-licensing of external assets and out-licensing of our internally developed assets, based on strategic fit, such as disease indications, modalities at different stages of drug discovery and development.

We intend to acquire or license-in high potential products from global enablers, including biopharmaceutical companies and research institutions. A strong emphasis will continue to be placed on assets that could provide us with global development and commercialization rights, have potential combination synergies with our current pipeline and have first-in-class potential. As of the Latest Practicable Date, we had no specific plans nor any identified target for asset acquisition or license-in.

Partnerships have been and will continue to be an important source of innovation for our drug portfolio. We intend to continue to explore partnerships with multinational pharmaceutical companies through strategic collaborations including co-development arrangements. We intend to identify the most suitable and resourceful partners for collaboration to maximize the clinical and commercial value of our drug candidates. We believe that such collaborations will not only provide us with technical and regulatory support for the implementation of successful global clinical development plans, but also enable us to partially monetize the global market opportunities of our assets at an early stage.



















Continue to protect our global IP by employing various life-cycle management patent strategies including a new molecular entity (a “composition-of-matter” patent), the process used to manufacture the drug, the way the drug is used and new formulations of the drug to protect our assets and maintain the market exclusivity

We believe that strong IP protection is critical to our innovative assets. We have developed a portfolio of intellectual property rights to protect our technologies and products, which provides an effective barrier to entry. We have successfully obtained composition of matter patent for HTD1801 in many countries and regions, including the United States, China, the European Union and Japan, as well as crystalline form patent in the United States and China. We will continue to seek patent protection for other product candidates globally and file additional patent applications, when appropriate, to cover the crystalline form and method of use for our drug candidates.

OUR PRODUCT PIPELINE

As of the Latest Practicable Date, we have researched and developed in-house a pipeline with five proprietary drug candidates covering nine indications, including five indications that are at clinical stage. The following chart summarizes the development status of our drug candidates as of the Latest Practicable Date.

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Candidate	Mechanism/Target	Indication	Right	Designations	Pre-Clinical	Phase I	Phase II	Phase III	Competent or regulatory authorities	Upcoming Milestone
HTD1801 	Berberine ursodeoxycholate (BUDC)	MASH	 Global ^(b)	FTD	Ph I is completed in US; Ph I is initiated in US and Hong Kong and to be initiated in Mexico and Mainland China				FDA, NMPA, The Federal Commission for Protection against Sanitary Risks, Department of Health	Ph I in Mexico and Mainland China initiated in late 2023 and studies in all clinical sites expected to be completed in 2025
		T2DM	 Global		Ph II completed in Mainland China, Ph III initiated in Mainland China ^(c)				NMPA	Ph III to be completed in 2025
		SHTG	 Global		Ph II to be initiated in US ^(e)				FDA	Ph II to be initiated in 1H 2024
		PSC	 Global ^(b)	FTD, ODD	Ph II completed in US and Canada; IND approval obtained in China ^(d)				FDA, Health Canada, NMPA	Joint collaboration strategy
		PBC	 Global		Ph II completed in US				FDA	Joint collaboration strategy
HTD4010	Polypeptide drug	AH	 Global		Ph I completed in Australia				TGA	Ph II to be initiated in late 2024 or beyond
HTD1804	Undisclosed	Obesity	 Global						N/A	IND-enabling
HTD1805	Undisclosed	Metabolic disease	 Global						N/A	IND-enabling
HTD2802	Undisclosed	IBD	 Global						N/A	IND-enabling

 **Core Product**

Abbreviations: MASH: metabolic dysfunction-associated steatohepatitis formerly known as nonalcoholic steatohepatitis or NASH; T2DM: type 2 diabetes mellitus; SHTG: severe hyperriglyceridemia; PSC: primary sclerosing cholangitis; PBC: primary biliary cholangitis; AH: alcoholic hepatitis; IBD: inflammatory bowel disease; FTD: Fast Track Designation; ODD: Orphan Drug Designation; Ph: Phase.

Notes:

1. Researched and developed in-house. We have granted Hepalink an exclusive, sublicensable (solely to Hepalink's designated wholly-owned subsidiaries), non-transferable license for the commercialization of HTD1801 for MASH and PSC in Europe. The Company reserved the rights to (i) research, develop and manufacturing HTD1801 globally; (ii) commercialize HTD1801 for any indications outside Europe; (iii) commercialize HTD1801 in Europe for any indications other than MASH and PSC; and (iv) import and export HTD1801. For details, see "Business — Collaboration Agreement — HTD1801 License-Out Agreement" and "Connected Transaction".
2. In November 2023, we initiated the two Phase III clinical trials (i.e. one with HTD1801 as a standalone treatment and one with HTD1801 as an add-on therapy with metformin) for the T2DM indication of our self-developed HTD1801 in China. We expect to complete those two Phase III studies in 2025. For details, see "Business — Clinical Stage Candidate — Core Product HTD1801 — Summary of Clinical Trials of HTD1801".
3. We have completed a Phase Ib/IIa trial for hypercholesterolemia in Australia and a Phase IIa trial for MASH in the United States. Based on FDA's written responses to the pre-IND meeting, the FDA concluded that the available preclinical and clinical data of the above trials was adequate to support the initiation of Phase II trial for SHTG.
4. We have obtained the IND approval from the NMPA to conduct the China part in the Phase II MRCT of PSC. However, due to COVID-19 pandemic, we did not initiate the China part of the Phase II clinical trial. After the completion of Phase II trials in the United States and Canada, the China part of the Phase II trial is not required because the Phase II trials had met the endpoints in the United States and Canada.
5. Competent authority in respective jurisdictions: US — FDA; Mainland China — NMPA; Canada — Health Canada; Australia — TGA; Hong Kong — The Department of Health; Mexico — The Federal Commission for Protection against Sanitary Risks.

BUSINESS

CLINICAL-STAGE CANDIDATES

Core Product HTD1801

Overview

Our Core Product, HTD1801, a new molecular entity, is a gut-liver anti-inflammatory metabolic modulator which targets multiple pathways pivotal to metabolic regulation, including those associated with metabolic and digestive diseases. It is a pivotal-stage, self-developed, multifunctional, multi-target, “pipeline-in-a-product” drug candidate. It is being developed for multiple metabolic and digestive indications, including MASH, T2DM, SHTG, PSC and PBC. HTD1801 contains two active moieties derived from natural ingredients, BBR and UDCA, both with an established efficacy and long-term safety profiles in humans. We have obtained FTD for HTD1801 for PSC and MASH, which facilitates an expedited regulatory review process and, potentially, earlier drug approval, as well as ODD for PSC, from the FDA. Under the Orphan Drug Act, the FDA granted the ODD to HTD1801 for PSC on the condition that HTD1801 is intended to treat a rare disease of PSC affecting fewer than 200,000 individuals in the United States. For more details, please see “Regulatory Overview — Laws and Regulations in the United States and EU — Orphan Drugs.” According to CIC, HTD1801 is the first PSC drug candidate that obtained FTD from the FDA. HTD1801’s clinical trial data demonstrated its therapeutic potential in the treatment of MASH, T2DM and PSC with favorable safety profiles. As of the Latest Practicable Date, we held 58 patents and patent applications in relation to our Core Product, representing four types of patents that have been applied in different jurisdictions, including a new molecular entity (a “composition-of-matter” patent), the process used to manufacture the drug, the way the drug is used and new formulations of the drug to protect our assets. The reasons for applying these patents in various jurisdictions are to provide an extensive patent protections and maintain our Core Product’s exclusivity in these jurisdictions. We have successfully obtained composition of matter patent for HTD1801 in many countries and regions, including the United States, China, the European Union and Japan, as well as crystalline form patent in the United States and China.

Molecular Structure

HTD1801 is an ionic salt formed from BBR and UDCA, representing a new molecular entity that offers the possibility of multi-functional therapy for chronic metabolic and non-viral liver diseases in a single treatment. These moieties work in tandem in the salt form with unique microstructure to produce distinct and improved properties of HTD1801 that are not observed with either of the individual active moieties or their physical mixture. HTD1801 exhibits improved physico-chemical characteristics and PK, efficacy and safety profiles, which is believed to owe to the unique interaction of BBR:UDCA in the ionized salt form. Given these unique attributes of the HTD1801, the FDA has recognized that HTD1801 is distinct from its individual constituent components or their physical mixture and has therapeutic potential.

- BBR is an isoquinoline alkaloid with a long history of use for its wide-ranging biological effects, particularly antimicrobial effects, in Chinese, Indian and Japanese medicine and is an approved drug for the treatment of intestinal infection in mainland China, Japan and Taiwan, according to CIC. In the United States and Canada, BBR is also used in various dietary supplements.

BUSINESS

- UDCA is an endogenous, secondary bile acid approved by the FDA for the non-surgical treatment of cholesterol gallstones dissolution and PBC. Clinical practice demonstrated that UDCA (15-20 mg/day) improves serum liver tests and certain surrogate markers of prognosis in PBC. According to CIC, UDCA is known for its beneficial effects on the liver by displacing toxic bile acids and protecting against apoptosis, through wide-ranging immunomodulatory, anti-inflammatory, anti-fibrotic and antimicrobial actions. UDCA's efficacy in other liver diseases have also been extensively studied in nonclinical and clinical studies, both as a single agent and in combination therapy with agents such as vitamin E and lipid-lowering fibrate drugs.

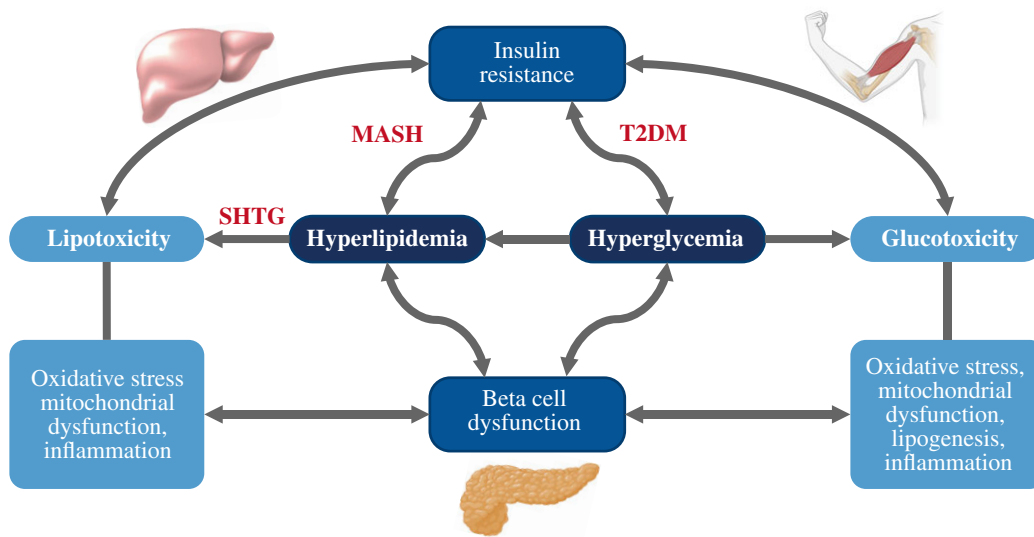
Mechanism of Action ("MOA")

MASH, T2DM and SHTG Are Interrelated Metabolic Diseases

MASH is liver inflammation and damage caused by a buildup of fat in the liver, T2DM is a disease in which blood glucose, or blood sugar, levels are too high, and SHTG is the presence of high levels of triglycerides, a type of fat, in the blood. MASH, T2DM and SHTG are interrelated metabolic diseases. In an insulin resistance state, more insulin is required to obtain the same metabolic effects, namely glucose uptake in the muscle, suppression of lipolysis and of hepatic glucose production. Insulin resistance is present in muscle, liver and adipose tissue in MASH. Therefore, hepatic glucose production and adipose tissue lipolysis are only in part suppressed by insulin, resulting in higher fasting glucose and free fatty acid concentrations, increasing the risk of HTG in these patients and predisposition to lipotoxicity. To overcome insulin resistance, the pancreas is stimulated to secrete more insulin, and the workload of pancreatic beta cells is increased, leading to beta-cell dysfunction and a reduction of beta-cell mass over time, thus a major risk factor for the development of hyperglycaemia and T2DM. In addition, glucotoxicity is defined as chronically elevated glucose concentrations causing glucose-induced insulin resistance, cellular dysfunction and a cycle of progressive metabolic deterioration. Glucotoxicity and lipotoxicity are closely interrelated and both contribute to worsening insulin resistance and impaired insulin secretion. Both lipotoxicity and glucotoxicity also contribute to oxidative stress, mitochondrial dysfunction, lipogenesis, inflammation, and finally to beta-cell dysfunction and vice versa. In MASH, lipotoxicity and insulin resistance have been recognized as pathophysiological mechanisms responsible of development and progression to a more severe form of this disease. T2DM is a chronic condition of glucotoxicity, although also lipotoxicity is often present and are responsible not only of insulin resistance but also of impaired insulin secretion.

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MASH, T2DM and SHTG Are Interrelated Metabolic Diseases

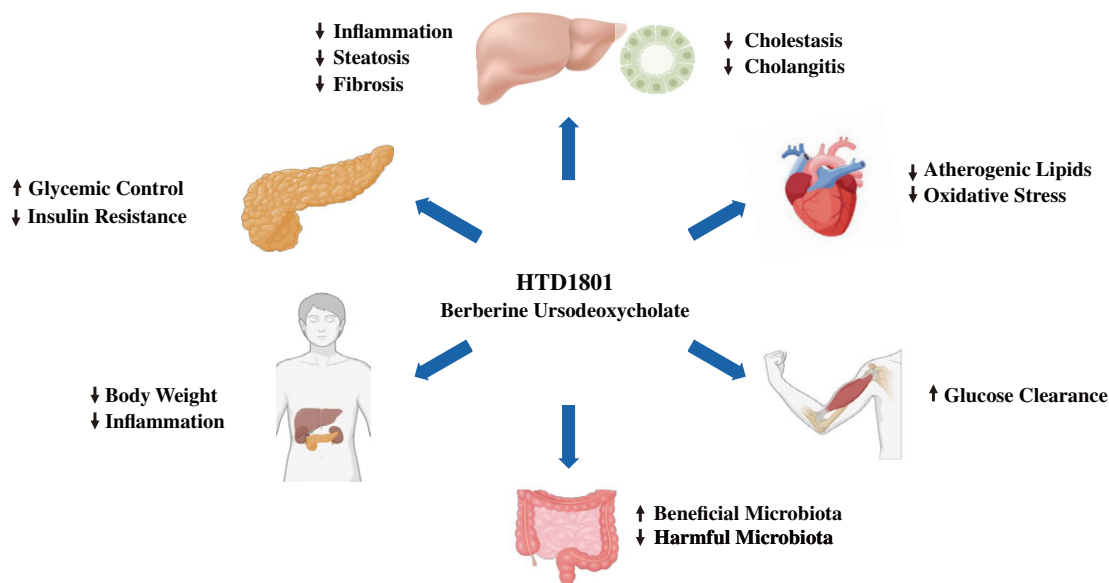


Source: Company Data, modified from Gastaldelli, A. Cusi K. JHEP Reports 2019, CIC analysis

MOA of HTD1801 for Metabolic Disease

The following diagram demonstrates mechanism of action of HTD1801 for metabolic disease:

HTD1801: A Gut-Liver Anti-inflammatory Metabolic Modulator (“GLAM”)



Source: Company Data

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MOA of HTD1801 for MASH

HTD1801 treats MASH through multiple pathways, which address the core aspects of the disease including induction of the insulin receptor, activation of AMP kinase, and induction of the LDL receptor. The BBR moiety induces the insulin receptor to improve insulin resistance, and also induces AMP kinase, thereby leading to stimulation of hepatic fatty acid oxidation, fatty acid oxidation and glucose uptake by skeletal muscle as well as inhibition of cholesterol and triglyceride synthesis and *de novo* lipogenesis. Finally, the BBR moiety induces the LDL receptor to lower circulating levels of LDL-C. BBR thus acts systemically but is also known to act locally within the gastrointestinal tract via modulation of the microbiome. Potential contributions of UDCA include anti-apoptotic effects, lowering serum tumor necrosis factor α concentrations, decreasing endoplasmic reticulum stress, and improving hepatic insulin sensitivity (*Naghbi Z, Rakhshandeh H, Jarahi L, Hosseini MR, Yousefi M. Evaluation of the effects of additional therapy with Berberis vulgaris oxymel in patients with refractory primary sclerosing cholangitis and primary biliary cholangitis: A quasi-experimental study. Avicenna J Phytomed, 2021; 11(2): 154-167.*). The UDCA moiety of HTD1801 is thought to act both systemically and with local gastrointestinal tract effect.

MOA of HTD1801 for T2DM

The rationale for the use of HTD1801 for the treatment of T2DM is consistent with that for the treatment of MASH, including induction of the insulin receptor, activation of AMP kinase, and induction of the LDL receptor. Specific to improved glucose metabolism, activation of the AMP kinase pathway by BBR inhibits gluconeogenesis, and increases insulin sensitivity. Moreover, results from published studies indicate that BBR promotes glycolysis, and inhibits the intestinal absorption of carbohydrates in the diet. Nonclinical and clinical data show that UDCA can ameliorate insulin resistance and promote insulin secretion. UDCA also exhibits clear anti-inflammatory and anti-oxidative stress effects and protects hepatocytes.

MOA of HTD1801 for SHTG

The rationale for use of HTD1801 for the treatment of SHTG is consistent with its use in MASH and T2DM. HTD1801 is thought to be effective in SHTG via activation of AMP kinase, and by improving systemic insulin resistance. Induction of the LDL receptor positively regulates lipoprotein metabolism. In addition, BBR via HTD1801 may reduce the degradation of the LDL receptor via inhibition of PCSK9 transcription. Furthermore, there have been examples of BBR treatment resulting in an increase in LDL receptor mRNA and protein. The combination of reducing the degradation of the LDL receptor along with the induction of LDL receptor expression would be expected to increase the clearance of proteins that bind the LDL receptor, resulting in a reduction in triglycerides. Other effects on cardiometabolic parameters such as glycemic control and body weight are important considerations, given the prevalence of such comorbidities in patients with SHTG.

MOA of HTD1801 for Digestive Disease

MOA of HTD1801 for PSC and PBC

HTD1801 is thought to be effective in cholestatic liver diseases, like PSC and PBC, through multiple mechanisms of action.

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The mechanisms of action of UDCA have been well studied in a variety of cholestatic liver diseases, including PBC and PSC. Some of the key actions of UDCA include its choleric effect (a cytoprotective effect probably achieved by displacing toxic bile acids from the bile acid pool) and a variety of anti-inflammatory effects. In addition, UDCA has been shown to mediate some positive changes in the gut microbiome, an important contributor to the pathogenesis of PSC. Patients with PBC have been also recently reported to have different gut microbiota relative to healthy volunteers with some strains being associated with worse outcomes. BBR is thought to act both locally within the gastrointestinal tract and biliary tree but also systemically. BBR has beneficial effects on the gut microbiome, which may lead to further benefits to both PSC and PBC patients. BBR has antimicrobial activity against a wide variety of microbes, including bacteria and yeast. In particular, BBR has activity against *Klebsiella pneumoniae*, a bacterium thought to be a pathobiont that is causally associated with development of PSC. BBR has anti-inflammatory activity as well as anti-fibrotic actions that are relevant mostly within the liver, where BBR has been shown to be concentrated. Plant-derived BBR has been shown to have beneficial effects in lowering ALP in patients with treatment-refractory PSC and PBC, and BBR has been shown to attenuate cholestatic liver and bile duct injury in multidrug resistance knockout mice, which is an animal model of cholestasis (Wang, Y., Xiang, D., Chen, W., Zhao, D., Gurley, E., Wang, X., Pu, G., Tai, Y., Zhang, Y., Chen, Z., Wu, J., Yan, J., Hylemon, P.B. and Zhou, H. (2020), *Berberine attenuates cholestatic liver and bile duct injury in Mdr2^{-/-} mice by maintaining bile acid homeostasis. The FASEB Journal, 34: 1-1. <https://doi.org/10.1096/fasebj.2020.34.s1.04758>*).

The following table sets forth the validation of BBR or UDCA in the digestive disease.

Validation of BBR

Drug name	Manufacturer	Pricing in USA	Pricing in China	Therapeutic areas	Clinical trials	2022 sales
Stoppa	Lion corporation	N/A	N/A	For the treatment of diarrhea accompanied by abdominal pain; diarrhea due to indigestion; food and water poisoning; diarrhea with vomiting; loose bowels; loose stool.	N/A	~10 million USD, mainly sold in Japan
Berberine	ChengDu JinHua	N/A	~15 CNY for 100mg*60 tablets	For the treatment of intestinal infections such as gastroenteritis and bacillary dysentery caused by sensitive pathogens.	N/A	~ 1.3 million USD, mainly sold in China
PHELLOBERIN	Nihon Generic	N/A	N/A	For the treatment of diarrhea by suppressing intestinal peristaltic movement, proliferation of intestinal bacteria and intestinal putrefaction/fermentation, and by convergence action.	N/A	~ 1 million USD, mainly sold in Japan
Berberine	ShenYang NO.1 Pharma	N/A	~10 CNY for 100mg*100 tablets	For the treatment of intestinal infection, such as gastroenteritis.	CTR20160712 CTR20200992	~ 1 million USD, mainly sold in China
Berberine	Reyoung Pharma	N/A	~10 CNY for 100mg*24 tablets	For the treatment of intestinal infections such as gastroenteritis	N/A	~ 1 million USD, mainly sold in China

About 200 other companies produce about 140 drugs containing BBR, with a total sales of about 6 million USD in 2022

Source: FDA; NMPA; Clinicaltrials.gov; CDE; Package insert; Drugs.com; China Insights Consultancy

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Validation of UDCA

Drug name	Manufacture	Pricing in USA	Pricing in China	Therapeutic areas	Clinical trials	2022 sales
Ursofalk	Dr. Falk Pharma	N/A	~115 CNY for 250mg*25 capsules	For the treatment of a condition where the bile ducts in the liver become damaged; leading to a build-up of bile. This may cause scarring of the liver. The liver should not be so damaged that it is not functioning properly. This condition is called primary biliary cirrhosis (PBC). – to dissolve gallstones caused by excess cholesterol in the gall bladder where the gallstones are not visible on a plain x-ray (gallstones that are visible will not dissolve) and not more than 15 mm in diameter. The gall bladder should still be working despite the gallstone(s). For liver disease associated with a condition called cystic fibrosis in children aged 6 to 18 years.	NCT01510860 NCT00285597 NCT00161083	~283 million USD, mainly sold in China and Europe
Udiliv	Abbott	N/A	N/A	For the treatment of liver-related disorders, such as cirrhosis and sclerosing cholangitis. It can also be used for treating hepatic diseases, such as Hepatitis A, B and C. Udiliv 300 side effects might include nausea, vomiting, diarrhoea, and jaundice.	PICTURE study, to evaluate the safety and efficacy of Udiliv	~99 million USD, mainly sold in India
Ursosan	Pro Med	N/A	N/A	For the treatment of liver diseases such as primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), and cystic fibrosis (CF)-related cholestasis.	NA	~53 million USD, mainly sold in Europe
Ursodeoxycholic Acid	WuHan PuYuan	N/A	~60 CNY for 250mg*24 tablets	For the treatment of cholesterol gallstones, the formation of cholestatic lipodystrophy, the prevention of drug-induced gallstones and the treatment of lipodystrophy (after ileectomy)	CTR20201099	~46 million USD, mainly sold in China
Deursil	ITC Farma	N/A	N/A	For dissolving cholesterol crystals and cholesterol stones in functional gallbladder, and as a pre-and post-treatment for destroying gallstones. For the treatment of chronic progressive liver disease (primary biliary cholangitis and sclerosing cholangitis) with bile stasis.	NA	~26 million USD, mainly sold in Europe

About 500 other companies produce about 600 drugs containing UDCA, with a total sales of about 830 million USD in 2022

Source: FDA; NMPA; Clinicaltrials.gov; CDE; Package insert; Drugs.com; China Insights Consultancy

Market Opportunity and Competition

MASH

MASH is a condition characterized by liver inflammation and damage caused by the buildup of fat in the liver. It is the more severe form of MASLD, an umbrella term for a range of liver conditions affecting people who drink little to no alcohol. If left untreated, MASH can cause scarring of the liver, potentially leading to permanent scarring (cirrhosis) and liver cancer. As of the end of 2022, the prevalence of MASH reached 40.4 million, 20.7 million and 35.0 million in China, the United States and Europe, respectively, according to CIC. Currently, the treatment of MASH is limited to lifestyle modifications and treatment of specific comorbidities. No evidence-based pharmacological therapy has been approved for MASH other than saroglitazar magnesium, which is approved in India but has not been accepted internationally. Given the disease’s pathogenetic complexity and heterogeneity, the treatment of MASH is trending toward a multifunctional therapeutic approach. There are five MASH drugs under Phase III clinical development globally and five MASH drugs under clinical development in China.

We may face uncertainties in clinical trial development for MASH. Intercept’s ocaliva, one of the most advanced MASH drugs in the pipeline, filed the second application for MASH but it was rejected by the FDA in June 2023. The FDA reviewers flagged increased risk of diabetes and liver injury from using the oral tablets, called obeticholic acid (“OCA”), for the treatment of MASH. The FDA concluded that benefits of ocaliva did not outweigh the risks in MASH patients with fibrosis based on current data. Intercept expressed that continuing a long-term outcomes study as requested by the FDA may not be economically feasible and has decided to discontinue all MASH-related investment, which has a negative impact on MASH market.

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In addition, we may also fail to develop the MASH indication, which is one of the major indications of HTD1801, as it progresses to the late-stage clinical trials. There exists probability of failure to achieve the primary and second efficacy endpoints in its late-stage clinical trials because HTD1801 is based on a new molecular entity, which is yet to be tested in large-scale clinical studies, thus facing higher clinical risks. Despite the fact that HTD1801 is different from ocaliva in many aspects, such as mechanism of actions, PK profiles and others as applicable, our development of HTD1801 may still be subject to development risks, including those faced by ocaliva in their development.

T2DM

According to CIC, China has the largest number of T2DM patients in the world with approximately 123.2 million in 2022, and this number is expected to increase to 141.8 million by 2032. Even though the diagnosed rate for T2DM is approximate 50% in 2022, the market size in T2DM treatment reached US\$7.9 billion in 2022 in China, indicating a large market potential with high unmet medical need, according to CIC. T2DM and MASLD are intricately and bi-directionally associated, where T2DM aggravates MASLD into more severe forms of liver disorders, such as MASH, cirrhosis and hepatocellular carcinoma, while the presence of MASLD increases the incidence and severity of T2DM and makes T2DM patients more susceptible to comorbidities such as CVDs. According to CIC, worldwide prevalence of MASLD among people with T2DM is 55.5% and the prevalence of T2DM with MASLD in China was 64.1 million as of the end of 2022. The therapeutic target in treating this patient population is to well control the progression of both T2DM and MASLD, and to control and improve the other CVD risk factors. Therefore, an ideal drug for T2DM and MASLD patients should lead to comprehensive benefits with high safety. To date, there is still clear unmet medical need in T2DM treatment, especially in the treatment of T2DM patients with MASLD. There are 10 T2DM with MASLD drugs under clinical development globally and two T2DM with MASLD drugs under clinical development in China.

SHTG

SHTG is the presence of high levels of triglycerides, a type of fat, in the blood. SHTG is well known to be associated with other complex and serious disorders such as acute pancreatitis and CVDs. As of the end of 2022, the prevalence of SHTG reached 1,586.4 thousand, 339.8 thousand and 813.0 thousand in China, the United States and Europe, respectively, according to CIC. Lifestyle changes and dietary modifications are the current standard treatment for patients with SHTG. Existing pharmacological interventions primarily include the use of fibrates, omega-3 fatty acids, statins and niacin, but these treatment options either have limited efficacy or are associated with safety concerns. Furthermore, while the existing therapies for SHTG offer a benefit in treating high TGs, they offer limited benefit in the treatment of the constellation of metabolic issues in orbit around or underlying the TG levels. It is clear that there remains a medical need for safe and effective therapies for the treatment of adult patients with SHTG, therapies that address not only TG levels but also comorbid conditions.

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PSC

PSC is a rare, chronic cholestatic liver disease characterized by intrahepatic and extrahepatic bile duct injury. Inflammation and fibrosis of the bile ducts lead to structural damage, impaired bile flow and progressive liver dysfunction. PSC has been identified by the European Association for the Study of the Liver as one of the largest unmet clinical needs in the category of liver disease. As of the end of 2022, the prevalence of PSC reached 171.9 thousand, 48.4 thousand and 60.7 thousand in China, the United States and Europe, respectively, according to CIC. Due to the diverse involvement of the liver, biliary tract and gastrointestinal tract in PSC, drugs targeting multiple pathways are needed to comprehensively treat the disease. There are two PSC drugs under Phase III clinical development in the United States and two PSC drugs under clinical development in China. Due to PSC's diversified involvement of the liver, biliary tract and GI tract, drugs that target multiple pathways are needed to comprehensively treat the disease. HTD1801 is precisely engineered to target the disease's complex pathogenic mechanisms through a multifunctional synergistic approach.

PBC

PBC is a rare and serious liver disease resulting from a slow, progressive destruction of the intra-hepatic small bile ducts. As of the end of 2022, the prevalence of PBC reached 789.8 thousand, 135.4 thousand and 175.6 thousand in China, the United States and Europe, respectively, according to CIC. There are two approved treatments for PBC to date, each with its own limitations. Treatment with UDCA is considered as first line therapy for PBC and can improve liver function tests and slow the progression of disease. However, up to 40% of patients with PBC have an inadequate response to UDCA alone. Obeticholic acid ("OCA"), a farnesoid x receptor agonist, is indicated for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Approximately 40% of patients with PBC who are incomplete responders to UDCA alone do not also do not achieve a complete response with the addition of OCA. Further, OCA is associated with worsened pruritus, a common symptom of PBC. Lastly, OCA is contraindicated for patients with PBC who have compensated cirrhosis with evidence of portal hypertension or patients with decompensated cirrhosis. Hence, there remains an unmet medical need in patients with PBC. To date, 10 drug candidates for PBC are under Phase II or Phase III clinical trial development in the United States and two drug candidates are under Phase III clinical trial development in China.

Competitive Advantages

We believe that HTD1801 has the following competitive advantages:

Combining innovation and absorbability for synergistic therapeutic effects: HTD1801 is an innovative molecular entity based on two moieties with efficacy and safety

In HTD1801, BBR and UDCA work in tandem in the salt form with unique microstructure to produce distinct and improved properties that makes it more superior than the combination of BBR and UDCA. HTD1801 exhibits unique physico-chemical properties which are distinct from the BBR alone, UDCA alone or their equimolar physical mixture. HTD1801's unique molecular structure can potentially translate into good efficacy with reduced safety concerns. With the new structure, HTD1801 demonstrates lower melting point and improved solubility and lipophilicity as

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compared with those of BBR and UDCA, suggesting that HTD1801 improves absorbability (the state or quality of being absorbable by an individual). The enhanced solubility and lipophilicity have been observed for HTD1801, and additionally the dissolution profiles of BBR and UDCA in HTD1801 exhibit a more "synchronized" pattern (i.e. peak dissolution for both BBR and UDCA moieties from HTD1801 occurring at the same time), which further points to a unique interaction of the moieties in HTD1801 and may further enhance the beneficial interactions (e.g. lipophilic ion pairing, micellar solubilization) because of the simultaneous availability of the moieties in solution.

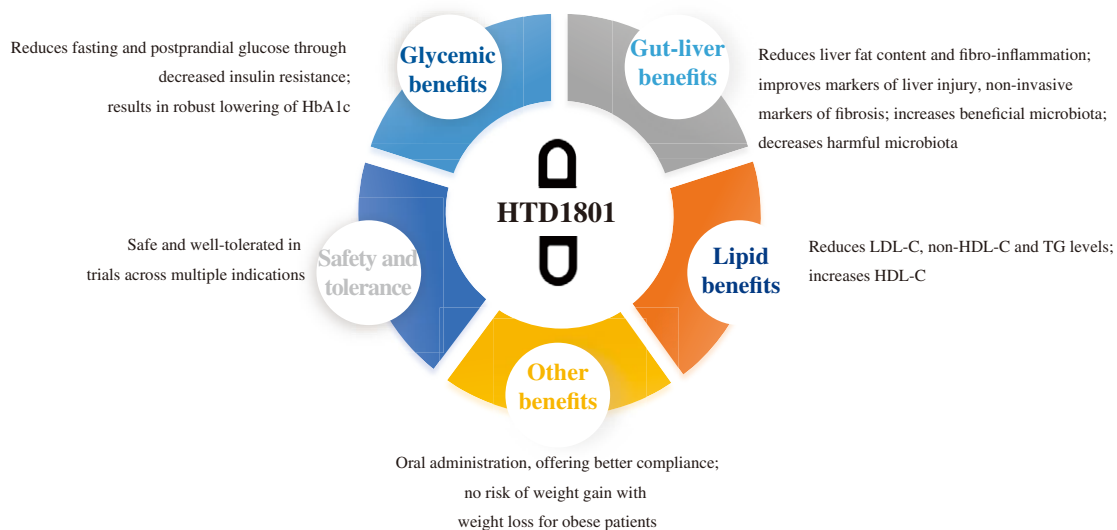
In addition, improved exposure of BBR and UDCA from the oral administration of HTD1801 has been observed in both systemic and enterohepatic circulation from preclinical studies. A PK test in golden hamster studies demonstrated a significant increase in BBR exposure in both plasma and liver in the HTD1801 group compared to BBR or physical mixture of BBR and UDCA at a 1:1 ratio. The results showed that the exposure of BBR in plasma and liver in the 100 mg/kg and 200 mg/kg groups increased approximately 2-fold and 6-fold, respectively, compared to equal molar of BBR-Cl alone. Thus, in our pre-clinical studies, HTD1801 significantly enhances the bioavailability of BBR, which is known for its low blood concentration and poor solubility in the body when administered alone. In addition, HTD1801 showed better synchronization of dissolution for BBR and UDCA. We believe that the release characteristic will facilitate the interaction between the two active components of HTD1801 and further promote synergistic effects and increase the potential for other beneficial interactions.

More importantly, the preclinical results also show synergistic therapeutic effects of HTD1801. In the golden hamster model of high fat diet-induced hyperlipidemia and MASLD, compared to BBR alone, UDCA alone and a physical mixture of BBR and UDCA at a 1:1 ratio, HTD1801 demonstrated efficacy in improvement of lipid profiles, reduction of liver fat content, reduction of liver enzymes and other biomarkers related to liver functions, and improvement of hepatic pathology. In the pre-clinical study, the golden hamster mice were fed with high-fat feed to create MASLD mouse model. The MASLD golden hamster mice were then divided into nine groups for six-week treatment: normal control group (treated with 0.5% CMC-Na, 10 mL/kg), model control group (treated with 0.5% CMC-Na, 10 mL/kg), HTD1801 low-dose group (treated with HTD1801 50 mg/kg), HTD1801 medium-dose group (treated with HTD1801 100 mg/kg), HTD1801 high-dose group (treated with HTD1801 200 mg/kg), UDCA low-dose group (treated with UDCA 53.9 mg/kg), UDCA high-dose group (treated with UDCA 107.8 mg/kg), BBR-Cl low dose group (treated with BBR-Cl 51.1 mg/kg), BBR-Cl high dose group (treated with BBR-Cl 102.2 mg/kg) and BBR and UDCA mixture group at a 1:1 ratio (treated with UDCA 53.9 mg/kg + BBR-Cl 51.1 mg/kg). The normal control group mice were treated normal feed, and other group mice were treated high-fat feed. The results showed that compared with the model control group, BBR alone, UDCA alone and PM, HTD1801 treatment showed a dose-dependent reduction for the indicators of serum total cholesterol and triglycerides, low-density lipoprotein cholesterol ("LDL-C"), alanine aminotransferase, aspartate aminotransferase, total bile acid and total bilirubin, liver weight, liver total cholesterol and triglycerides, MASLD activity score and fibrosis. Importantly, while BBR alone, UDCA alone and the PM showed some efficacy across most parameters, the HTD1801 200 mg/kg group showed the most significant improvement, where the indicators of LDL-C, alanine aminotransferase, aspartate aminotransferase, total bile acid and total bilirubin, liver weight and liver triglycerides were reduced to normal levels, suggesting the MASLD disease state was completely reversed.

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“Pipeline-in-a-product” with significant potential

HTD1801 has therapeutic benefits to patients through multiple mechanisms such as improvement of metabolism, protection of liver and bile, anti-inflammation and anti-oxidative stress. It is an oral therapeutic drug that can simultaneously lower blood sugar, protect liver and comprehensively improve cardiovascular risk factors with no risk of weight gain. HTD1801 has demonstrated good safety and efficacy in clinical trials across MASH, T2DM, hypercholesterolemia, PSC and PBC, yielding therapeutic benefits in patients across multiple indications. We believe the demonstrated good safety and efficacy strongly support the “pipeline-in-a-product” potential of HTD1801 for additional metabolic and digestive diseases with suboptimal or no approved therapies.



Source: Company Information

Positive progress of HTD1801 in multiple clinical programs: efficacy endpoints have been met in multiple studies globally across several indications with a good safety and tolerability profile

We have initiated 11 clinical studies of HTD1801 in the United States, China, Canada, and Australia, ten of which have been completed and one is currently on-going. In these studies, we cumulatively enrolled over 500 subjects. In completed clinical trials, HTD1801 demonstrates promising efficacy in reduction of liver fat content, improvement of both glucose and lipid metabolism, weight loss as well as improvement in markers of liver fibrosis and inflammation. For details of those clinical results, see “— summary of clinical trials of HTD1801” below in this section.

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Global development strategy in both the United States and China

HTD1801 has entered late stage development for various programs, with a solid expectation of success. In the United States, we have received FTD from the FDA for HTD1801 for the treatment of MASH, and for PSC, as well as the ODD for PSC. According to CIC, HTD1801 is the first PSC drug candidate to receive a FTD from the FDA. The FTD is based on available preclinical and clinical data that demonstrate the potential to address an unmet medical need and is intended to facilitate an expedited regulatory review process. In China, we received government support from “Major National Science and Technology Projects for New Drug Development” under the “National 13th Five-Year Plan”, which may further accelerate the domestic market approval for HTD1801. According to the current development progress and timeline, we expect to submit the first NDA for HTD1801 for T2DM in 2025 in China.

Summary of Clinical Trials of HTD1801

We have completed 10 clinical studies of HTD1801, including four Phase I studies in healthy subjects in Australia and China; a Phase Ib/IIa study in adults with hypercholesterolemia in Australia; a Phase IIa study in adults with MASH and T2DM in the United States; a Phase Ib and a Phase II study in Chinese subjects with T2DM; a Phase II study in subjects with PSC in the United States and Canada; and a Phase II study in subjects with PBC in the United States. One clinical study is ongoing, namely a Phase IIb study for the treatment of MASH with T2DM or prediabetes in the United States.

The following table sets forth an overview of the completed and ongoing clinical studies of HTD1801:

Study	Study Number	Phase	Study Design	Sites	Indications	Status	Actual Patient Enrollment	Trial Start Date	Trial (Expected) Completion Date
MASH study	HTD1801.PCT012	Ia	Randomized, double-blind, parallel-group, proof-of-concept, dose ranging study comparing multiple doses of HTD1801 to placebo	United States	MASH and T2DM ⁽¹⁾	Completed	100	November 2018	March 2020
	HTD1801.PCT014	Ib	Randomized, double-blind, placebo-controlled study to evaluate efficacy and safety	United States (initiated), Hong Kong (initiated), Mexico (to be initiated) and Mainland China (to be initiated)	MASH and T2DM or pre-diabetes ⁽¹⁾	Ongoing	Ongoing (152 subjects enrolled as of November 23, 2023)	December 2022	2025
T2DM study	HTD1801.PCT101	I ⁽²⁾	Randomized, double-blind, placebo-controlled, single ascending dose study to assess PK and safety	Mainland China	Healthy subjects	Completed	24	September 2021	November 2021

BUSINESS

Study	Study Number	Phase	Study Design	Sites	Indications	Status	Actual Patient	Trial (Expected)	
							Enrollment	Trial Start Date	Completion Date
	HTD1801.PCT104 ⁽³⁾	I	Randomized, open-label, three-way crossover study to evaluate the drug-drug interaction of HTD1801 with metformin	Mainland China	Healthy male subjects	Completed	33	November 2022	February 2023
	HTD1801.PCT102	Ib ⁽²⁾	Randomized, double-blind, placebo-controlled study to assess safety and tolerability, PK, and pharmacodynamics (“PD”)	Mainland China	T2DM	Completed	49	June 2022	September 2022
	HTD1801.PCT103	II	Randomized, double-blind, placebo-controlled study to evaluate efficacy and safety	Mainland China	T2DM	Completed	113	March 2022	January 2023
	HTD1801.PCT105	III	Randomized, double-blind, placebo-controlled, dose-ranging study to evaluate efficacy and safety of HTD1801 monotherapy		T2DM	Ongoing	Ongoing (Two subjects dosing as of November 21, 2023)	November 2023	2025
	HTD1801.PCT106	III	Randomized, double-blind, placebo-controlled, dose-ranging study to evaluate efficacy and safety of HTD1801 add-on therapy after metformin treatment		T2DM	Ongoing	Ongoing (Two subjects dosing as of November 21, 2023)	November 2023	2025
PSC study	HTD1801.PCT003	II	Randomized, double-blind, with concurrent placebo-control except in Period 2, proof-of-concept study investigating the efficacy and safety of HTD1801	United States and Canada	PSC	Completed	59	February 2018	August 2020

BUSINESS

Study	Study Number	Phase	Study Design	Sites	Indications	Status	Actual Patient	Trial (Expected)	
							Enrollment	Trial Start Date	Completion Date
PBC study	HTD1801.PCT013	II	Open-label, proof-of-concept study in subjects with primary biliary cholangitis with inadequate response to standard of care	United States	PBC	Completed	24	May 2021	May 2022
Hypercholesterolemia study	HTD1801.PCT004	Ib/IIa	Randomized, double-blind, placebo-controlled, multicenter, multiple ascending dose study to assess safety and tolerability, PK, and PD	Australia	hypercholesterolemia and overweight/obese	Completed	50	March 2018	December 2018
Healthy subjects . . .	HTD1801.PCT002 ⁽⁴⁾	I ⁽⁵⁾	Randomized, double-blind, placebo-controlled, single ascending dose study to assess PK, safety and tolerability	Australia	Healthy subjects	Completed	32	March 2017	October 2017
	HTD1801.PCT016	I ⁽⁶⁾	Randomized, open-label, single-dose, cross-over study to assess relative bioavailability of capsule vs tablet and food effect	United States	Healthy subjects	Completed	48	May 2022	July 2022

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Notes:

- (1) For example, the Phase IIa and Phase IIb trial (HTD1801.PCT012/014) IND approval of our Core Product as well as its FTD approval were granted for the treatment of MASH in general. Although we conducted Phase IIa and Phase IIb trials for the treatment of MASH with T2DM and MASH with T2DM or prediabetes, respectively, our planned pivotal Phase III clinical trial for our Core Product and its planned NDA are intended to enroll MASH patients with or without diabetes. However, the FDA may require us to conduct additional clinical trials on MASH in general in order to issue marketing authorization of HTD1801 for the treatment of MASH in general. See "Risk Factors — Risks Relating to Manufacturing and Commercialization of Our Drug Candidates — If the market opportunities for our drug candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer" in this document for more details.
- (2) There are two Phase I stage clinical trials for T2DM designed and conducted for different objectives. Such design can reduce clinical risks. The Phase I clinical trial treated healthy subjects to assess PK and safety, and the Phase Ib clinical trial treated T2DM patients to assess safety and tolerability, PK, and PD.
- (3) The purpose of this HTD1801.PCT104 study is to evaluate the drug-drug interaction of HTD1801 with metformin. In other clinical trials such as HTD1801.PCT101, HTD1801.PCT102 and HTD1801.PCT103, the investigated drug is only HTD1801 or corresponding placebo. We plan to conduct a Phase III clinical trial to evaluate the efficacy and safety of HTD1801 as add-on therapy with metformin treatment, and the results of HTD1801.PCT104 Phase I study result will offer necessary supporting information to initiate this planned Phase III clinical trial. It is a separate and standalone clinical trial program from the completed Phase II clinical trial for T2DM. HTD1801.PCT104 study is used to evaluate drug-drug interaction, PK and safety of HTD1801 as add-on therapy with metformin treatment in healthy subjects and the Phase II clinical trial is used to evaluate efficacy and safety of HTD1801 in T2DM patients. These two studies have different trial designs and primary endpoints.
- (4) The PK, safety and tolerability results in healthy subjects from HTD1801.PCT002 Phase I clinical trial in Australia provide safety profile of HTD1801 for approval of Phase II studies for several indications in the United States, including MASH, SHTG, PSC and PBC. For more information, please see "— Material Communications with Competent Authorities."
- (5) HTD1801.PCT002 was a Phase I, randomized, double-blind, placebo-controlled, single ascending dose study to assess the PK and safety of HTD1801 in healthy volunteers. 24 subjects (six per one dose group) received a single oral dose of HTD1801 500 mg, 1000 mg, 2000 mg or 4000 mg; and eight subjects were randomized to placebo. Following a single oral dose of HTD1801 of 500 to 4000 mg, dose proportionality was observed for BBR AUC and UDCA C_{max} and AUC. However, BBR C_{max} increased in a less than dose proportional manner but was linear within the range of 1000 to 4000 mg. HTD1801 was found to be safe and well tolerated at all doses tested.
- (6) HTD1801.PCT016 was a Phase I, randomized, open-label, single dose, cross-over study to assess relative bioavailability of HTD1801 capsule vs. tablet and food effects in healthy volunteers. The capsules are the clinical formulation for currently ongoing and planned studies and have improved stability relative to the tablets previously utilized. After administration of the HTD1801 capsule formulation under fasting conditions, the mean peak (C_{max}) and total (AUC_{last} and AUC_{inf}) plasma exposures of BBR, unconjugated UDCA and total UDCA (sum of UDCA and glycine-UDCA and taurine-UDCA) were overall comparable to the tablet formulation. As a result, no dose adjustments are recommended based on the utilization of the capsules vs. tablets for future studies.

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All clinical trials showed improved efficacy results. The follow-up periods in the Phase II clinical trial for PBC, during which HTD1801 treatment was withdrawn, showed a worsening in liver biochemistry compared with baseline, also suggesting the efficacy of HTD1801. In addition, there has been no impact of severe and/or life threatening TEAEs on the clinical development of HTD1801. The following table sets forth an overview of results of key clinical studies of HTD1801:

Study	Study Number (Study Phase/Type)	Study Design	Intent-to-Treat Population	Key Entry Criteria	Number of Subjects Enrolled	HTD1801 Dose(s)	Treatment Duration	Follow-up Period	TEAE Reported by Respective Clinical Trials (Mild/Moderate/Severe/Life Threatening)	Frequently Occurring TEAE (Number of Subjects)	Reasons for Discontinuation ⁽¹⁾	Key Efficacy Results (Change from Baseline to End of Treatment: Placebo vs 1,000 mg BID)
MASH study	HTD1801.PCT012 (Phase IIa)	Randomized, double-blind, parallel-group, proof-of-concept, dose ranging study to evaluate efficacy and safety	MASH and T2DM	<ul style="list-style-type: none"> Diagnosis of MASH with LFC ≥ 10% T2DM BMI > 25 kg/m² 	100 Total (67 active/33 placebo)	500 mg BID 1,000 mg BID Tablet	18 weeks	30 days	Placebo: 8/11/1/0 500 mg BID: 11/9/1/0 1,000 mg BID: 1,000 mg	Occurring in five or more subjects (Placebo/500 mg BID/1,000 mg BID): Diarrhea: 3/6/11 Nausea: 3/4/7 Headache: 2/1/3 URT: 4/1/1 Abdominal Pain Upper: 2/2/1	Placebo: one subject due to adverse event 500 mg BID: one subject due to AE, two subjects lost follow up, one subject due to protocol violation, one subject due to personal reason 1,000 mg BID: four subjects due to AE, two subjects lost follow up, one subject withdrew consent	LFC (absolute) (%): -1.9 vs -4.8 cTI (ms): -14.7 vs -60.9 HbA1c (%): 0.1 vs -0.6 ALT (U/L): -3 vs -19 Weight (kg): -1.1 vs -3.5
MASH study	HTD1801.PCT014 (Phase IIb)	Randomized, double-blind, placebo-controlled study to evaluate efficacy and safety	MASH and T2DM or pre-diabetes	<ul style="list-style-type: none"> biopsy-confirmed MASH and evidence of stage 2 or stage 3 liver fibrosis 	210 Total Planned (140 active/70 placebo)	1,250 mg BID Capsule	Up to 60 weeks	Four weeks	Ongoing with no interim data to analyze	Ongoing with no interim data to analyze	Ongoing with no interim data to analyze	Ongoing with no interim data to analyze

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Study	Study Number (Study Phase) Type	Study Design	Intent-to-Treat Population	Key Entry Criteria	Number of Subjects Enrolled	HTD1801 Dose(s) Formulation	Treatment Duration	Follow-up Period	TEAE Reported by Respective Clinical Trials (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Subjects)	Reasons for Discontinuation ⁽¹⁾	Key Efficacy Results (Change from Baseline to End of Treatment: Placebo vs 1,000 mg BID)
T2DM study	HTD1801.PCT103 (Phase II)	Randomized, double-blind, placebo-controlled study to evaluate efficacy and safety	T2DM	<ul style="list-style-type: none"> HbA1c $\geq 7.0\%$ and $\leq 10.5\%$ 	113 Total (75 active/38 placebo)	500 mg BID 1,000 mg BID Capsule	12 weeks	Four weeks	Placebo: 10/50/0 500 mg BID: 10/61/0 1,000 mg BID: 18/9/0/0	Occurring in five or more subjects (Placebo/500 mg BID/1,000 mg BID): Hypertinglyceridemia: 2/3/3 Sinus bradycardia: 1/2/3 Upper respiratory tract infection: 1/2/2	Placebo: one subject lost follow up 500 mg BID: one subject withdrew consent, and one subject due to PI decision	Week 12 Results HbA1c (%): -0.32 vs -1.04 Fasting glucose (mmol): 0.018 vs -1.023 ALT (U/L): -0.5 vs -6.9 AST (U/L): 0.6 vs -3.6 GGT (U/L): 2.9 vs -9.3 LDL-c (mmol/L): 0.077 vs -0.316 TC (mmol/L): 0.08 vs -0.43 non-HDL-c (mmol/L): -0.001 vs -0.452

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Study	Study Number (Study Phase: Type)	Study Design	Intent-to-Treat Population	Key Entry Criteria	Number of Subjects Enrolled	HTD1801 Dose(s) Formulation	Treatment Duration	Follow-up Period	TEAE Reported by Respective Clinical Trials (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Subjects)	Reasons for Discontinuation ⁽¹⁾	Key Efficacy Results (Change from Baseline to End of Treatment: Placebo vs 1,000 mg BID)
PSC study	HTD1801.PCT003 (Phase II)	Randomized, double-blind, with concurrent placebo-control except in Period 2, proof-of-concept study to evaluate efficacy and safety	Primary sclerosing cholangitis	<ul style="list-style-type: none"> Diagnosis of PSC ALP ≥1.5xULN 	55 Total	500 mg BID (n=22) 1,000 mg BID Tablet (n=31)	18 weeks	Four weeks	Placebo: 10/62/0 500 mg BID: 9/4/1/0 1,000 mg BID: 6/11/5/0	Occurring in five or more subjects (Placebo/500 mg BID/1,000 mg BID): Pruritus: 2/2/5 Diarrhea: 0/0/7 ALP Increase: 5/0/0 Nasopharyngitis: 2/0/3 Pyrexia: 1/2/2	Placebo: one subject due to AE, one subject withdrew consent 500 mg BID: one subject lost follow up, two subjects due to AE HTD1801 1,000 mg: three subjects due to AE	Week 6 Results ALP (U/L): 94 vs -73 ALP <1.5xULN (%): 5 vs 26 GGT (U/L): 256 vs -286 ALT (U/L): 40 vs -46

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Study	Study Number (Study Phase: Type)	Study Design	Intent-to-Treat Population	Key Entry Criteria	Number of Subjects Enrolled	HTD1801 Dose(s) Formulation	Treatment Duration	Follow-up Period	TEAE Reported by Respective Clinical Trials (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Subjects)	Reasons for Discontinuation ⁽¹⁾	Key Efficacy Results (Change from Baseline to End of Treatment: Placebo vs 1,000 mg BID)
PBC study	HTD1801.PCT013 (Phase II)	Open-label, proof-of-concept study to evaluate efficacy, PK, and safety	Primary biliary cholangitis	<ul style="list-style-type: none"> Diagnosis of PBC ALP ≥1.5XULN 	24 Total (24 active)	1,000 mg BID Tablet	12 weeks	Four weeks	1,000 mg BID; 14/81/0	Occurring in two or more subjects Diarrhea: 9 Abdominal distension: 4 Vomiting: 3 Abdominal Pain Upper: 2 Constipation: 2 Nausea: 2 Pyrexia: 2 Bronchitis: 2 URTI: 2 Liver Function Test Increased: 4 ALT Increased: 2 AST Increased: 2 Decreased Appetite: 2 Arthralgia: 2 Headache: 3 Oropharyngeal Pain: 2 Pruritus: 5	Two subjects due to AE	ALP (U/L): -30.2 ALP Reduction ≥20% (%): 35 Total Bilirubin (mg/dL): -0.1 GGT (U/L): -34.1 LDL-C (mg/dL): -17.0 Triglycerides (mg/dL): -10.7 IgM (mg/dL): -36.8

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Hypercholesterolemia study	HTD1801.PCT004 (Phase Ib/IIa: MAD)	Randomized, double-blind, placebo-controlled, multicenter, multiple ascending dose study to assess safety, tolerability, PK, and PD	Overweight and obese adult subjects with hypercholesterolemia	<ul style="list-style-type: none"> BMI >25 and $\geq 45 \text{ kg/m}^2$ LDL-c $\geq 2.59 \text{ mmol/L}$ 	50 Total (38 active / 12 placebo)	250 mg BID (n=12) 500 mg BID (n=12), 1,000 mg BID (n=4) (single dose only Day 1 and Day 28) Tablet	28 days	Two weeks	Placebo: 8/3/1/0 250 mg BID: 9/3/0/0 500 mg BID: 7/2/0/0 1,000 mg BID: 1/0/5/0/0	Occurring in two or more subjects (Placebo/250 mg BID/500 mg BID/1,000 mg BID): Headache: 5/5/4/3 Dizziness: 0/2/0/0 Nausea: 1/2/1/0 Flatulence: 2/0/0/0 Decreased Appetite: 0/0/3/0	500 mg BID: one subject withdrew consent 1,000 mg BID: one subject due to AE, one subject due to PI decision	Non-HDL Cholesterol (mmol/L): 10.8 vs -10.4 LDL-C (mmol/L): -1.7 vs -10.4 Triglycerides (mmol/L) 40.0 vs -1.6

Note:

(1) Such discontinuation had no material impact on the progress of the respective clinical trials.

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The following sets forth an overview of the key clinical studies of HTD1801:

MASH

HTD1801.PCT012: A Phase IIa study to evaluate the efficacy and safety of HTD1801 in adults with MASH and T2DM in the United States

Overview. This was a multicenter, randomized, double-blind, placebo-controlled, parallel-group, proof-of-concept, and dose ranging Phase IIa study. The primary endpoint of the study was absolute change from baseline to week 18 in liver fat content as assessed by magnetic resonance imaging-derived proton density fat fraction ("MRI-PDFF"). The primary endpoint of the MASH clinical programs was in line with other global clinical trials for the MASH indication. Despite the recent evolvement of the measurement of efficacy of MASH treatment after multiple rounds of discussions around ocaliva from Intercept which was declined for approval eventually by the FDA, it had no impact on the clinical development of HTD1801 because (i) our preliminary clinical results showed that HTD1801 had improvements on measures such as LDL, markers of glycemic control, and body weight with no signal for liver toxicity, and (ii) the primary endpoint of the MASH clinical programs of HTD1801 was in line with other global clinical trials for the MASH indication.

Trial design. A total of 100 subjects with MASH and T2DM were randomized 1:1:1 and received doses of HTD1801 (500 mg or 1,000 mg) or placebo, administered BID during an 18-week time frame. The trial enrolled 33 subjects in the HTD1801 500 mg BID treatment group, 34 subjects in the HTD1801 1,000 mg BID treatment group, and 33 subjects in the placebo group. The key inclusion criteria for the Phase IIa clinical trial included: (1) clinical diagnosis of MASH as assessed by magnetic resonance imaging; (2) clinically documented diagnosis of T2DM; and (3) body mass index >25 kg/m². The key exclusion criteria included: (1) liver disease unrelated to MASH; (2) poorly controlled T2DM or type 1 diabetes mellitus; (3) history of alcohol or substance abuse or dependence; (4) inability to undergo magnetic resonance imaging for any reason; or (5) history of significant cardiovascular disease. Overall, 88 subjects (87%) completed the study: 32 subjects (97%) in the placebo group and 56 subjects (82%) in the two HTD1801 treatment groups. Standard of care was continued during the study as a "real world" assessment of HTD1801. 32% of subjects continued to use GLP-1 or SGLT-2 medication, and 52% of subjects continued to use statins.

Trial status. The Phase IIa clinical trial of HTD1801 was initiated in November 2018 and was completed in March 2020 in the United States.

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Efficacy data. The following table summarizes the improvement of key efficacy parameters associated with HTD1801 1000 mg BID dose treatment and predicted impact on liver histology and comorbidities in MASH.

Parameter	Baseline	Reductions from Baseline	p-value ¹	Predicted Impact on Liver Histology and Comorbidities
Liver fat content	19.6%	-24.1% (37% ²) ⁴	0.011	Improvement in Fibrosis and NAS
MRI-cT1	942 ms	-61 ms (39% ³) ⁴	0.019	
ALT	62 U/L	-19 U/L (44% ⁵)	0.007	
FIB-4	1.28	-0.11	N/A	
LDL-C	107 mg/dL	-16 mg/dL	0.072	Improvement in T2DM/CV Risk
HbA1c	7.4%	-0.6%	0.005	
Weight	101.2 kg	-3.5 kg	0.012	
Triglycerides	174 mg/dL	-18%	0.120	

Abbreviation: cT1: corrected T1; NAS: NAFLD activity score

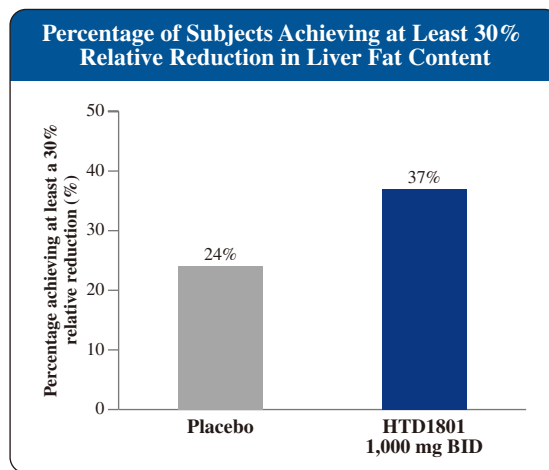
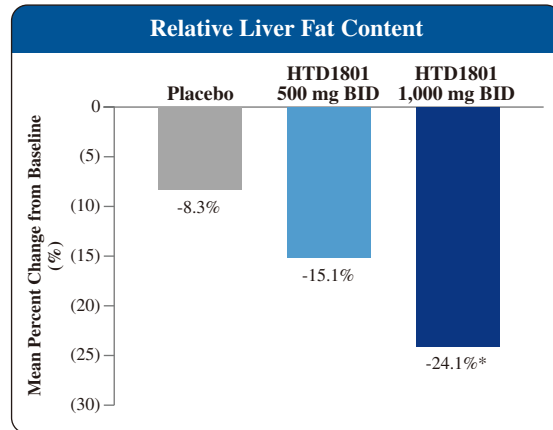
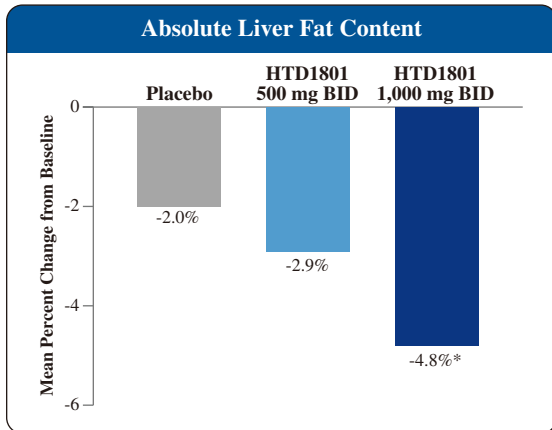
Notes: ¹ versus placebo, ² percentage achieving at least a 30% relative reduction, ³ percentage achieving at least a 80 ms reduction, ⁴ 22% of all patients randomized to HTD1801 treatment vs. 12% of all patients randomized to placebo achieved both the liver fat content and cT1 criteria, ⁵ percentage achieving at least a 17 U/L reduction

The P value is defined as the probability under the assumption of no effect or no difference (null hypothesis), of obtaining a result equal to or more extreme than what was actually observed. The P stands for probability and measures how likely it is that any observed difference between groups is due to chance. A P-value less than 0.05 indicates the pattern observed is statistically significant, while a value higher than 0.05 the null hypothesis is true, hence the pattern observed is not statistically significant. The higher the P value, the less likely that the data generated could have occurred under the null hypothesis.

Source: Company data

Treatment with HTD1801 in subjects with MASH and T2DM resulted in meaningful improvements in liver fat content as assessed by MRI-PDFF. MRI-PDFF was commonly used to assess treatment response in early-phase, proof-of-concept clinical studies in MASH and has been shown to be closely correlated with liver steatosis grades from histology. The primary endpoint of the study was achieved with a treatment difference being observed between the HTD1801 1,000 mg BID group and placebo (p=0.011) based on the primary analysis throughout the treatment period and follow-up period, as shown in the following figure. The mean absolute liver fat content was reduced by -4.8% in the group receiving HTD1801 1,000 mg BID, which was statistically more significant than the reduction of -2.0% noted in the placebo group. The relative changes of liver fat content from baseline (19.6%) in the placebo group and groups receiving HTD1801 500 and 1,000 mg BID were 8.3%, 15.1% and 24.1%, respectively. MRI response criterion was achieved by 2-fold more patients treated with HTD1801 (52%) compared to placebo (24%). In addition, 37% of subjects treated with HTD1801 1,000 mg BID experienced at least a 30% reduction in liver fat content which predicted histologic benefit in MASH. More reduction in liver fat content from baseline after treatment indicates better efficacy.

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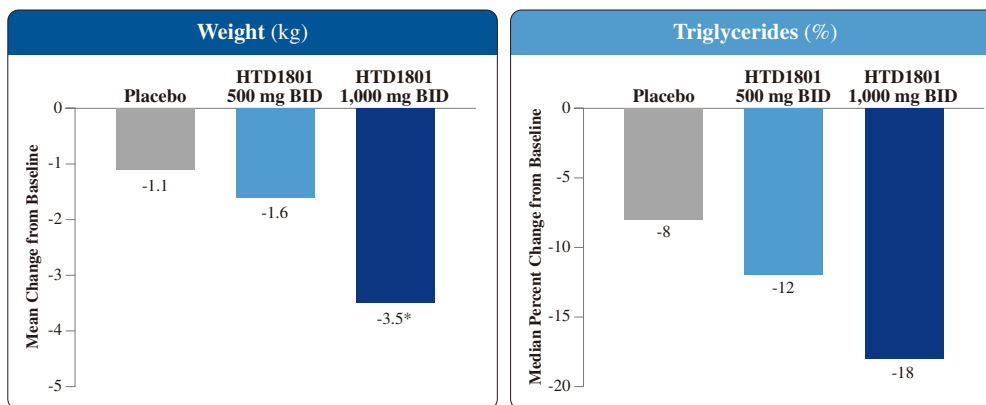


Note: * $p < 0.05$

Source: Company data

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In this study, HTD1801 1,000 mg BID was associated with a 3.5 kg weight loss and marked improvements in triglycerides relative to placebo in only 18 weeks — both independent risk factors for cardiovascular disease. The following figure illustrates changes of parameters of secondary endpoints from baseline throughout the treatment period and follow-up period. More reduction in weight and improvement in triglycerides from baseline after treatment indicates better efficacy.



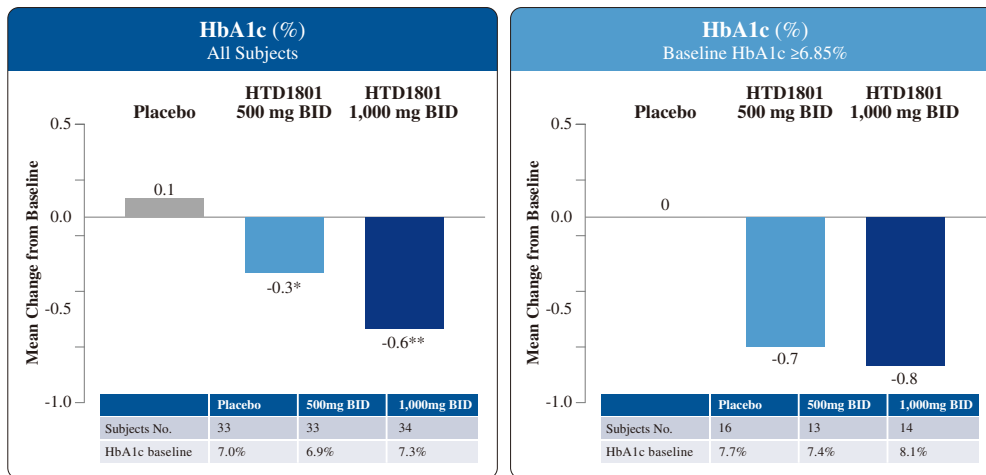
Note: * $p < 0.05$

Source: Company data

Given the frequent occurrence of impaired glucose tolerance and T2DM in subjects with MASH, it was important to assess the effects of HTD1801 on glycemic parameters. A positive effect of HTD1801 on glucose metabolism was evident. In particular, a mean reduction in HbA1c (-0.6%) was observed with HTD1801 1,000 mg BID that was statistically significant compared with a placebo, as shown in the following figure. A trend for improved fasting glucose with HTD1801 1,000 mg BID was also apparent but the difference from a placebo was not statistically significant. These glycemic effects appeared greater in those with worse glycemic control at baseline.

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The following figure shows changes of key biomarkers from baseline throughout the treatment period and follow-up period. More reduction in HbA1c from baseline after treatment indicates better efficacy.



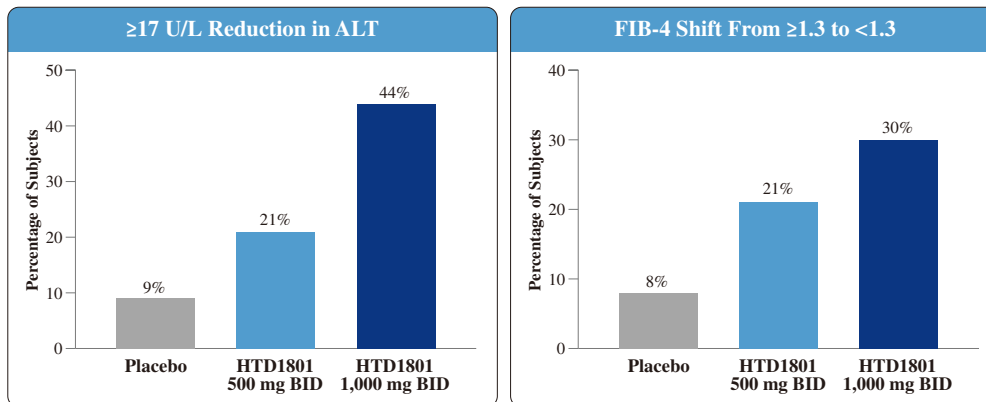
Note: * $p < 0.05$

The P value is defined as the probability under the assumption of no effect or no difference (null hypothesis), of obtaining a result equal to or more extreme than what was actually observed. The P stands for probability and measures how likely it is that any observed difference between groups is due to chance. A P-value less than 0.05 indicates the pattern observed is statistically significant, while if a value is higher than 0.05, it fails to reject the null hypothesis, and hence the pattern observed is not statistically significant. The higher the P value, the less likely that the data generated could have occurred under the null hypothesis.

Source: Company data

The beneficial effect of HTD1801 on liver fat was accompanied by additional improvements in liver health including liver biochemistry (alanine transaminase (“ALT”), aspartate transaminase (“AST”), gamma-glutamyl transferase (“GGT”)), and non-invasive markers of fibrosis (“FIB-4”). The following figures demonstrate the reduction of ALT and the shift of FIB-4 for the HTD1801 500 mg and 1,000 mg treatment groups throughout the treatment period and follow-up period. Over three times more subjects treated with HTD1801 achieved FIB-4 of less than 1.3, which was associated with less severe fibrosis by histology. Approximately five times more subjects treated with HTD1801 achieved greater than 17 U/L reduction in ALT, which was also associated with less severe fibrosis by histology. More reduction in ALT and lowering of FIB-4 from baseline after treatment indicates better efficacy.

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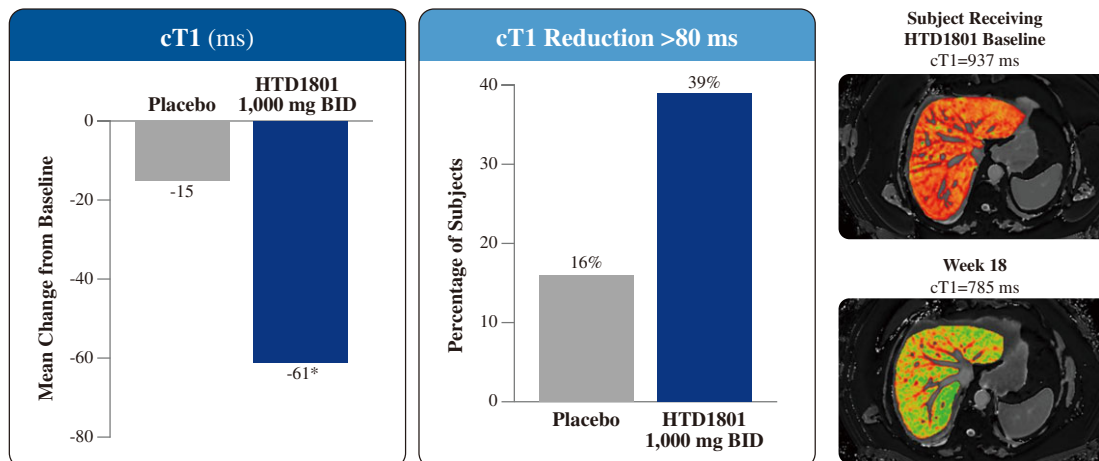


Source: Company data

Corrected T1 (“cT1”) is an MRI-based quantitative metric for assessing liver inflammation and fibrosis. Previous studies have reported that cT1 reduction >80 ms is significantly correlated with histologic improvements in NAS and fibrosis and cT1 levels are associated with clinical outcomes (liver and CVD) in patients with MASH. The clinical study results of HTD1801 indicated that after just 18 weeks of treatment there was a significant reduction in cT1 with HTD1801 1,000 mg BID compared to placebo (-61 ms vs. -15 ms, p<0.05). As an impressive case in HTD1801 1,000 mg BID group, a subject with the cT1 of 937 ms at baseline was with cT1 of 785 ms at Week 18, showing a reduction of 152 ms. Furthermore, A larger proportion of subjects receiving HTD1801 compared to placebo experienced at least an 80 ms reduction in cT1 at Week 18 (39% vs. 16%, respectively). These data provide further evidence that HTD1801 has potential in improving measures of inflammation and fibrosis of the liver in patients with MASH and T2DM.

The following figure shows changes of key biomarkers from baseline throughout the treatment period and follow-up period. More reduction in cT1 from baseline after treatment indicates better efficacy.

Significant Reductions in Liver Fibro-Inflammation (cT1)



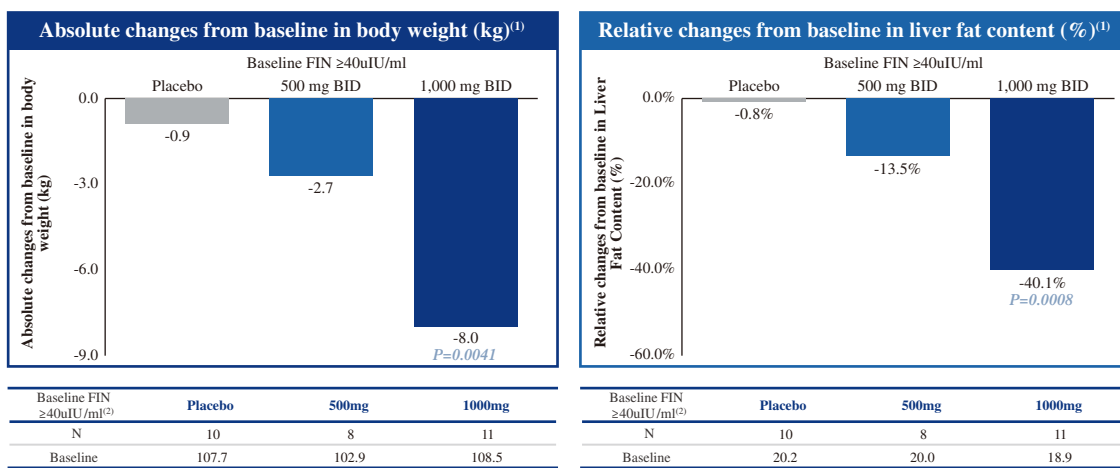
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Note: * $p < 0.05$. P-values are obtained from an ANCOVA model with treatment group as a fixed effect, and Baseline cT1 and Baseline ALT as covariates. The P value is defined as the probability under the assumption of no effect or no difference (null hypothesis), of obtaining a result equal to or more extreme than what was actually observed. The P stands for probability and measures how likely it is that any observed difference between groups is due to chance. A P-value less than 0.05 indicates the pattern observed is statistically significant, while a value higher than 0.05 the null hypothesis is true, hence the pattern observed is not statistically significant. The higher the P value, the less likely that the data generated could have occurred under the null hypothesis.

Abbreviations: ALT, alanine aminotransferase; ANCOVA, analysis of covariance; BID, twice daily dosing; cT1, Corrected T1

Source: Company data

In addition, we conducted a post hoc analysis for the subgroup subjects with hyperinsulinemia. As shown in the chart below, the results demonstrated that after HTD1801 treatment, body weight and liver fat content were significantly reduced from baseline, compared to placebo treatment.



Notes:

- (1) Based on efficacy population, N = 10 in placebo group; seven in 500 mg BID group; nine in 1,000 mg BID group;
- (2) Based on full population, N = 10 in placebo group; eight in 500 mg BID group; 11 in 1,000 mg BID group.

Source: Company data

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Safety data. HTD1801 was found to be generally safe and well tolerated in this study. Approximately two-thirds (67%) of subjects in the study overall had TEAEs. The incidence of TEAEs was higher in the HTD1801 1,000 mg BID group (76%, 59 events) compared with the HTD1801 500 mg BID group (64%, 47 events) and the placebo group (61%, 47 events). TEAEs related to the study drug were more common in the HTD1801 1,000 mg BID group (50%, 25 events) compared with the HTD1801 500 mg BID group (24%, 14 events) and the placebo group (15%, 9 events). The most common TEAEs and treatment-related TEAEs were gastrointestinal disorders (diarrhea and nausea). 95.5% of TEAEs were Grade 1 (mild) and Grade 2 (moderate). Other than gastrointestinal-related events, which were more common with HTD1801 1,000 mg BID compared with HTD1801 500 mg BID and placebo, the incidence of TEAEs was low and generally not different from placebo. There were no TEAEs leading to death in the study. Three treatment-emergent SAEs occurred during the course of the study, with one subject in each treatment group, suggesting that the incidence of SAEs was low. In addition, incidence of SAEs with HTD1801 was the same as placebo and all were considered unrelated to the study drug with no pattern observed in terms of the types of events. Furthermore, TEAEs leading to discontinuation of the study drug were also more common in the HTD1801 1,000 mg BID group (18%) compared with the HTD1801 500 mg BID group (3%) and the placebo group (3%), as shown in details in the following chart.

Preferred Term, n (%)⁽¹⁾	HTD1801 500 mg (N=33)	HTD1801 1000 mg (N=34)	Placebo (N=33)
Any TEAE Leading to Discontinuation of Study Drug . . .	1 (3%)	6 (18%)⁽²⁾	1 (3%)
Diarrhoea	0	2 (6%)	0
Abdominal Distension	0	1 (3%)	0
Gastrooesophageal Reflux Disease	1 (3%)	0	0
Melaena	0	1 (3%)	0
Myocardial Infarction	0	1 (3%)	0
Bladder Transitional Cell Carcinoma	0	0	1 (3%)
Headache	0	1 (3%)	0
Rash	0	1 (3%)	0

Note:

- (1) Percentages are based on the number of subjects randomized into each group.
- (2) One subject can experience two or more AEs.

HTD1801.PCT014: A Phase IIb study to evaluate efficacy and safety of HTD1801 in adult subjects with MASH and liver fibrosis who have T2DM or pre-diabetes in the United States, Hong Kong, Mexico and Mainland China.

Overview. This is a multicenter, randomized, double-blind, placebo-controlled Phase IIb study to evaluate the effect of HTD1801 on histologic improvements in adult subjects with MASH and liver fibrosis who have T2DM or pre-diabetes. The clinical sites are expected to be in the United States, Hong Kong, Mexico and Mainland China.

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Trial design. The study plans to enroll approximately 210 subjects in the United States, Hong Kong, Mexico and Mainland China with biopsy-confirmed MASH and evidence of stage 2 or stage 3 liver fibrosis. The subjects plan to be randomized 2:1 to receive HTD1801 1,250 mg twice daily (BID) or placebo BID, for up to 60 weeks. The primary endpoint is a decrease of ≥ 2 -points in NAFLD activity score ("NAS") with ≥ 1 -point decrease of either lobular inflammation or ballooning and no worsening of fibrosis; or resolution of MASH, defined as the overall histopathologic interpretation of "no fatty liver disease" or "fatty liver disease (simple or isolated steatosis) without steatohepatitis" and an NAS of 0 for ballooning and 0–1 for inflammation and no worsening of fibrosis. The key inclusion criteria for the Phase IIb clinical trial included: (1) clinical diagnosis of MASH upon central read of a liver biopsy obtained no more than 6 months before Day 0; (2) histologic evidence of fibrosis stage 2 or stage 3 as defined by the MASH critical ranking number scoring of fibrosis; (3) clinical diagnosis of T2DM or pre-diabetes at screening at least 6 months prior to screening or prediabetes at screening; and (4) BMI >25 kg/m² (>23 kg/m² for Asian subjects). The key exclusion criteria included: (1) fibrosis stage 4; (2) history of alcohol or substance abuse or dependence; (3) liver disease unrelated to MASH; (4) history of significant cardiovascular disease; (5) history of type 1 diabetes; or (6) inability or unwillingness to undergo two planned liver biopsies or one planned biopsy if historical liver biopsy was used to confirm eligibility at entry. There were challenges of conducting liver biopsy in clinical trial subjects including the willingness of subjects to have a biopsy, detecting appropriate histologic disease severity for inclusion in the study, inter-reader variability between pathologists (if multiple pathologists are utilized), and the subjectivity/inconsistency related to the histologic staging of the biopsy by a given pathologist. However, we believe they had no impact on our clinical trial because we tackled such challenges by (i) providing every study site with a prescreening algorithm designed to help detect subjects with sufficiently severe disease and to rule out subjects who are not suitable for conducting a liver biopsy; (ii) providing guidelines for interpretation of each of the parameters and cut-off values for patients who are reasonably likely to have sufficient disease severity; and (iii) having one single pathologist to evaluate liver biopsies of patients in order to avoid inter-reader variability in histologic staging.

Trial status. The clinical trial was initiated in the United States in December 2022 and in Hong Kong in October 2023, and is currently recruiting subjects, with no interim data to analyze. As of November 23, 2023, we have enrolled 150 subjects and initiated 54 clinical sites in the United States and also enrolled two subjects and initiated two clinical sites in Hong Kong. We obtained the IND approval from the NMPA in Mainland China on September 8, 2023. On July 11, 2023, we submitted an IND application to initiate Phase IIb study (HTD1801.PCT014) for MASH with T2DM or prediabetes in Mexico. We plan to initiate the Phase IIb MRCT in four clinical sites in Mexico and four clinical sites in Mainland China in December 2023. The large time gap between the completion of Phase IIa clinical trial and the initiation of the Phase IIb clinical trial for MASH is due to the prioritization of our resources for clinical development of HTD1801 for T2DM.

T2DM

HTD1801.PCT102: A Phase Ib study to assess safety, tolerability, PK and PD of HTD1801 for patients with T2DM in China

Overview. This was a single-center, randomized, double-blind, placebo-controlled, multiple-dose, repeated-dose phase Ib study to evaluate the safety, tolerability, PK and PD characteristics of HTD1801 in Chinese patients with type 2 diabetes mellitus. Safety evaluation was the primary purpose of the study.

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Trial design. HTD1801.PCT102 included Part A study with three treatment dose groups of 500 mg, 750 mg and 1,000 mg HTD1801 and Part B study with one treatment dose group of 1,000 mg HTD1801. A total of 48 patients with primary T2DM who had poor results with diet and exercise therapy were enrolled in this study. For Part A study, 36 naïve T2DM patients were randomized into four groups with nine patients for each group. Each group was administered orally for 28 consecutive days, twice a day, with an interval of 12 h \pm 2 h between doses. For Part B study, 12 patients with T2DM treated with stable doses of metformin for not less than 3 months were enrolled for two groups, with nine patients for 1,000 mg HTD1801 dose group and three patients for placebo group. Each group was administered orally for 28 consecutive days, twice a day, with an interval of 12 h \pm 2 h between doses, while maintaining the same metformin regimen.

The primary endpoint of this Phase Ib clinical trial was to evaluate adverse events, laboratory test values (including hematology, blood biochemistry, blood glucose, glycosylated hemoglobin, coagulation function, urinalysis), electrocardiogram test, vital signs and physical examination. The key inclusion criteria for the Phase Ib clinical trial included: (1) signing the informed consent form before the trial, and fully understanding the content, process and possible adverse effects of the trial; (2) being able to complete the study according to the requirements of the trial protocol; (3) subjects (including partners) who are willing to voluntarily use effective contraception from screening until 90 days after the last dose of study drug; (4) male and female subjects between the ages of 18 (inclusive) and 75 (inclusive) years at the time of signing the informed consent form; (5) male subjects with no less than 50 kg weight and female subjects with no less than 45 kg weight at screening, with body mass index ≥ 18 kg/m²; (6) diagnosis of T2DM that was confirmed according to the 1999 World Health Organization ("WHO") criteria; (7) at screening: 7.0 mmol/L \leq fasting glucose \leq 13.3 mmol/L, and 7.5% \leq HbA1c \leq 11.5%; and (8) patients with fatty liver diagnosed by ultrasound. The key exclusion criteria included but not limited to: (1) being allergic to multiple drug and food, or allergic to the active ingredients of the drug under study or its excipients determined by the investigator; (2) subjects who have undergone gastrointestinal or other gastrointestinal-related surgery within one year prior to screening, other surgery within six months prior to screening that may have an impact on this study, or those who are scheduled to undergo surgical treatment within three months of enrollment; (3) subjects who have lost a significant amount of blood (>400 mL), received a blood transfusion, or used blood products within three months prior to screening; (4) subjects who have consumed a significant amount of alcohol within 30 days prior to screening; (5) history of substance abuse or dependence within one year prior to screening; or (6) subjects who, in the opinion of the investigator, have factors that make participation in this trial inappropriate.

Trial status. The Phase Ib clinical trial was initiated in June 2022 and completed in September 2022 with 49 patients enrolled.

Safety data. HTD1801 treatment for 28 consecutive days demonstrated good safety and tolerability in both treatment-naïve patients and the patients with stable metformin treatment. The most common TEAEs were Grades 1-2 gastrointestinal events.

Efficacy data. HTD1801 showed clear potential in metabolism improvement after the relatively short treatment period. The fasting blood glucose, and 2-hour post-prandial glucose of HTD1801 groups demonstrated a dose-dependent decrease from baseline after 28-day treatment. In addition, dose-dependent reductions in total cholesterol, triglyceride ("TG"), LDL-C and non-HDL-C were observed.

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HTD1801.PCT103: A Phase II, multicenter, randomized, double-blind study to evaluate the efficacy and safety of HTD1801 in subjects with T2DM in Mainland China

Overview. The Phase II study was a multi-center, randomized, double-blind, placebo-parallel controlled trial to assess safety and efficacy of HTD1801 for patients with T2DM after 12 weeks of treatment. The primary objective of this study was to evaluate the effect of HTD1801 on glycemic control in patients with T2DM.

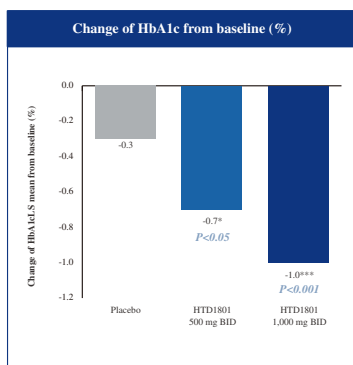
Trial design. Subjects enrolled in this study were randomized 1:1:1 to receive the 500 mg HTD1801, 1,000 mg HTD1801 or placebo, administered BID during a 12-week time frame. The primary endpoint of Phase II clinical trial was to evaluate glycated hemoglobin ("HbA1c") during the entire clinical trial period. The key inclusion criteria for the Phase II clinical trial included: (1) female or male subjects with ages of 18 years (inclusive) and 75 years (inclusive) at the time of signing the informed consent form; (2) confirmed diagnosis of T2DM according to the 1999 World Health Organization criteria; (3) being treated with diet and exercise alone for ≥ 8 weeks prior to screening; (4) HbA1c criteria: HbA1c at screening: $7.5\% \leq \text{HbA1c} \leq 11.0\%$; HbA1c before randomization: $7.0\% \leq \text{HbA1c} \leq 10.5\%$; (5) fasting blood glucose criteria: Fasting blood glucose at screening: < 13.9 mmol/L; fasting plasma glucose before randomization: < 13.9 mmol/L; (6) body mass index ranged from 18 to 40 kg/m² (including end values) at screening; (7) subject who agrees to maintain the same dietary and exercise habits throughout the trial, and is willing and able to accurately use a home blood glucose meter for self-monitoring of blood glucose and recordings; and (8) ability to understand and willingness to sign a written informed consent form and comply with the study protocol. The key exclusion criteria included but not limited to: (1) type 1 diabetes, or a specific type of diabetes (e.g., diabetes due to pancreatic injury, diabetes due to Cushing's syndrome or acromegaly, etc.); (2) diabetic ketoacidosis or hyperglycemic hyperosmolar state within 6 months prior to screening; (3) proliferative retinopathy or macular degeneration, severe diabetic neuropathy, diabetic foot, or intermittent claudication that was unstable or required treatment within 6 months prior to screening; (4) history of ≥ 2 grade 3 hypoglycemic episodes in the 12 months prior to screening; (5) any condition that may cause hemolysis or red blood cell instability that would interfere with HbA1c testing, such as hemolytic anemia, at screening; or (6) other conditions deemed by the investigator to be inappropriate for participation in this trial.

Trial status. The Phase II clinical trial was initiated in March 2022 and completed in January 2023 with 113 patients enrolled in Mainland China. The number of randomized subjects assigned to the placebo, 500 mg, and 1,000 mg groups was 38, 37, and 38, respectively. A total of 110 subjects completed the study (one subject in the placebo group and two subjects in the 500 mg group withdrew early from the study).

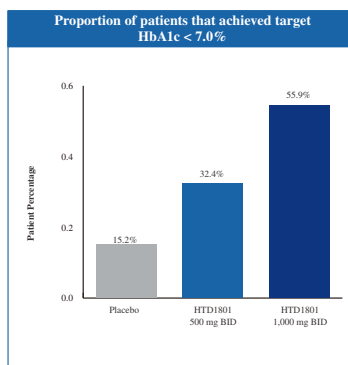
Efficacy data. HTD1801 demonstrated a strong therapeutic effect in improving glucose metabolism of subjects with T2DM, including statistically significant decreases in HbA1c and glucose levels. Improvements in other disease-relevant parameters were also observed, including reduced liver biomarkers (ALT, AST, GGT) and improvement of lipid profiles, such as reduction of LDL-c and non-HDL-c levels.

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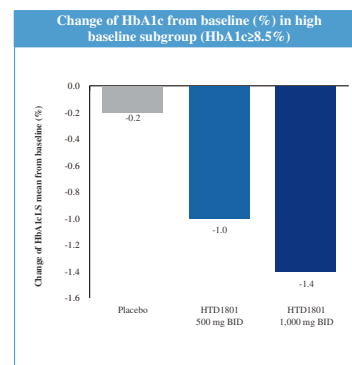
During the treatment period, subjects in the HTD1801 500 mg and 1,000 mg BID groups exhibited reduced level of HbA1c compared to the baseline, with statistically significant superiority over that of the placebo group. At Week 12, both HTD1801 500 mg BID and 1,000 mg BID treatment groups showed significant reduction in HbA1c compared to placebo group. As shown in the chart below, compared to baseline, 500 mg BID group showed a reduction in HbA1c(%) by -0.7 and 1,000 mg BID group showed a reduction in HbA1c (%) by -1.0. The proportions of patients achieving glucose control target (HbA1c <7% and <6.5%) in HTD1801 groups were 55.9% and 29.4% in 1,000 mg treatment group, compared with 15.2% and 6.1% in placebo group, respectively. HTD1801 also demonstrated better effects in glucose metabolism improvement for patients in high baseline subgroup with poorer glycemic control (HbA1c≥8.5%), and 12-week HTD1801 treatment led to reduction in HbA1c by 1.0 in 500 mg treatment group and 1.4 in 1,000 mg treatment group, compared to the baseline. The results demonstrated a clear dose-effect relationship for HTD1801 treatment.



	Placebo	500mg BID	1000mg BID
N	38	37	38
Baseline	8.32	8.18	8.18



At 12 weeks of HTD1801 1000mg treatment, nearly **one-third** of patients had HbA1c less than the diagnostic criteria for diabetes (**HbA1c<6.5%**)



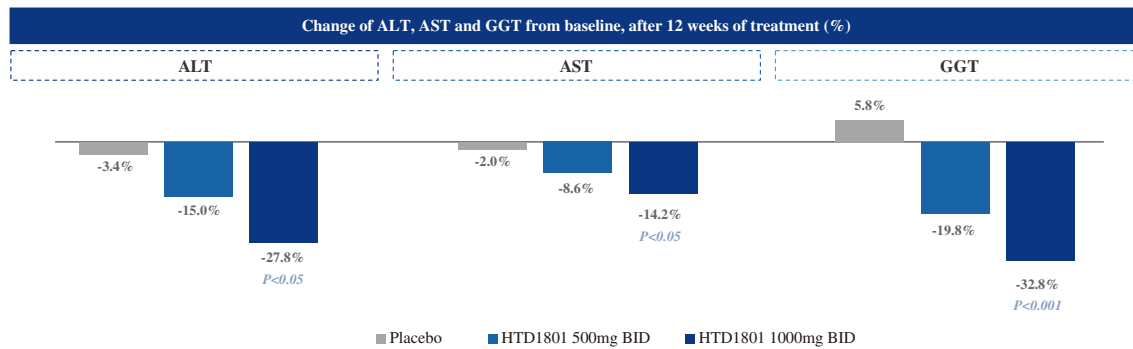
	Placebo	500mg BID	1000mg BID
N	13	13	14
Baseline	9.38	9.00	9.08

Source: Company data

In addition, as shown in the chart below, subjects in the HTD1801 500 mg and 1,000 mg BID groups after 12 weeks of HTD1801 treatment also exhibited reduced liver biomarkers (ALT, AST, GGT) compared to the baseline in an approximately dose-dependent manner, with statistically significant superiority over that of the placebo group. After 12 weeks of HTD1801 treatment, improvement of liver function is observed even in people with normal liver enzymes. The total cholesterol profile, LDL-c and non-HDL-c indicated similar meaningful reduction in the HTD1801 groups.

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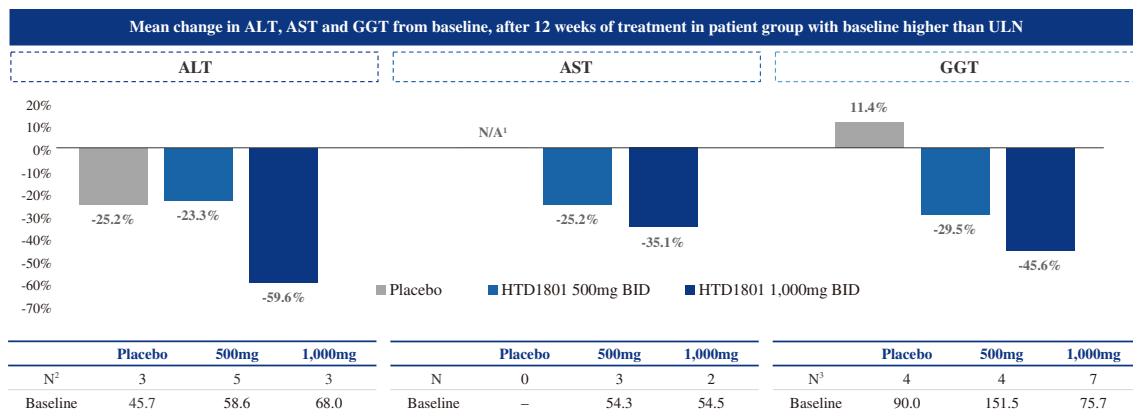
Change of ALT, AST and GGT from Baseline



	Placebo	500mg BID	1000mg BID		Placebo	500mg BID	1000mg BID		Placebo	500mg BID	1000mg BID
N	38	37	38	N	38	37	38	N	38	37	38
Baseline	23.8	26.6	24.8	Baseline	20.3	24.4	22.6	Baseline	34.2	41.4	33.5

Source: Company data

After 12 weeks of HTD1801 treatment, enhanced improvement was also observed in patients with abnormal liver biochemistry. As shown below, mean changes in ALT, AST and GGT from baseline in the HTD1801 1,000 mg BID treatment group after 12 weeks of treatment were much improved compared with the placebo group. Thus, HTD1801 treatment resulted in improvements in measures of hepatic inflammation and damage (ALT, AST and GGT), particularly relevant with the risk and frequent overlap of MASLD in patients with T2DM.



Notes:

1. There was no subjects enrolled in this subgroup.
2. Efficacy is based on efficacy population at week 12 (N=3, 4, 3), and baseline is for enrolled population (N=3, 5, 3) in placebo, 500mg treatment group and 1,000mg treatment group, respectively.
3. Efficacy is based on efficacy population at week 12 (N=4, 4, 6), and baseline is for enrolled population (N=4, 4, 7) in placebo, 500mg treatment group and 1,000mg treatment group, respectively.

Source: Company data

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Safety data. HTD1801 was generally well-tolerated in both 500 mg and 1,000 mg BID groups. TEAEs that may relate to HTD1801 were reported by 13 of these subjects (11.5%), of which five were from placebo group (13.2%), two were from HTD1801 500 mg BID group (5.4%) and six were from HTD1801 1,000 mg BID group (15.8%). All drug-related TEAEs were Grade 1 or 2, and no drug-related SAE was reported. No life-threatening AE occurred nor did any AE lead to permanent discontinuation of a subject from the Phase II clinical trial.

PSC

HTD1801.PCT003: A Phase II study comparing two doses of HTD1801 (500 mg BID and 1,000 mg BID) to placebo in adult subjects with PSC in the United States and Canada

Overview. This was a Phase II, multicenter, randomized, double-blind, proof-of-concept 18-week study comparing two doses of HTD1801 (500 mg BID and 1,000 mg BID) to placebo in adult subjects with PSC in the United States and Canada. The primary endpoint was the absolute change in ALP from baseline to Week 6.

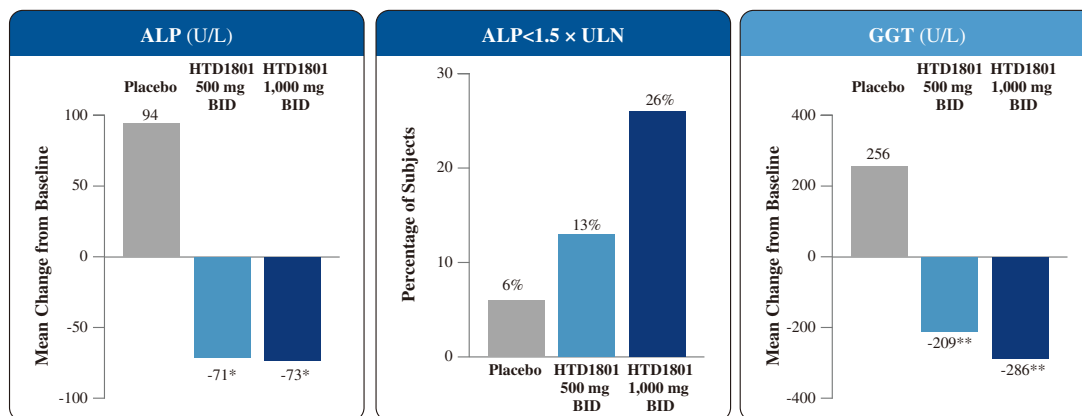
Trial design. The study design consisted of an initial randomized, double-blind, placebo- and dose-controlled, parallel-group period (Period 1), followed by a dose-controlled extension period (Period 2), followed by a placebo-controlled randomized withdrawal period (Period 3). In the Period 1, subjects were randomized to receive BID doses of 500 mg, 1,000 mg, or matching placebo for 6 weeks. The primary analysis was based on this initial six-week randomized, double-blind, placebo- and dose-controlled, parallel-group period. In the Period 2, subjects previously randomized to 500 mg BID or 1,000 mg BID continued for six more weeks at that previous dose, while subjects previously randomized to placebo were re-randomized to receive six weeks of either 500 mg BID or 1,000 mg BID. In the Period 3, subjects were re-randomized to either continue on the active treatment they received in Period 2 or be assigned to placebo. Clinic visits for efficacy assessments and safety monitoring occurred every two weeks throughout the 18-week study, with a final follow-up assessment 30 days after the last dose of study drug. A total of 59 subjects were randomized into the study. The key inclusion criteria for the Phase II clinical trial included: (1) male or female between 18 and 75 years of age; (2) having a clinical diagnosis of PSC as evident by chronic cholestasis of more than six months duration with either a consistent magnetic resonance cholangiopancreatography/endoscopic retrograde cholangiopancreatography showing sclerosing cholangitis; (3) subjects having inflammatory bowel disease evident by prior endoscopy or in previous medical records for ≥ 6 months; subjects with a partial Mayo score (an index to assess severity of current ulcerative colitis) of 0-4, inclusively; subjects on treatment who are stable for 3 months if taking 5-amino salicylic acid drugs, azathioprine, 6-mercaptopurine, or methotrexate biologics; (4) a serum ALP $\geq 1.5 \times$ upper limit of normal; (5) being able to understand and sign a written informed consent form; (6) receiving allowed concomitant medications that need to be on stable therapy for 28 days prior to the baseline visit, with the exception of UDCA that should be stable for at least six weeks prior to the baseline visit. The key exclusion criteria included: (1) presence of documented secondary sclerosing cholangitis (such as ischemic cholangitis, recurrent pancreatitis, intraductal stone disease, severe bacterial cholangitis, surgical or blunt abdominal trauma, recurrent pyogenic cholangitis, choledocholithiasis, toxic sclerosing cholangitis due to chemical agents, or any other cause of secondary sclerosing cholangitis) on prior clinical investigations; (2) small duct PSC; (3) presence of percutaneous drain or bile duct stent; (4) history of cholangiocarcinoma or clinical suspicion of new dominant stricture within one year by magnetic resonance cholangiopancreatography/endoscopic retrograde

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cholangiopancreatography; presence of dominant stricture without endoscopic retrograde cholangiopancreatography evidence of cholangiocarcinoma is acceptable if stable for ≥ 1 year; (5) ascending cholangitis within 60 days prior to screening; (6) history of alcohol or substance abuse or dependence; (7) prior or planned liver transplantation; presence of alternative causes of chronic liver disease, including alcoholic liver disease, MASH, PBC, autoimmune hepatitis; (8) platelet count below $125,000/\text{mm}^3$, albumin below 3.0 g/dL, international normalized ratio >1.2 , or a history of ascites, or encephalopathy, or history of esophageal variceal bleeding; or (9) severe active IBD or flare in colitis activity within the last 90 days requiring intensification of therapy beyond baseline treatment.

Trial status. We initiated the Phase II clinical trial of HTD1801 for PSC in the United States and Canada in February 2018 and completed the trial in August 2020.

Efficacy data. The following figure shows changes of key biomarkers from baseline throughout the treatment period and follow-up period. The clinical trial study showed improvements in key markers of cholestasis and liver injury at Week 6. In particular, a clinically meaningful, statistically significant decrease in ALP from baseline to Week 6 was observed for both the HTD1801 500 mg BID and the 1,000 mg BID groups compared to placebo. Greater ALP responses in the active treatment groups compared to placebo were apparent as early as Week 2 and sustained through Week 6 with a similar magnitude of response at each visit between the two HTD1801 treatment groups. The percentage of patients with ALP of $<1.5 \times$ upper limit of normal (“ULN”) was much higher for both the HTD1801 500 mg BID and the 1,000 mg BID groups compared to placebo at Week 6. In addition, there was a decrease of GGT from baseline to Week 6 compared to placebo for both the HTD1801 500 mg group ($p=0.0082$) and the HTD1801 1,000 mg group ($p=0.0007$).



Note: * $p < 0.05$; ** $p < 0.001$

The P value is defined as the probability under the assumption of no effect or no difference (null hypothesis), of obtaining a result equal to or more extreme than what was actually observed. The P stands for probability and measures how likely it is that any observed difference between groups is due to chance. A P -value less than 0.05 indicates the pattern observed is statistically significant, while a value higher than 0.05 the null hypothesis is true, hence the pattern observed is not statistically significant. The higher the P value, the less likely that the data generated could have occurred under the null hypothesis.

Source: Company data

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Safety data. Most TEAEs were mild or moderate in intensity and considered by the Investigator to be unrelated to study drug. TEAEs were reported for 18 (51%) of 35 subjects during placebo treatment, 14 (64%) of 22 subjects during HTD1801 500 mg BID treatment, and 20 (65%) of 31 subjects during HTD1801 1,000 mg BID treatment, see the table below.

Summary of TEAEs (Safety Population)

Number (%) of Subjects with:	Placebo (N=35) ^a	HTD1801	
		500 mg BID (N=22) ^a	1,000 mg BID (N=31) ^a
TEAEs.....	18(51)	14(64)	20(65)
TEAEs related to study drug.....	7(20)	5(23)	9(29)
TEAEs leading to discontinuation.....	4(11)	1(5)	3(10)
Severe TEAEs.....	2(6)	1(5)	3(10)
SAEs related to study drug.....	0	0	0

a Overall N = the number of subjects receiving a given treatment during any period of the study.

Note: Subjects are summarized according to the treatment taken on the start date of the AE. AEs are coded using MedDRA V20.1. TEAE are those that are reported on or after the initiation of the study drug. AEs are attributed to the most recent treatment received.

Source: Investigator's Brochure, Company Data

PBC

HTD1801.PCT013: A Phase II open-label, proof-of-concept study in subjects with PBC with inadequate response to standard of care in the United States

Overview. This was a Phase II, multicenter, single-arm, 12-week, open-label, proof-of-concept study of HTD1801 in adult subjects with PBC with an inadequate response to standard therapy. The primary endpoint is the percent change from baseline in ALP.

Trial design. 24 subjects received at least one dose of HTD1801 and were included in the HTD1801 1,000 mg BID (intention-to-treat (“ITT”) population). Inadequate response was defined as ALP ≥1.5x upper limit of normal despite having been on adequate doses of UDCA for at least six months. Subjects discontinued use of UDCA at baseline, prior to transitioning to HTD1801. On average subjects were on a lower dose of UDCA when administered as HTD1801. The key inclusion criteria included: (1) a clinical diagnosis of PBC as confirmed by patient history consistent with the American Association for the Study of Liver Diseases Practice Guideline confirmed by two of the following three criteria: biochemical evidence of cholestasis with elevation of ALP activity, presence of anti-mitochondrial antibody and histopathologic evidence of non-suppurative cholangitis and destruction of small or medium-sized bile ducts if biopsy performed; (2) taking a stable, adequate dose of at least (13-15 mg/kg/day) of UDCA for at least 6 months with a serum ALP of at least ≥1.5 × ULN at any time after being on UDCA for >6 months (historical value) and at screening; subject who may be screened and a second ALP value should be obtained as part of screening if the historical ALP was obtained less than 6 months prior to study start as part of standard of care, and there must be at least a 4-week interval between the ALP

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values and the ALP values must be $\geq 1.5 \times \text{ULN}$; (3) subject who must be on a stable dose no more than once a day for at least 8 weeks prior to baseline visit, if the subject is taking cholestyramine or other bile acid sequestrant for pruritus, and must be willing and able to take cholestyramine at least 2 hours before or after study medication; (4) females of child-bearing potential and males participating in the study who must either agree to use at least two approved barrier methods of contraception or be completely abstinent from sexual intercourse, if this is their usual and preferred lifestyle, throughout the duration of the study and for three months after stopping study drug, and post-menopausal females who must have appropriate documentation; and (5) subject who is able to provide consent. The key exclusion criteria included but not limited to: (1) uncontrolled concomitant autoimmune hepatitis, that subject should be on no more than 5 mg per day of prednisone (or equivalent dose for other corticosteroids) or no more than 150 mg per day of azathioprine at stable doses and serum ALT should be $\leq 5 \times \text{ULN}$; enrollment of subjects with controlled AIH will be limited to a total of 5 subjects; (2) history of alcohol or substance abuse; (3) prior liver transplantation or currently listed for liver transplantation; (4) history of chronic viral hepatitis, types B or C; (5) platelet count $\leq 150,000/\text{mm}^3$, albumin $< 3.0 \text{ g/dL}$, international normalized ratio > 1.2 , or a history of ascites, or encephalopathy, or history of variceal bleeding; or (6) any other clinically significant disorders or prior therapy that, in the opinion of the investigator, would make the subject unsuitable for the study or unable to comply with the dosing and protocol requirements.

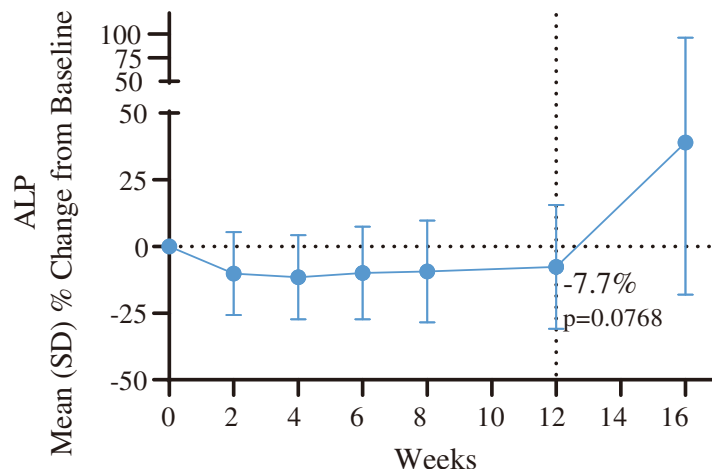
Trial status. We initiated the Phase II PBC clinical trial in the United States in May 2021 and completed the trial in May 2022.

Efficacy data. The efficacy data of the Phase II clinical trial for PBC was favorable. The follow-up periods in the clinical trial, during which HTD1801 treatment was withdrawn, showed the significant rebound of ALP compared with baseline, also suggesting the efficacy of HTD1801. Therefore, we believe it has no impact on its clinical development. Following treatment with HTD1801 1,000 mg BID for 12 weeks, the primary endpoint of percent change from baseline in ALP at Week 12 showed a reduction of -7.7% ($p=0.0768$) with $>30\%$ achieving $\geq 20\%$ reduction. Improvements in ALP were observed early in the study by Week 2 and -10.0% reductions were observed at Week 6 ($p=0.0061$). Although reductions were maintained through Week 12, the difference was no longer statistically significant. Following discontinuation of study drug at Week 12, a clear rebound in ALP back to levels higher than baseline was observed at the Week 16 follow up visit, suggesting that the ALP level was worsened as compared with baseline. This rebound was due to the discontinuation of HTD1801 treatment. In addition, a 7.5% reduction in total bilirubin was observed at Week 12 with HTD1801 treatment along with reductions in immunoglobulin M which was classically elevated in PBC. Subjects with PBC were typically dyslipidemic. The trial results demonstrated that HTD1801 treatment resulted in reductions in LDL-C, triglycerides and total cholesterol.

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The following figure shows changes of primary endpoint from baseline throughout the treatment period and follow-up period:

**Primary Endpoint: Percent Change from Baseline in ALP at Week 12
(ITT Population) Study HTD1801.PCT013**



Source: Company data

Safety data. 24 subjects received at least one dose of HTD1801 and were included in the ITT population. Treatment with HTD1801 1,000 mg BID was safe and generally well tolerated. There were no deaths in the study. Overall, 23 (96%) subjects reported a TEAE; the majority were mild (58%) in severity. One subject experienced a severe SAE of COVID-19 pneumonia requiring hospitalization. Two subjects experienced TEAEs that lead to treatment discontinuation and were considered possibly related to study drug. One subject experienced TEAEs of a decrease in appetite and diarrhea at Week 2, which were considered mild and moderate in severity, respectively. The subject discontinued treatment and completed the follow-up visit four weeks later. A significant proportion of patients with PBC experience pruritus that can markedly influence quality of life. Although subjects included in this study generally had mild pruritus at baseline, improvements in both the average itch and worst itch in the past 24 hours were observed at Week 12 to levels near no pruritus.

Hypercholesterolemia

HTD1801.PCT004: A randomized, double-blind, placebo-controlled, multicenter, multiple ascending dose Phase Ib/IIa study to evaluate the safety and tolerability of HTD1801 in adults with hypercholesterolemia in Australia

Overview. This was a Phase Ib/IIa randomized, double-blind, placebo-controlled, multiple ascending dose study to evaluate the safety, tolerability, PK, and PD of HTD1801 in subjects with hypercholesterolemia. Given that the subjects enrolled in this study were obese with a history of hypercholesterolemia, the focus of the efficacy and PD endpoints was lipid metabolism. Since all subjects, with the exception of two subjects (4%), were euglycemic with normal liver-associated enzymes at baseline, the focus of the exploratory endpoints of glucose metabolism and liver function was safety.

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Trial design. HTD1801 was administered orally, once per day immediately after the morning meal on Day 1 (250, 500 and 1,000 mg single dose), twice per day after the morning and evening meals on Day 2 to Day 27 inclusive (250, 500 and 1,000 mg BID), and once per day immediately after the morning meal on Day 28 (250, 500 and 1,000 mg single dose). The baseline (pre-dose) and post-dose PK samples were collected. 50 overweight or obese adults with hypercholesterolemia were enrolled and treated with HTD1801 in this Phase I/II study. Of those 50 enrolled subjects, 47 completed the study as planned. The key inclusion criteria for the Phase Ib/IIa clinical trial included: (1) having given written informed consent; (2) males or females aged 18 to 70 years old at the time of first dosing; (3) having a body mass index of >25.0 and ≤ 45.0 kg/m² at screening; and (4) having a documented history of hypercholesterolemia, defined as LDL-C ≥ 2.59 mmol/L. The key exclusion criteria included: (1) use of any anti-dyslipidemia agent within 28 days prior to dosing; (2) history of a total cholesterol ≥ 10.35 mmol/L or triglyceride ≥ 11.3 mmol/L; (3) history of a clinically significant cardiac arrhythmia or clinically significant abnormal ECG results at screening; (4) significant peripheral or coronary vascular disease; (5) clinically significant abnormal blood pressure at screening or baseline, defined as supine blood pressure $\geq 160/100$ mmHg, or $\leq 90/60$ mmHg; (6) primary hypothyroidism (thyroid stimulating hormone $>$ upper limit or normal and free T4 $<$ lower limit of normal), primary subclinical hypothyroidism (screening TSH $>$ ULN and free T4 within normal limits), or secondary hypothyroidism (screening TSH $<$ LLN and free T4 $<$ LLN) at screening; or (7) glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Trial status. We initiated the Phase Ib/IIa trial of HTD1801 for hypercholesterolemia in March 2018 and completed the trial in December 2018 in Australia.

Efficacy data. Among subjects receiving HTD1801, serum lipid levels generally decreased in a dose-dependent fashion. Statistically significant improvements were observed with HTD1801, at various dose levels, compared with placebo for triglycerides, total cholesterol, LDL-C, non-HDL-C, very low density lipoprotein-cholesterol ("VLDL-C"), and lipoprotein-a. With regard to liver enzymes, there were no changes in ALT or AST observed over the 28 days of treatment. With regard to glucose metabolism, only two subjects presented with a history of T2DM at study entry. All others were euglycemic at baseline. No subjects who received HTD1801 experienced hypoglycemia. The results demonstrated favorable trends of HTD1801 treatment in efficacy endpoints related to lipid metabolism.

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Lipid Metabolism by Mean (SD) Percent Change from Baseline (Efficacy Population)

Visit on Day 28, Mean% (SD)	Placebo N=12	HTD1801		
		250 mg BID (N=12)	500 mg BID (N=12)	1,000 mg BID (N=14)
Non-HDL Cholesterol	10.8 (14.7)*	-2.9 (15.4)	-2.3 (14.5)	-10.4 (7.6)***
Triglycerides	39.9 (29.1)*	10.5 (38.1)**	15.1 (29.5)**	-1.6 (18.5)**
Cholesterol	5.9 (14.0)	-3.6 (10.7)	-3.8 (10.9)	-8.2 (6.5)***
HDL-C	-7.6 (16.7)	-7.0 (10.0)*	-6.9 (11.4)	-0.1 (8.3)
LDL-C	-1.7 (18.5)	-5.2 (16.3)	-3.3 (13.3)	-10.4 (8.5)*
VLDL-C	36.6 (36.9)	11.9 (40.6)	13.5 (28.7)	-2.6 (22.8)**
Lipoprotein-a	42.9 (85.0)	-11.3 (32.3)	184.2 (394.6)	-15.8 (31.8)*

Note: Baseline is the average of results at the screening and baseline visits. The last observation carried forward was used for missed timepoints and timepoints with no results.

* p-value ≤0.05; based on a *t*-test for within treatment change over time.

** p-value ≤0.05; based on a *t*-test for between treatment difference vs placebo in change over.

*** p-value ≤0.05 for both *t*-tests.

Source: Company data

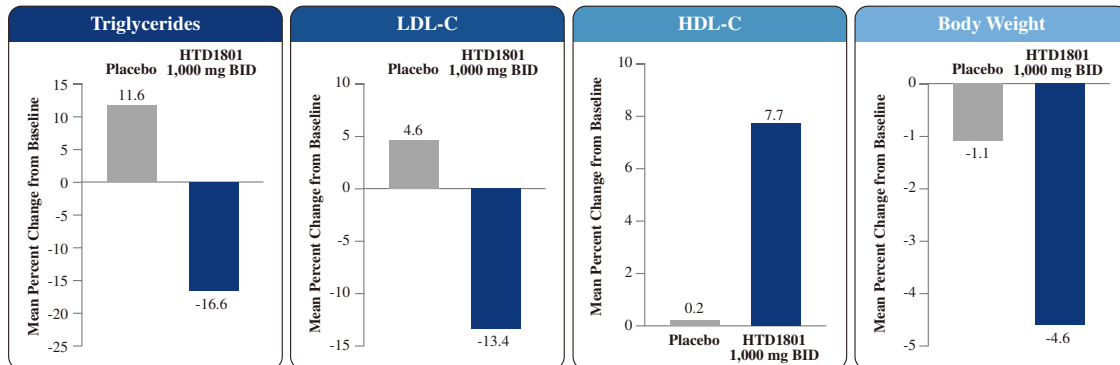
Safety data. The majority of subjects reported at least one TEAE during the study, but most TEAEs were mild in severity and considered by the Investigator to be unrelated to study drug. TEAEs were reported for eight (66.7%) of 12 subjects in the placebo group, 10 (83.3%) of 12 subjects in the HTD1801 250 mg BID group, eight (66.7%) of 12 subjects in the HTD1801 500 mg BID group, and 11 (78.6%) of 14 subjects in the HTD1801 1,000 mg BID group. The most frequently reported TEAE in this study was headache, which was reported for five subjects in the placebo group, five subjects in the HTD1801 250 mg BID group, four subjects in the HTD1801 500 mg BID group, and three subjects in the HTD1801 1,000 mg BID group. Other TEAEs reported by more than two subjects in any of the treatment groups included dizziness, nausea, flatulence, and decreased appetite. There was no relationship between the overall frequency of TEAEs and treatment or dose group, or between the occurrence of TEAEs in a specific organ class, or individual TEAE, and treatment or dose group. There were no deaths during the study, and no subjects met dose escalation stopping criteria.

Pooled Analysis of HTD1801.PCT012 and HTD1801.PCT004 — Relevant to SHTG

In a pooled analysis (evaluating placebo, HTD1801 500 mg BID and HTD1801 1,000 mg BID) of HTD1801.PCT004 (the Phase Ib/IIa study in adults with hypercholesterolemia, 4-week treatment) and HTD1801.PCT012 (the Phase IIa study in adults with MASH and T2DM, 18-week treatment), we compared results of HTD1801 1,000 mg treatment with placebo treatment. In a subgroup of subjects with HTG (elevated above 200 mg/dL) at baseline, a clinically meaningful reduction in TGs was observed (mean percent change from baseline for HTD1801 1,000 mg BID: -16.6% vs. placebo: +11.6%). Furthermore, lowering of TGs was accompanied by improvements in key cardiometabolic parameters (such as body weight, HDL-C, and LDL-C, etc.). These beneficial effects are also important considerations given the prevalence of such comorbidities in patients with SHTG, and support potential efficacy of HTD1801 for the treatment of SHTG.

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Strong Clinical Evidence Supporting HTD1801 as a Treatment for SHTG (Subjects with Baseline TG>200 mg/dL)



Source: Company data

Licenses, Rights and Obligations

We have granted Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司) (“**Hepalink**”) an exclusive, sublicensable (solely to Hepalink’s wholly-owned subsidiaries), non-transferable license of HTD1801 for all aspects of commercialization for the indications of MASH and PSC in Europe. We retain the rights to (i) research and develop HTD1801 worldwide; (ii) manufacture HTD1801 worldwide; (iii) commercialize HTD1801 for any indications outside Europe; (iv) commercialize HTD1801 in any region in Europe for indications other than for MASH and PSC; and (v) import and export HTD1801 for the purposes described above. Please see the paragraphs headed “— Collaboration Agreement — HTD1801 License-Out Agreement” in this section for more details.

Clinical Development Plan

We will continue to advance the global development of Core Product HTD1801 for metabolic and digestive diseases. For the T2DM program, we filed the Phase Ib and Phase II clinical results and Phase III study protocol to the NMPA in April 2023. We initiated registrational Phase III trials in November 2023 and plan to complete enrollment in 2024 in Mainland China. For the MASH program, a Phase IIb study for the treatment of MASH with T2DM or pre-diabetes is currently ongoing. We have initiated the sites in the United States and Hong Kong and plan to initiate sites in Mexico and Mainland China in December 2023. For the SHTG program, we plan to file IND application to the FDA for a Phase II clinical trial of HTD1801 in the United States by the end of 2023 and initiate a Phase II clinical trial in 2024.

Considering the market size and addressable patient population of MASH and T2DM, we have and will continue to prioritize our resources for the clinical development of our MASH and T2DM indications of HTD1801. We are currently conducting the Phase IIb clinical trial for the MASH indication of our self-developed HTD1801, and may seek joint development opportunities for its Phase III clinical trials. In November 2023, we initiated the two Phase III clinical trials (i.e. one with HTD1801 as a standalone treatment and one with HTD1801 as an add-on therapy with metformin) for the T2DM indication of our self-developed HTD1801 in China. We plan to complete these two Phase III clinical trials in 2025. We have no immediate plans to conduct

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clinical trials for and commercialise T2DM outside of China. Since the completion of Phase II clinical trials for PSC in August 2020 and for PBC in May 2022, no clinical development progress has been made for the PSC and PBC indications of HTD1801. Considering our resources allocation, we have no immediate development plans and will not allocate any [REDACTED] of the [REDACTED] these two indications, and we are seeking collaboration opportunities with global partners for future clinical development and commercialisation of HTD1801 for PSC and PBC. As of the Latest Practicable Date, no partners had been identified. Despite the rebound in liver biochemistry during the follow-up period in the Phase II trial for PBC and a long period of clinical development suspension for the PBC and PSC indications, we have not encountered any difficulties in identifying collaboration opportunities with global partners for future clinical development and commercialisation of HTD1801 for PBC and PSC.

We designed the MRCTs for HTD1801 for MASH and PSC indications. The use of MRCT for MASH and PSC was determined in 2017. The Phase IIb clinical trial for MASH and Phase II clinical trial for PSC were conducted in the form of MRCT, and MRCT would also be the approach for the clinical trials going forward for MASH and PSC. We believe MRCTs can expedite global clinical development and facilitate registration in multiple regions across the globe. We use the same study protocol for IND approval of clinical trials and conducting clinical trials in different phases after obtaining IND approvals in each of MRCT’s jurisdictions. The clinical results of the MRCT in various jurisdictions can be used to support registration approval by the competent authorities in those jurisdictions. There are no differences in primary endpoints, extent or type of clinical trials to be conducted across various jurisdictions but might be slight differences in materials to be submitted among the different regulatory bodies.

For Phase IIb MRCT of HTD1801 for MASH indication in the United States, Hong Kong, Mexico and Mainland China, the details of communications with competent authorities have been set forth in the section “— Clinical-Stage Candidates — Core Product HTD1801 — Material Communications with Competent Authorities”. In April 2023, we submitted the Phase IIb study protocol to the FDA and we did not receive any comments or rejections from the FDA within the 30-day clearance period. We also obtained the IND approvals in Hong Kong and Mainland China in August and September 2023, respectively, and filed an IND application in Mexico in July 2023.

For Phase II MRCT of HTD1801 for PSC in the United States, Mainland China and Canada, the details of communications with competent authorities have been set forth in the section “— Clinical-Stage Candidates — Core Product HTD1801 — Material Communications with Competent Authorities”. We obtained IND approvals from the FDA in 2017, and from the NMPA and the Health Canada in 2019.

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The following table sets forth details of our clinical and registration plans of HTD1801 for T2DM, MASH and SHTG in each planned jurisdiction.

Study	Indication	Jurisdictions	Initiation Date	Expected Completion Date	Trial Design	Expected NDA Submission
Phase III	T2DM	China	November 2023	2025	<p>There are two randomized, double-blind, placebo-controlled, dose-ranging Phase III studies to evaluate the efficacy and safety of HTD1801 for monotherapy or add-on therapy after metformin treatment in approximately total 1000 adult subjects with T2DM. In the monotherapy trial, subjects will be administered with placebo BID for four weeks, then divided into two groups. The experiment group will be administered HTD1801 1000 mg BID for 24 weeks and the placebo group will be administered with placebo accordingly. After 24 weeks, both groups will be administered with HTD1801 1000 mg BID for 24 weeks, followed by a four-week safety follow-up period. The primary endpoint of the monotherapy Phase III study is to evaluate changes of HbA1c relative to baseline in the HTD1801 treatment group compared to the placebo group after 24 weeks of treatment. The secondary endpoints are to evaluate a series of physiological indicator levels after 24 and 52 weeks of HTD1801 treatment.</p> <p>In the add-on therapy trial, subjects will be administered with placebo and metformin BID for four weeks, then divided into two groups. The experiment group will be administered HTD1801 1000 mg BID and metformin for 24 weeks and the placebo group will be administered with placebo and metformin accordingly. After 24 weeks, both groups will be administered with HTD1801 1000 mg BID and metformin for 24 weeks, followed by a four-week safety follow-up period. The primary endpoint of the add-on therapy Phase III study is to evaluate changes of HbA1c relative to baseline in the HTD1801 treatment group compared to the placebo group after 24 weeks of treatment. The secondary endpoints are to evaluate a series of physiological indicator levels after 24 and 52 weeks of HTD1801 treatment.</p>	2025

BUSINESS

Study	Indication	Jurisdictions	Initiation Date	Expected		Trial Design	Expected NDA
				Completion Date	Submission		
Phase Ib	MASH	United States Hong Kong Mexico Mainland China	December 2022 October 2023 December 2023 (expected) December 2023 (expected)	2025		The study plans to enroll approximately 210 subjects in the United States, Hong Kong and Mexico and Mainland China with biopsy-confirmed MASH and evidence of stage 2 or stage 3 liver fibrosis. The subjects plans to be randomized 2:1 to receive HTD1801 1,250 mg twice daily (BID) or placebo BID, for up to 60 weeks. The primary endpoint is a decrease of ≥ 2 -points in NAS with ≥ 1 -point decrease of either lobular inflammation or ballooning and no worsening of fibrosis; or resolution of MASH, defined as the overall histopathologic interpretation of “no fatty liver disease” or “fatty liver disease (simple or isolated steatosis) without steatohepatitis” and an NAS of 0 for ballooning and 0 for inflammation and no worsening of fibrosis.	2029
Phase II	SHTG	United States	First half of 2024 ⁽¹⁾	2025		It is a randomized, double-blind, placebo-controlled, Phase II study to evaluate the efficacy and safety of HTD1801 in approximately 60 adult subjects with SHTG (TG level of ≥ 500 mg/dL).	2028

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

Note:

- (1) The reasons for the large time gap between the completion of Phase Ib/IIa clinical trial for hypercholesterolemia in December 2018 in Australia and initiation of Phase II clinical trial for SHTG in first half of 2024 are: (i) we expanded the indication from hypercholesterolemia to SHTG in the Phase II trial by taking reference from trial results of Phase II study for MASH (HTD1801.PCT012) which will also be submitted as supplementary data reference for FDA to assess our IND application for Phase II study of SHTG and (ii) we prioritized resources on the HTD1801 trial for MASH and T2DM.

Material Communications with Competent Authorities

- **For MASH indication:** We have completed a Phase I trial (HTD1801.PCT002) in Australia and a Phase IIa trial (HTD1801.PCT012) in the United States. There are not any overlapping primary efficacy endpoints for the Phase I clinical trial conducted in Australia and Phase IIa clinical trial conducted in the United States for MASH. The FDA concluded that our Phase IIa MASH study could proceed forward based on pre-clinical pharmacology, and human safety and PK data from Phase I trial HTD1801.PCT002 results. We completed the Phase IIa trial and the FDA confirmed we can proceed to Phase IIb trial based on safety and efficacy data from the Phase IIa trial. The Phase IIa and Phase IIb clinical trials are regarded as two standalone trials by the FDA due to their different endpoints and trial designs.

BUSINESS

- **For T2DM indication:** We have completed one Phase I trial (HTD1801.PCT101) in China with the primary endpoints met. We also obtained an approval for initiation of a Phase II trial (HTD1801.PCT103) in China from the NMPA. The Phase II clinical trial was initiated in March 2022 and completed in January 2023. In November 2023, we initiated the two Phase III clinical trials (i.e. one with HTD1801 as a standalone treatment and one with HTD1801 as an add-on therapy with metformin) for the T2DM indication of our self-developed HTD1801 in China. We plan to complete these two Phase III clinical trials in 2025.
- **For PSC indication:** The Company has completed a Phase I trial (HTD1801.PCT002) in Australia, and a Phase II trial (HTD1801.PCT003) for PSC in the United States. The FDA concluded that our Phase II PSC study could proceed forward based on preclinical pharmacology, and human safety and PK data from Phase I trial HTD1801.PCT002 results. We held a successful EOP2 meeting with the FDA and the FDA has no objection for us to commence forward from Phase II clinical trial to conduct a Phase III clinical trial.
- **For PBC indication:** The Company has completed a Phase I trial (HTD1801.PCT002) in Australia, and a Phase II trial (HTD1801.PCT013) for PBC in the United States. The FDA concluded that our Phase II PBC study could proceed forward based on pre-clinical pharmacology, and human safety and PK data from Phase I trial HTD1801.PCT002 results.

We will evaluate commercialization plans for HTD1801 in Australia once we receive market authorisation from the TGA in the future. We had strategically chosen to conduct HTD1801's Phase I clinical trials in Australia because we have taken into account that (i) the technical requirements, the R&D preparation and standards for conducting and completing the clinical trials in Australia, the United States and Mainland China would be relatively similar, according to CIC and that the development and approval process of assessing the robustness of a product candidate in Australia, the United States and Mainland China is comparable with each other; (ii) the standards and expertise of TGA have been consistently recognized by the international biopharmaceutical community, and (iii) the approval processes and clinical trials in Australia is more time-efficient than that of the United States or Mainland China based on our experience. We continue to conduct Phase II clinical trials in the United States because we intend to commercialize HTD1801 in the United States and the Phase II trial evaluates efficacy data in the U.S. population, which allows us to smoothly navigate through FDA regulation. These trials are strategically designed to be in the best interest of the Company.

The grant of approval by the FDA for us to commence the Phase II clinical trial of HTD1801 in the United States for MASH, PSC and PBC demonstrates that the FDA, being Competent Authorities under Chapter 18A of the Main Board Rules have (i) reviewed and taken into account the clinical trial design and data of the Phase I clinical trial in Australia in granting the approval for us to commence the Phase II clinical trials on HTD1801 in the United States and (ii) confirmed its acknowledgement and acceptance of the results of the Phase I clinical trial in Australia and that it had no objection for us to progress to the Phase II clinical trials on HTD1801 based on the clinical results of the Phase I study of HTD1801 in Australia. The completion of Phase I clinical trials in Australia is regarded as comparable to the completion of Phase I clinical trials in the United States

BUSINESS

by the FDA for MASH, PSC and PBC and the FDA does not require us to conduct any additional work or impose any other condition before the commencement of the Phase II clinical trials in the United States on the basis that: (i) it is common practice that a foreign clinical trial being accepted by the FDA provided that the trial meets certain criteria as set out by the FDA, according to CIC, and (ii) the FDA accepted our well-designed, well conducted Phase I clinical trials in Australia on healthy subjects as support for an IND because our Phase I clinical trials in Australia meet certain criteria, including that our Phase I clinical trials in Australia were conducted in accordance with ICH GCP, which have been incorporated by reference in the Therapeutic Goods Regulations 1990 in Australia, and the FDA is able to validate the data from the Phase I clinical trials in Australia through an onsite inspection, if necessary.

The following table sets forth a detailed chronology of the material communications with the TGA and FDA regarding our Phase I trials conducted in Australia and Phase II clinical trials conducted or to be conducted in the United States for MASH, PSC, PBC and SHTG studies. We have not yet commenced any material communications with the FDA in relation to the pre-clinical and Phase Ib/IIa clinical trials conducted for hypercholesterolemia in Australia.

Clinical trials	Jurisdiction	Application to the FDA/TGA	Approval received from the FDA/TGA	Material reviewed by the FDA	Material reviewed by the TGA	Scope of IND approval	Additional information requested by the FDA/TGA regarding the pre-clinical and Phase I results	Any proposed or recommended revisions to the study protocol by the FDA/TGA
Phase IIa trial (HTD1801.PCT012) for MASH with T2DM and Phase IIb trial (HTD1801.PCT014) for MASH with T2DM or prediabetes	United States	September 2018	October 2018	PK, safety and tolerability results from preclinical results, Phase I trial (HTD1801.PCT002) results, Phase IIa trial (HTD1801.PCT012) study protocol and Phase IIb trial (HTD1801.PCT014) study protocol	N/A	Approval with non-hold comments ⁽¹⁾	None	No
Phase II trial (HTD1801.PCT003) for PSC	United States	November 2017	December 2017	PK, safety and tolerability results from preclinical results, Phase I trial (HTD1801.PCT002) results, Phase II trial (HTD1801.PCT003) study protocol	N/A	Unconditional approval	None	No

BUSINESS

Clinical trials	Jurisdiction	Application to the FDA/TGA	Approval received from the FDA/TGA	Material reviewed by the FDA	Material reviewed by the TGA	Scope of IND approval and Phase I results	Additional information requested by the FDA/TGA regarding the pre-clinical protocol by the	
							Any proposed or recommended revisions to the study	FDA/TGA
Phase II trial (HTD1801.PCT013) for PBC	United States	October 2020	January 2021	PK, safety and tolerability results from preclinical results, Phase I trial (HTD1801.PCT002) results, Phase II trial (HTD1801.PCT013) study protocol	N/A	Approval with non-hold comments ⁽²⁾	None	No
Phase I trial (HTD1801.PCT002) for healthy subjects	Australia	February 2017	March 2017	N/A	PK, safety and tolerability results from preclinical results, Phase I trial (HTD1801.PCT002) study protocol	Unconditional approval	None	No
Phase Ib/IIa (HTD1801.PCT004) for Hypercholesterolemia.	Australia	December 2017	January 2018	N/A	PK, safety and tolerability results from preclinical results, Phase I trial (HTD1801.PCT002) results, Phase Ib/IIa (HTD1801.PCT004) study protocol	Unconditional approval	None	No

Notes:

1. The FDA issued Study May Proceed Letter to allow us to proceed the Phase IIa study with non-hold comments to (1) stratify randomization by HbA1c at screening, and (2) use histologic endpoints and clinical endpoints for the Phase IIb and Phase III trial(s) and collect data from this Phase IIa proof of concept trial that could assist with the design of the Phase IIb and Phase III trial(s). We filed the revised protocol to reflect FDA’s comments.
2. The FDA issued Safe to Proceed Letter to allow us to proceed the Phase II study with non-hold comments to collect sparse PK samples in all subjects and intensive PK samples in a subset of patients. We collected additional PK samples in the PBC clinical trial accordingly to reflect FDA’s comments.

In addition, for T2DM study, we have completed a Phase I trial in China and the NMPA has no objection for us to commence our Phase II trial in China. We have also completed a Phase II clinical trial for PSC and the FDA confirmed no objection to commence Phase III clinical trial. Our clinical development demonstrates that for each indication of T2DM, MASH, PSC and PBC above, it has been developed beyond concept stage, namely it has completed Phase I trial and the competent authorities had no objections to initiate Phase II study, it is eligible as Core Product under the Guidance Letter GL92-18 of the Stock Exchange.

BUSINESS

The following table sets forth details of our material communications with competent or regulatory authorities for our key ongoing and completed clinical trials.

Study	Study Number	Phase	Study Sites	Competent or regulatory authorities	Details of IND application and approvals	Status
MASH Study	HTD1801.PCT012	Ila ⁽¹⁾	US	FDA	<p>(i) In September 2018, we submitted study protocol for IND approval of Phase IIa study (HTD1801.PCT012) for MASH with T2DM.</p> <p>(ii) On October 11, 2018, the FDA communicated with us by email to provide comments on our study protocol including conservative enrollment criteria and expanded safety monitoring.</p> <p>(iii) On October 16, 2018, we discussed with FDA for the entry criterion of HbA1c for T2DM.</p> <p>(iv) On October 24, 2018, the FDA issued Study May Proceed Letter to allow us to proceed the Phase IIa study with non-hold comments to (1) stratify randomization by HbA1c at screening, and (2) use histologic endpoints and clinical endpoints for the Phase IIb and Phase III trial(s) and collect data from this Phase IIa trial that could assist with the design of the Phase IIb and Phase III trial(s).</p> <p>(v) On November 13, 2018, we filed the revised protocol to reflect FDA’s comments.</p>	Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the FDA.
	HTD1801.PCT014	Iib ⁽¹⁾	US	FDA ⁽²⁾	<p>(i) On October 13, 2022, we filed the study protocol for HTD1801.PCT014 for MASH with T2DM or prediabetes to the FDA.</p> <p>(ii) On February 24, 2023, the FDA issued advice/information request letter for statistical comments and recommendations on the protocol.</p> <p>(iii) On April 4, 2023, we provided an updated clinical protocol, and we did not receive any comments or objections from the FDA within the 30-day clearance period.</p>	Ongoing (150 subjects enrolled as of November 23, 2023)
	HTD1801.PCT014	Iib ⁽¹⁾	Hong Kong	The Department of Health ⁽²⁾	<p>(i) On June 28 and 29, 2023, we submitted IND applications for two sites to initiate Phase IIb study (HTD1801.PCT014) for MASH with T2DM or prediabetes in Hong Kong.</p> <p>(ii) On August 24, 2023, the Department of Health issued the two approvals without inquiries or objections.</p>	Ongoing (2 subjects enrolled as of November 23, 2023)
	HTD1801.PCT014	Iib ⁽¹⁾	Mexico	The Federal Commission for Protection against Sanitary Risks ⁽²⁾	On July 11, 2023, we submitted an IND application to initiate Phase IIb study (HTD1801.PCT014) for MASH with T2DM or prediabetes in Mexico.	To be initiated in December 2023
	HTD1801.PCT014	Iib ⁽¹⁾	Mainland China	NMPA ⁽²⁾	<p>(i) On June 13, 2023, we submitted an IND application to initiate Phase IIb study (HTD1801.PCT014) for MASH with T2DM or prediabetes in Mainland China.</p> <p>(ii) On September 8, 2023, the NMPA issued the approval without inquiries or objections.</p>	To be initiated in December 2023

BUSINESS

Study	Study Number	Phase	Study Sites	Competent or regulatory authorities	Details of IND application and approvals	Status
T2DM study	HTD1801.PCT101	I	Mainland China	NMPA	(i) In March 2021, we submitted our IND application with study protocols of study HTD1801.PCT101 to the NMPA. (ii) In May 2021, The NMPA issued an umbrella IND approval ⁽³⁾ for Phase I, Phase II and Phase III T2DM studies and recommended us to communicate with the NMPA regarding relevant issues of pharmacological study before Phase III study	Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the NMPA.
	HTD1801.PCT102	Ib	Mainland China	NMPA	(iii) In April 2023, we submitted the Phase III clinical trial protocol and the study results of Phase I and Phase II clinical trials for T2DM in China to the NMPA for review. (iv) In the EOP2 meeting in October 2023, the NMPA provided formal confirmation to proceed to the Phase III clinical trials in China.	Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the NMPA.
	HTD1801.PCT103	II	Mainland China	NMPA	(v) The two Phase I clinical trials (HTD1801.PCT101 and HTD1801.PCT104) and the Phase Ib clinical trial (HTD1801.PCT102) are all required by the NMPA.	Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the NMPA.
	HTD1801.PCT104	I	Mainland China	NMPA		Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the NMPA.
	HTD1801.PCT105	III	Mainland China	NMPA		Ongoing (Two subjects dosing as of November 21, 2023)
	HTD1801.PCT106	III	Mainland China	NMPA		Ongoing (Two subjects dosing as of November 21, 2023)

BUSINESS

Study	Study Number	Phase	Study Sites	Competent or regulatory authorities	Details of IND application and approvals	Status
PSC study	HTD1801.PCT003	II	US	FDA	<ul style="list-style-type: none"> (i) On November 9, 2017, we submitted our IND application with study protocols of study HTD1801.PCT003 to the FDA. (ii) On December 5, 2017, the FDA provided written questions on the trial design of the protocol. (iii) On December 7, 2017, we provided an email with response to the questions on our study protocol to the FDA. (iv) On December 8, 2017, the FDA issued Study May Proceed Letter to allow us to proceed the Phase II study. (v) On December 13, 2017, we filed revised protocol according to the Study May Proceed Letter. 	Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the FDA.
	HTD1801.PCT003	II	Mainland China	NMPA	<ul style="list-style-type: none"> (i) In July 2019, we submitted our IND application with study protocols of study HTD1801.PCT003 to the NMPA. (ii) In October 2019, The NMPA issued an IND approval for PSC studies and also recommended us to (1) assess benefit and risk of the safety data of HTD1801.PCT004 to determine whether to support the conduct of HTD1801.PCT003 and communicate with the NMPA at a critical stage; and (2) file a request for a communication meeting with the NMPA before Phase III study. 	Completed in the United States and Canada: we achieved each endpoint set out in the clinical trial design. Due to COVID-19 pandemic, we did not initiate the Phase II clinical trial in China. After the completion of Phase II trials in the United States and Canada, the Phase II trial in China is not required because the Phase II trials in the United States and Canada had met the endpoints.
	HTD1801.PCT003	II	Canada	Health Canada ⁽⁴⁾	<ul style="list-style-type: none"> (i) In October 2019, we submitted our IND application with study protocols of study HTD1801.PCT003 to the Health Canada. (ii) In November 2019, the Health Canada issued no objection letter for HTD1801.PCT003 clinical study. 	Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the Health Canada.
PBC Study	HTD1801.PCT013	II	US	FDA	<ul style="list-style-type: none"> (i) On January 5, 2021, we filed HTD1801.PCT013 protocol with amendments for PBC to the FDA. (ii) On January 26, 2021, the FDA issued Safe to Proceed Letter to allow us to proceed the Phase II study with non-hold comments to collect sparse PK samples in all subjects and intensive PK samples in a subset of patients. (iii) In August 2023, we submitted the clinical data from the Phase II clinical trial for PBC to the FDA. 	Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the FDA.

BUSINESS

Study	Study Number	Phase	Study Sites	Competent or regulatory authorities	Details of IND application and approvals	Status
SHTG study	HTD1801.PCT201	II	US	FDA	(i) On February 9, 2023, we submitted a pre-IND meeting request to the FDA to discuss the development of HTD1801 for treatment of patients with SHTG. (ii) On February 15, 2023, the FDA granted our pre-IND meeting. (iii) On March 13, 2023, we submitted background package with questions to the FDA for the discussion of initiation of study HTD1801.PCT201 in the pre-IND meeting. (iv) On April 7, 2023, the FDA provided written response to our questions in the background package. According to the FDA, the available nonclinical and clinical data appear adequate to support the initiation of the proposed phase II study in subjects with SHTG.	To submit IND application with the FDA by the end of 2023 and initiate Phase II clinical trial in 2024.
Hypercholesterolemia Study	HTD1801.PCT004	Ib/IIa	Australia	TGA	(i) On December 13, 2017, we filed application of HTD1801.PCT004 study for hypercholesterolemia with the Bellberry Human Research Ethics Committee (HREC). (ii) On January 3, 2018, we held a meeting with the HREC for HTD1801.PCT004 study for hypercholesterolemia. (iii) On January 16, 2018, the HREC approved the HTD1801.PCT004 study for hypercholesterolemia. (iv) On January 18, 2018, we registered the HTD1801.PCT004 study for hypercholesterolemia with TGA.	Completed: we achieved each endpoint set out in the clinical trial design. No adjustments were made to the endpoint or extension of the study as required by the TGA.

Notes:

- (1) In line with market practice, our Phase II studies are divided into Phase IIa and Phase IIb. Phase IIa studies are pilot studies designed to demonstrate clinical efficacy or biological activity, the proof of concept study. Phase IIb studies are designed to determine the optimal dose at which the drug shows biological activity with minimal side-effects, the dose-finding study. Such trial design can reduce the risk of trial failure and is cost-efficient because the sponsor can decide whether to modify Phase IIb trial design and initiate Phase IIb study based on Phase IIa study results.
- (2) The clinical trial study sites in Hong Kong, Mexico, and Mainland China for MASH study are regulated by the Department of Health of Hong Kong, the Federal Commission for Protection against Sanitary Risks of Mexico and the NMPA of Mainland China, respectively.
- (3) The original protocol communicated with the CDE covers Phase I, Phase II and Phase III clinical trials of HTD1801, and Phase I, Phase II and Phase III clinical trials are three separate trials with different endpoints. On July 5, 2023, our PRC Legal Advisor consulted the CDE regarding the commencement of a Phase III clinical trial after completion of the Phase II clinical trial, and commencement of a Phase II clinical trial after the completion of the Phase I clinical trial. According to the CDE, (i) the NMPA is not responsible for either certifying or providing assurance for the completion of any clinical trials and the NMPA will not confirm the completion of a Phase I clinical trial before initiation of the Phase II clinical trial, and it will not confirm the completion of a Phase II clinical trial before initiation of the Phase III clinical trial, (ii) for Phase I, Phase II and Phase III clinical trials for new drugs, the NMPA has optimized its review and approval procedure and accordingly adopts one-time approvals instead of phased declarations, reviews and approvals, and (iii) a company shall report information about suspected and unexpected serious adverse reactions and other potential serious safety risks to the CDE during the clinical trials, and submit the application for communication session to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol upon the completion of Phases I and II clinical trials before commencing the Phase III clinical trial. Therefore, a company does not have to obtain additional approval or confirmation from the NMPA for commencing the Phase II after it completes the Phase I trial if that company has obtained an umbrella IND approval to carry out Phase I, Phase II and Phase III clinical trial without any pre-requisite conditions imposed.
- (4) The clinical trial study site in Canada for PSC is regulated by Health Canada.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET HTD1801 SUCCESSFULLY.

Phase I clinical-stage product HTD4010

Overview

Our HTD4010 is a polypeptide drug for the treatment of complex, life-threatening diseases such as AH, which is caused by chronic heavy alcohol abuse or a sudden, drastic increase in alcohol consumption. It is characterized by severe inflammation and, ultimately, liver failure and death. There is currently no approved treatment for AH and only a few drug candidates are in clinical development. The current standard of care focuses on symptom management, including abstinence, treating inflammation and providing nutrition. Our HTD4010, however, has the potential to address the underlying disease mechanism. In animal studies, for example, HTD4010 demonstrated potent beneficial effects for AH, alleviating characteristic signs of severe liver injury and reducing systemic inflammation. Our completed Phase I clinical trial of HTD4010 on healthy subjects also demonstrated its favorable safety profile.

Mechanism of Action

AH is a type of alcohol-associated liver disease ("ALD") characterized by acute liver inflammation. A variety of genetic, lifestyle and environmental factors may contribute to AH, including alcohol consumption, obesity and ethnicity. Severe cases of AH can lead to the progression of liver fibrosis and cirrhosis, even a high risk of death. Toll-like receptor 4 ("TLR4") is an activator of some proinflammatory cytokines that play an important role in mediating the innate immune response during the progress of AH.

HTD4010 is a synthetic peptide composed of 15 amino acids, homologous to an active peptide fragment of the human regenerating islet-derived protein 3 α ("Reg3 α "), or "pancreatic associated protein" ("PAP"). HTD4010 acts as a TLR4 inhibitor potentially capable of dampening the innate immune response and liver inflammation of AH pathogenesis. Thus, HTD4010 has anti-apoptotic, anti-inflammatory, anti-bacterial, and pro-regenerative effects in the pancreas, GI tract and other tissues, both in vitro and in vivo.

Market Opportunity and Competition

AH is caused by chronic heavy alcohol use or a drastic increase in alcohol consumption. It is characterized by severe inflammation and, ultimately, liver failure and death. According to CIC, the market size of AH drugs is expected to reach US\$1.1 billion, US\$2.9 billion and US\$2.2 billion in 2032 in China, the United States and Europe, respectively. Currently, there is no approved treatment for AH, and some drugs are in development. Corticosteroids are the only recommend treatment, and the current standard of care focuses on abstinence, treating inflammation, and providing nutrition, which is often inadequate in moderate and severe patients, indicating unmet medical needs.

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The following table sets forth the details of all AH drugs under development globally.

Pipeline of AH drugs, registered at ClinicalTrials

Drug Name	Target	Company	Indications	Phase	First Posted Date	Trial Number	Competent Authority
TAK-242	TLR4	Akaza Bioscience	AH	II	2020/11/06	NCT04620148	FDA
DUR-928	DNMTs	Durect	AH	I Ib	2020/09/24	NCT04563026	FDA
Canakinumab	IL-1	Novartis	AH	II	2018/12/13	NCT03775109	FDA
INT-787	FXR	Intercept Pharmaceuticals	SAH	II	2022/12/06	NCT05639543	FDA

Note: Information as of November 27, 2023.

Source: Clinical trials; China Insights Consultancy

Summary of Clinical Trial for HTD4010

Phase I clinical trial of HTD4010 in healthy adults in Australia

Overview. This was a Phase I, first-in-human, randomized, double-blind study to assess safety and tolerability, PK and PD effects of HTD4010 in healthy adults in Australia. The primary endpoint was incidence, severity and causality of adverse events.

Trial design. A total of 32 healthy subjects were randomized 3:1 to receive single doses at four levels (50, 100, 200, or 300 mg) of HTD4010 or placebo. The PK procedures involved collecting 5 mL of peripheral blood from the arm contralateral to that of drug administration at the following time points: pre-dose (5 min prior to dosing) and 5 min, 15 min, 30 min, 1 h, 2 h, 4 h, 8 h, 24 h post-dose. To maintain the study blind, blood samples were taken from all subjects receiving either HTD4010 or placebo. The inclusion criteria for the Phase I clinical trial included: (1) body mass index ≥ 18.0 to ≤ 30.0 kg/m²; (2) non-diabetic, fasting plasma glucose < 5.6 mmol/L; female subjects who must be non-pregnant and non-lactating, and either surgically sterile (e.g., tubal occlusion, hysterectomy, bilateral salpingectomy, bilateral oophorectomy) or post-menopausal for ≥ 12 months; and (3) male subjects who must be surgically sterile, abstinent or if engaged in sexual relations of child-bearing potential, the participant and his partner must be using an acceptable, highly effective, contraceptive method from screening and for a period of 60 days after the last dose of study drug; and (4) ability to provide written informed consent. The exclusion criteria included: (1) systolic blood pressure > 160 mmHg and/or diastolic blood pressure > 90 mmHg at screening; (2) pregnant or lactating women; (3) participation in an investigational study within 30 days prior to dosing or five half-lives within the last dose of investigational product whichever is longer; (4) current use of any prescription or over-the-counter medications, including herbal products and supplements, within 14 days prior to Day one or five half-lives, whichever is longer; use of ≤ 2 g paracetamol per day is allowed prior to and during the study at the investigator's discretion; (5) any use of non-steroid anti-inflammatory drugs within 7 days prior to dosing; (6) history of any major surgery within six months prior to screening; (7) history of any serious adverse reaction or hypersensitivity to any of the product components; or (8) use of parenterally administered proteins or antibodies within 12 weeks of screening.

Trial status. We initiated the Phase I clinical trial of HTD4010 in healthy adults in Australia in October 2015 and completed the study in March 2016.

BUSINESS

Safety data. The most common AE was injection site reaction. All AEs reported were mild in intensity, which were all resolved without action taken. No subjects withdrew due to an AE, and no SAEs were reported. HTD4010 was well-tolerated up to the highest dose level (300 mg).

PK finding. This study indicate that single doses of HTD4010 exhibit linear PK over doses ranging from 50 to 300 mg.

Clinical Development Plan for HTD4010

As HTD4010 is internally discovered and developed by us, we maintain the global rights to develop, manufacture and commercialize HTD4010.

In October 2015, we received an approval from the TGA to initiate a Phase I clinical trial of HTD4010 (HTD4010.PCT001) in healthy adults in Australia. We completed the Phase I clinical trial of HTD4010 in Australia in March 2016. We expect to initiate Phase II clinical trial of HTD4010 for AH in the United States as early as the end of 2024. This Phase II, multi-center, open-label, dose escalation study will evaluate the safety, PK, and efficacy of HTD4010 in approximately 24 clinically diagnosed subjects with AH. Subjects will be followed-up for a total of 28 days. The large time gap between the completion of the Phase I clinical trial and initiation of the Phase II clinical trial for HTD4010 was because we prioritized our resources to the clinical development of our Core Product HTD1801.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET HTD4010 SUCCESSFULLY.

PRECLINICAL STAGE CANDIDATES

HTD1804

We are evaluating HTD1804 for the treatment of obesity. Obesity is a rising global health risk associated with a wide range of comorbidities, primarily cardiovascular disease and T2DM. The current treatment regimen may include lifestyle therapy, anti-obesity medication and surgical intervention based on disease stage. There are two innovative medications approved for indication of obesity globally, but none has been approved by NMPA. Some drugs are under clinical trial development in China. Preclinical studies have shown that HTD1804 may be an important modulator in energy metabolism, cardiovascular protection and lipid- and sugar-lowering effects.

HTD1805

Our HTD1805 is a preclinical-stage, multifunctional small molecule drug for the treatment of metabolic diseases. HTD1805 is prepared with the similar design rational as HTD1801, and the efficacy and safety profiles of the active moieties forming demonstrate the potential of HTD1805 in treating various metabolic diseases.

BUSINESS

HTD2802

Our HTD2802 is a preclinical-stage, multifunctional drug for the treatment of IBD, a common GI tract disorder. The existing IBD drugs fail to adequately control the symptoms and complications in many patients. In preclinical studies, HTD2802 has shown positive effects on stool formation and occurrence of fecal occult blood, as well as reducing inflammatory cytokine levels and preventing pathological injury.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET HTD1804, HTD1805, and HTD2802 SUCCESSFULLY.

COLLABORATION AGREEMENT

HTD1801 License-Out Agreement

On August 29, 2020, we entered into a license-out agreement (“**HTD1801 Agreement**”) with Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司) (“**Hepalink**”) to promote the commercialization of innovative drug formulations containing HTD1801 in Europe. Hepalink is a leading multinational biopharmaceutical company dual-listed in Hong Kong and mainland China, a connected person of the Company. The commercial rationale for granting Hepalink the exclusive rights to commercialise MASH and PSC indications of our Core Product in Europe is that we do not plan to expand European market by our own due to cost efficiency consideration. In addition, Hepalink’s strong commercialization capabilities in Europe with an experienced and specialized in-house sales and marketing team for pharmaceutical products with international exposure enable us to achieve market penetration of our Core Product in Europe.

Pursuant to the HTD1801 Agreement, we have granted Hepalink an exclusive, sublicensable (solely to Hepalink’s wholly-owned subsidiaries), non-transferable license of HTD1801 for all aspects of commercialization for the indications of MASH and PSC in Europe, including, but not limited to, distribution, dispensing, promotion, sales, branding, pricing, import, export and use of the product, use of the product name and packaging (“**Commercialization Right**”). Under the HTD1801 Agreement, we reserved the rights to (i) research and develop HTD1801 worldwide; (ii) manufacture HTD1801 worldwide; (iii) commercialize HTD1801 for any indications outside Europe; (iv) commercialize HTD1801 in any region in Europe for indications other than for MASH and PSC; and (v) import and export HTD1801 for the purposes described above. Hepalink is the owner of new intellectual property rights generated from the commercialization of HTD1801 by Hepalink.

As we license-out Commercialization Right in Europe for only two indications, we have exclusive control over R&D activities, manufacturing, ownership of and protection for intellectual properties, registration for HTD1801. We are the sole decision-maker for the aforesaid matters. Hepalink enjoys the exclusive Commercialization Right and is responsible for sales of HTD1801 for the indication of MASH and PSC in Europe and may determine at its sole discretion for the commercialization and sales plan of HTD1801 for these two indications in Europe. All disputes arising from the contract shall be settled amicably by the parties. If the dispute is not resolved by negotiation within 15 days from the date of occurrence, either party shall have the right to submit the dispute to arbitration. Hepalink shall use commercially reasonable efforts with good faith to

BUSINESS

implement commercialization of HTD1801 for the indication of MASH and PSC in Europe and bear the cost for such commercialization activities. We will bear all the costs, other than costs incurred for commercialisation activities, in relation to the R&D, manufacturing, registration and other costs if any for HTD1801 in Europe. We are responsible for applying for marketing authorization, registration of pharmaceutical products, registration of drugs or drug licenses, or any license or registration required for marketing or sale for HTD1801 for the indication of MASH and PSC in Europe, preparing all documents required for marketing authorization, registration or license and communicating with the regulatory authorities in Europe. We are the sole trial sponsor and marketing authorisation holder of HTD1801 for all indications in all jurisdictions.

The cost of manufacturing HTD1801 for the two indications in Europe will be transferred to Hepalink through payment to be received in accordance with the HTD1801 Agreement. The pricing policy is based on our supply price of HTD1801 in similar licensed territories and Hepalink's target sales. In consideration of the license grant, Hepalink shall pay milestone payments, including (i) MASH indication milestone payments, including the first milestone fee of RMB50.0 million payable no later than five business days from the date of the new drug application of HTD1801 for MASH indication obtaining the first marketing authorization in any licensed territory in European Union, UK or Switzerland and the second milestone fee of RMB50.0 million payable no later than the first anniversary of obtaining such marketing authorization; (ii) PSC indication milestone payments, including the first milestone fee of RMB30.0 million payable no later than five business days from the date of the new drug application of HTD1801 for PSC indication obtaining the first marketing authorization in any licensed territory in European Union, UK or Switzerland and the second milestone fee of RMB30.0 million payable no later than the first anniversary of obtaining such marketing authorization. In addition, during the royalty term of HTD1801 in Europe, Hepalink is also obligated to pay tiered royalty payments calculated as a percentage ranging from 10% to 25% of total annual net sales of HTD1801 in Europe. After expiration of the royalty term (the patent term and/or other regulatory exclusivity terms under administrative protection) of HTD1801 in Europe, both parties shall agree in advance on a separate written agreement regarding the sales royalties if Hepalink plans to continue sales of HTD1801. If the parties do not reach a separate agreement on the new sales royalties and Hepalink continues to sell HTD1801 in Europe after expiration of the royalty term, then sales royalties shall continue to accrue based on the foregoing royalty rates.

In the event that we propose to transfer our interest in the intellectual properties and know-how in relation to HTD1801 for the indications of MASH and PSC in Greater China, Hepalink is granted a right of first refusal in connection with the acquisition of the above interest. If Hepalink decides to exercise its right of first refusal, it shall notify us within 15 days of receiving our transfer notice, and both parties should use their best efforts to negotiate and sign a transfer agreement. If no agreement is signed within 60 days of receiving Hepalink's exercise notice, the right of first refusal shall be terminated upon written notice by the Company to Hepalink. If Hepalink does not expressly exercise the right of first refusal within 15 days after receiving our transfer notice, Hepalink shall be deemed to have waived its right of first refusal. The grant of the first right to acquire the intellectual properties and know-how of HTD1801 for the indications of MASH and PSC in the Greater China territory to Hepalink will not affect our operations as the consideration for the acquisition will not be less favorable than the amount offered by other independent third parties.

BUSINESS

The term of HTD1801 Agreement shall continue in full force until the date of expiration of the last applicable royalty term (which is either the patent expiration date or the expiration date of regulatory exclusion for other administrative protections, whichever is later), or the date of earlier termination in accordance with the terms therein, whichever is earlier. We have the right to terminate the HTD1801 Agreement and are not required to return any payment that we have received from Hepalink under the HTD1801 Agreement, if (i) Hepalink fails to pay the milestone fee and sales royalties payment on time and rectify this breach within one month after our written demand; (ii) Hepalink fails to commence marketing HTD1801 within one year from the date of HTD1801 obtaining the first marketing authorization in any one or more of the licensed territories in European Union, UK or Switzerland; (iii) Hepalink or any of its affiliates directly or indirectly initiates, engages in, or participates in a patent challenge regarding HTD1801, or knowingly, willfully, or indulgently assists in initiating such a patent challenge; (iv) Hepalink or its sublicensee becomes insolvent, enters bankruptcy, liquidation or reorganization proceedings; or (v) Hepalink fails to obtain and maintain comprehensive general liability insurance for HTD1801. Hepalink has the right to terminate the HTD1801 Agreement, if (i) we enter bankruptcy, liquidation or reorganization proceedings; or (ii) we fail to obtain and maintain comprehensive general liability insurance for HTD1801. Both parties may agree in writing to terminate the HTD1801 Agreement. If one party is unable to exercise its rights under the HTD1801 Agreement due to a breach by the other party, and the breaching party fails to rectify the breach within one month of receipt of notice, the non-breaching party shall be entitled to suspend performance of its obligations under the HTD1801 Agreement to the breaching party or terminate the HTD1801 Agreement. If Hepalink's actual sales in each of two consecutive fiscal years is lower than the applicable target sales for the applicable fiscal year, we have the right to terminate the HTD1801 Agreement but need to return to Hepalink 50% of the milestone payments that have been received by us.

In the event of termination of the HTD1801 Agreement, (i) the Commercialization Right granted to Hepalink and its sublicensee shall terminate; (ii) Hepalink shall use commercially reasonable efforts to cooperate with us or our designee to achieve a smooth and orderly transfer of commercialization of HTD1801 in Europe; and (iii) if the first commercial sale has occurred before the termination of the HTD1801 Agreement, upon request by us, Hepalink shall use commercially reasonable efforts to continue to distribute HTD1801 in each licensed territory in which regulatory approval for HTD1801 has been obtained, until we notify Hepalink in writing an alternative supplier or distributor for HTD1801, but in no event shall Hepalink be required to do so after six months upon termination. One party of the HTD1801 Agreement shall indemnify and hold harmless the other party from losses suffered by the other party arising from any breach of the breaching party's obligations or representations and warranties under the HTD1801 Agreement. One party of the HTD1801 Agreement shall not be liable to the other party for consequential or punitive damages resulting from the breach.

The commercial rationales for only out-licensing MASH and PSC out of five indications of HTD1801 in Europe include (i) the clinical trials of HTD1801 for those two indications were at the most advanced clinical stage when the agreement was reached, and (ii) commercialization of MASH and PSC drugs is more likely to capture the market in Europe since no therapies have been approved for MASH and PSC there.

BUSINESS

The long period of clinical development suspension of the PSC indication of HTD1801 since the completion of the Phase II clinical trial in August 2020 will not impact HTD1801 Agreement. Hepalink was not involved in the research and development of HTD1801 and there is not any R&D personnel transferred from Hepalink to us since the discovery of HTD1801.

RESEARCH AND DEVELOPMENT

We believe that our continued research and development is the key driver of our business growth and competitiveness. Our R&D efforts are primarily driven by unmet clinical demand in complex diseases with a mission of treating the patients as a whole, by targeting multiple disease-critical pathways synergistically to improve overall clinical benefits in a well-balanced manner.

Our R&D team

Our R&D team has strong expertise, deep understanding, and broad development experience in metabolic and digestive diseases. Our R&D team pioneered the identification of compounds designed to modulate multiple pathways underlying chronic diseases, providing a unique advantage in addressing the unmet clinical needs across complex pathologies. Our R&D team is led by a team of world-class scientists with years of drug development experience. As of the Latest Practicable Date, our core R&D personnel consisted of 11 members covering the fields of chemistry, biology, pharmacology and medicine. Our core R&D personnel have been working in the biopharmaceutical industry for an average of 15 years. 10 of our core R&D personnel have been involved in and contributed to the R&D activities of the Core Product. During the Track Record Period, none of core R&D personnel left our Group. To incentivize core R&D personnel to remain at our Group, in addition to salary and cash incentives, we have provided share incentives that vest over time. However, the loss of our core R&D personnel could impede the achievement of our research, development and commercialization of our Core Product. For details, see “Risk Factors — Risks Relating to Our Business and Industry — Our future success depends on our ability to retain key executives and to attract, hire, retain and motivate other qualified and highly skilled personnel” in this document.

Our R&D team is generally responsible for the global development of our Core Products and other pipeline products. Our R&D team has the capacity to conduct nine clinical programs at various development stages in China and other jurisdiction. For our internally discovered and developed drug candidates, we conducted drug discovery, quality assurance and clinical activities including: (i) coordinating all clinical development activities; (ii) designing the key aspects of the clinical studies; (iii) designing and coordinating the selection process for qualified CROs to assist in engaging clinical sites and coordinating clinical studies once commenced; (iv) supervising the clinical studies; and (v) overseeing extensive regulatory outreach and coordination in China and other jurisdictions.

BUSINESS

The following table sets forth a breakdown of the number of R&D team by function and jurisdiction as of the Latest Practicable Date:

Function of R&D team	Jurisdiction	Number of employees
Early discovery	China	4
Clinical development	China	25
	United States	7
Regulatory affairs	China	5
Quality Assurance	China	4
Total		45

The following table sets forth the identities, positions, expertise of core R&D personnel and their involvement and contributions to the R&D activities since the discovery of the Core Product and up to the Latest Practicable Date. There is not any core R&D personnel that have left the Company since the discovery of the Core Product.

Identities	Positions	Expertise	Involvement and contributions to the R&D activities since the discovery of the Core Product	Date of joining our Group
Dr. LIU Liping (劉利平)	CEO	Over 24-year experience of drug R&D with education experiences in Johns Hopkins University and Nankai University	Drug discovery of the Core Product	November 15, 2011
Ms. YU Li (于莉)	Vice president	Over 20-year experience of drug R&D, registration and management with education experience in Shanghai University of Traditional Chinese Medicine	Registration and project management of the Core Product	November 15, 2011
Mr. LIU Kui (劉奎)	Senior director ⁽¹⁾	Over 15-year experience of medical experiments with education experience in Fudan University	Medical experiments of the Core Product	January 4, 2022
Ms. YU Meng (于萌)	Deputy general manager	Over eight-year experience of clinical trial management with education experience in University of Nevada, Reno	Clinical trial management of the Core Product	May 4, 2015
Ms. BAI Ru (白茹)	Director of non-clinical development	Over 11-year experience of preclinical trial R&D with education experience in Nankai University	Preclinical trials of the Core Product	February 6, 2012
Dr. MACCONELL Leigh Anne	Chief development officer	Over 23-year experience of clinical trial R&D with education experience in University of California, San Diego	Clinical trials of the Core Product ⁽²⁾	February 1, 2021

BUSINESS

Identities	Positions	Expertise	Involvement and contributions to the R&D activities since the discovery of the Core Product	Date of joining our Group
Mr. CHEN	Drug formulation manager	Over 10-year experience of drug formulation with education experience in Nanjing University	CMC of the Core Product	March 13, 2019
Dr. CHEN	Senior vice president	Over 17-year experience of clinical trial pharmaceutical R&D with education experience in State University of New York, Buffalo	Regulatory affairs & quality assurance of the Core Product	January 3, 2022
Mr. FU Xinxiang (付鑫祥)	Director of CMC	Over eight-year experience of CMC with education experience in Nankai University	CMC of the Core Product	May 18, 2015
Mr. XIE Liming (謝黎明)	Clinical quality assurance manager	Over eight-year experience of clinical trial quality management with education experience in University of Southern California	Clinical trial quality management of the Core Product	July 27, 2015

Note:

- (1) The term “director” refers to the working title of the employee, not the member of the Board.
- (2) Dr. MACCONELL focused on clinical trial management and non-clinical development, especially for the clinical trials of the PBC and MASH indication as well as communication with the FDA regarding the EOP2 meeting for the PSC program. Prior to the joining of Dr. MACCONELL, the rest of the core R&D personnel had sufficient experience to support the R&D of our Core Product and had been contributing to the R&D of the Core Product throughout the process under the leadership of Dr. LIU Liping, including but not limited to drug discovery and clinical trial management, as set out in the table above.
- (3) Dr. MA Tianwei (馬天偉) is one of the core R&D personnel with the position of vice president of discovery research. He joined our Group on February 1, 2023, and has over 20-year experience of drug R&D with education experiences in University of Georgia, Beijing Medical University and Nankai University.

Our FUSIONTX™ development approach

Achieving good balances of efficacy and safety is the major challenge in developing multifunctional and multi-target therapies. The successful development of HTD1801 enabled us to establish the FUSIONTX™ drug discovery approach that ensures higher probability of success for the design of multifunctional and multi-target drug candidates, through which, we integrate real-world clinical data, network pharmacology, known and established molecules with desired therapeutic benefits and known safety profiles to design novel, multifunctional drug candidates to treat complex diseases with a systemic approach. Drug discovery and design through this approach enables systematic, precise, and efficient early-stage drug development that potentially facilitates a higher rate of clinical success at an accelerated pace and lowers development risks, enabling our sustained pipeline expansion. We believe our approach in creating multifunctional drug candidates is paradigm-shifting and could lead to disruptive discovery and development of next-generation therapies in many diseases.

BUSINESS

Our FUSIONTX™ development approach serves as the foundation for our continued discovery and design of multifunctional drugs. The platform technology is self-developed. In addition to our in-house know-how, we have also leveraged external AI technologies as a supplementary analytical tool for big data.

Leveraging our profound understanding of metabolic and digestive disease biology, we have developed FUSIONTX™, a development approach to develop drugs with multi-functions, through which we strive to use real world data to map the network biology of the disease, screen known molecules with desired therapeutic benefits, and design novel, multi-functional drug candidates with synergistic effects across multiple organs. During the Track Record Period, FUSIONTX™ development approach contributes to our R&D and embodies our drug development goal to enhance overall clinical benefits and improve patient compliance, while increasing accessibility and lowering treatment costs, and also greatly increasing the success rate of drug development.

The following illustrates our drug discovery and design process conducted through the FUSIONTX™ development approach and a description of major steps in the process by using HTD1801 for MASH as an example:

- Step One: Mapping the network biology of complex diseases. Leveraging our profound expertise in metabolic and digestive diseases, we identified the driving role of metabolism disorders and the other important aspects (such as oxidative stress and inflammation, liver wound-healing process, gut-liver axis, etc.) in MASH's pathogenesis and progression through an in-depth analysis of the existing studies and real world data. We also took into consideration epidemiological and natural history studies that showed an essential relationship between obesity, T2DM, insulin resistance, hypertension, dyslipidemia and MASH, supporting that MASH is not a pure hepatic disease but a complex metabolic liver disease.
- Step Two: Screening known molecules for desired therapeutic benefits. We gathered and evaluated the pharmacology profiles of known molecules through real world data mining, based on which we screened and selected those molecules with the most desirable therapeutic benefits. For example, we observed the use of UDCA as a common hepatic protection treatment with high reputation in safety, and its multi-pathway mechanisms of action, such as anti-apoptotic effects, lowering serum TNF- α concentrations, decreasing endoplasmic reticulum stress, and improving hepatic insulin sensitivity. Meanwhile, we took note of UDCA's shortcomings; UDCA appears to have only modest effects in MASH, which may be led by its modest effects in metabolism improvement. The possible increased risk of hepatotoxicity at very high doses was also noted.
- Step Three: Matching the selected molecules with targeted pathogenic pathways. We categorized the molecules selected in step two according to their distinctive mechanisms and then, based on real-world safety data, we identified the lead molecule candidates for each targeted pathogenic pathway. For example, given our focus on both the metabolism improvement and hepatic protection, we chose UDCA over other molecules known for their hepatocyte protection effects, and BBR as a top candidate among agents with comprehensive metabolism modulatory properties. These two active moieties together were hypothesized to improve both the hepatic and metabolic features of MASH.

BUSINESS

- Step Four: Validating active moieties and molecular structure. After rounds of dose-matching experiments, we decided on UDCA and BBR as the final active moieties for HTD1801, based on their compatibility from having comparable molecular weight and effective dose. At this stage, we focused on synergizing the therapeutic benefits, and mitigating the potential side effects of individual moieties. For HTD1801, for example, we built on BBR's well-known effects on metabolism modulation and UDCA's hepatic protection effect, to achieve the multi-therapeutical effects for MASH. We further discovered that these moieties, BBR and UDCA, would work in tandem in a novel salt form to produce, through their interaction, distinct and preferred synergistic properties that were not observed with either of the individual active moieties or the physical mixture of both (as in the case of drug combination). The novel salt form would offer preferred physio-chemical properties, including improved solubility and synergized dissolution and melting point. In our nonclinical studies, HTD1801 significantly enhances the bioavailability of BBR, which, when administered alone, is recognized for its low blood concentration and poor solubility in the body. For more details, see "— Our Product Pipeline — Clinical Stage Candidates — Core Product HTD1801 — Molecular Structure."
- Step Five: Designating the drug candidate. We conduct pre-clinical pharmacological and PK/PD studies and preliminary toxicity studies for each new molecular entity or combination therapy we have designed. Only entities that have passed these preliminary tests with a validated safety profile and pharmacodynamic effects will be designated as our drug candidates. The pre-clinical studies we have conducted demonstrate that HTD1801, in its unique ionized salt form, exhibits distinct PK/PD properties and an enhanced efficacy and safety profile compared to BBR alone, UDCA alone, or their physical mixture, and thus has the potential to offer improved overall clinical benefits beyond a simple combination of BBR and UDCA. For more details, see "— Our Product Pipeline — Clinical Stage Candidates — Core Product HTD1801 — Molecular Structure."

Our FUSIONTX™ development approach serves as the foundation for our continued discovery and design of multi-functional drugs. In addition to our in-house know-how, we have also leveraged external AI technologies as a supplementary analytical tool.

Drug Discovery

As of the Latest Practicable Date, our drug discovery members have on average 11 years' experience. We have worked on our product candidates' advancement for more than 10 years and developed product candidates in-house. Our drug discovery team members have expertise in biology, medicinal chemistry, drug metabolism and pharmacokinetics ("DMPK"), chemistry and early clinical areas, which support our product development, and all of them have obtained post-graduate degrees.

BUSINESS

Our drug discovery comprises (i) identifying unmet medical needs and integrating real-world data, network pharmacology, known and established molecules with desired therapeutic benefits to design novel, multifunctional drug candidates; (ii) performing in vitro and in vivo assays of drug candidates including but not limited to pharmacological activities, pharmacokinetics and toxicities; and (iii) developing formulations, and analytical assays for quality control and assurance. During the drug discovery stage, our R&D chemistry team carries out synthesis and optimization of the target molecules for potential drug candidates. During the drug evaluation stage, our drug discovery team coordinates and accomplishes preclinical R&D activities in relation to the product candidates' pharmacology, pharmacokinetics and toxicology.

Clinical Development

Clinical Development Team

As of the Latest Practicable Date, the clinical development team consisted of 30 members, including scientists and physicians with strong drug development experience, who participate in clinical development strategy development, clinical trial protocol design, clinical trial operation organization, drug safety monitoring, and clinical trial quality control. Our clinical development team members have average 11 years' experience. Among our clinical development team members, over 60% have obtained post-graduate degrees. Our clinical development staff represent a highly skilled and experienced team of professionals who work collaboratively to design and execute complex clinical trials and drug development programs. Our core capabilities in the area of development include clinical trial design, regulatory and quality compliance, project management, clinical operations, medical writing, safety monitoring and drug development strategy. Our team has the expertise to design clinical trials that are rigorous and compliant with regulatory requirements. This involves collaborating internally, with experts and regulatory authorities to determine the appropriate patient population, defining endpoints, and selecting appropriate control groups. Our regulatory team has a thorough understanding of regulatory requirements for clinical trials in the relevant countries and regions, including knowledge of Good Clinical Practice guidelines. The team has proven to be able to manage complex projects, including clinical trials that involve multiple sites and stakeholders. This involves developing and managing timelines, budgets, and resources, as well as monitoring and mitigating risks. Our team has the strategic vision to guide drug development programs from early-stage research through clinical development and regulatory approval.

Clinical Trial Design and Implementation

The clinical development unit of our Company manages all stages of clinical trials, including protocol design and oversees, operations/conduct, and the collection and analysis of clinical data. Our rapid trial advancements are driven by (i) our strategic decision to initiate clinical phase trials globally based on our outstanding preclinical results, (ii) rigorous trial design, (iii) long-term partnership with various hospitals and principal investigators from different regions globally and (iv) seamless execution.

Our clinical operations unit is also responsible for the selection of trial sites. Our site selection criteria includes 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

BUSINESS

principal investigators located in the United States, China and Australia that can support our clinical trials of different indications at different stages. We believe the size and geographic diversity of these facilities provide us with an advantage in implementing large-scale clinical trials and also enable us to conduct multiple clinical trials concurrently. With the support of our partner hospitals, we are capable of recruiting participants from specific populations for studies that would otherwise be difficult to fulfill enrollment.

In 2021 and 2022 and the six months ended June 30, 2023, we cooperated with two, seven and two leading principal investigators (“**PIs**”), respectively, to conduct the clinical trials of our drug candidates. To the best of our Company’s knowledge, none of them have any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates. The PIs are responsible for conducting site-level clinical research activities according to our trial protocols and in accordance with laws, regulations, and the GCP Guideline, a quality standard for the overall conduct of the clinical trial. Each trial has a leading PI with primary responsibility to ensure compliance with trial protocol and good clinical practice over the entire trial.

Clinical Translational Research

We conduct clinical translational research to assess the effectiveness of treatment, evaluate different ways to customize therapies, and improve personalized medicine guidelines using the new data generated. These insights help further guide us toward new directions in novel drug discovery and efficiently obtain proof of concept results. We also maintain extensive collaboration with physicians, scientists and key opinion leaders, and further develop products based on their clinical feedback to our drug candidates, whether in terms of indications or potential treatment combinations. We have established a rich network of top tier CROs, research institutions and hospitals, so that our drug candidates can be quickly moved to the clinical stage.

Relationship with CROs and SMOs

We collaborate with CROs and SMOs to conduct and support our preclinical and clinical studies in line with industry practice. We select our CROs and SMOs by weighing various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. To the best of our Company’s knowledge, none of them have any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates.

In terms of the involvement and contributions of each of the major CROs and SMOs to the development of our product candidates, the preclinical CROs mainly provide us with services related to preclinical toxicity and safety evaluations, such as animal studies, of our product candidates in accordance with agreed study design and under our supervision. 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. SMOs provide a comprehensive suite of services to assist us in implementing and managing clinical trials, including trial preparation, clinical safety management, data management, and report preparation. We choose to engage a CRO and SMO based on the complexity and workload of a specific trial. We closely monitor the work of our CROs and SMOs 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

BUSINESS

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 and SMOs 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.

We mainly determine the service fees paid to the CROs and SMOs in accordance with market prices of similar services, the number of enrolled patients, the duration of the clinical trials, and the quality and contents of the services provided.

During the Track Record Period, we engaged 22 CROs in 2021, 49 CROs and four SMOs in 2022, and 35 CROs and two SMOs in the six months ended June 30, 2023 respectively. The following table sets forth the details of our major CROs and SMOs engaged during the Track Record Period:

Major CROs	Background	Involvement and Contribution	Annual Transaction Amount
<i>(RMB in thousand)</i>			
<i>For the year ended December 31, 2021</i>			
CRO A	A global CRO headquartered in US for drug, biologic, and medical device programs	Safety evaluation, clinical trial execution for Core Product	6,670.7
CRO B	A global CRO headquartered in Hangzhou, providing innovative clinical research solutions across the full life cycle of biopharmaceutical and medical device products	Safety evaluation, clinical trial execution for Core Product	5,899.0
CRO C	A CRO based in Jiangsu, mainly providing biopharmaceutical technology research and development services, technology transfer services and testing services	Safety evaluation, clinical trial execution for Core Product	1,676.4
CRO D	A CRO headquartered in Shanghai, a leading institution with innovative drug research service	Safety evaluation, clinical trial execution for Core Product	1,050.4
<i>For the year ended December 31, 2022</i>			
CRO E	A global CRO headquartered in US for early phase research, delivering translational medicine	Safety evaluation, clinical trial execution for Core Product	14,283.1

BUSINESS

<u>Major CROs</u>	<u>Background</u>	<u>Involvement and Contribution</u>	<u>Annual Transaction Amount</u>
<i>(RMB in thousand)</i>			
CRO A	A global CRO headquartered in US for drug, biologic, and medical device programs	Safety evaluation, clinical trial execution for Core Product	12,807.2
CRO B	A global CRO headquartered in Hangzhou, providing innovative clinical research solutions across the full life cycle of biopharmaceutical and medical device products	Safety evaluation, clinical trial execution for Core Product	12,606.4
CRO F	A global CRO headquartered in UK, a drug development and manufacturing accelerator providing integrated programs and tailored services across the entire development pathway	Safety evaluation, clinical trial execution for Core Product	5,357.6
<i>For the six months ended June 30, 2023</i>			
CRO A	A global CRO headquartered in US for drug, biologic, and medical device programs	Safety evaluation, clinical trial execution for Core Product	21,102.6
CRO C	A CRO based in Jiangsu, mainly providing biopharmaceutical technology research and development services, technology transfer services and testing services	Safety evaluation, clinical trial execution for Core Product	3,123.6
CRO G	A global CRO based in Nanjing, providing fully integrated laboratory R&D and manufacturing services from drug discovery and development to marketability	Safety evaluation, clinical trial execution for Core Product	2,159.9
CRO H	A global CRO headquartered in UK, providing clinical trial supplies services and biological sample management services	Depot project management for Core Product	1,951.0

BUSINESS

SMOs	Background	Involvement and Contribution	Annual Transaction Amount
<i>(RMB in thousand)</i>			
<i>For the year ended December 31, 2022</i>			
SMO A	A SMO based in Shanghai, providing all-in-one medical research services	Assist us in implementing and managing clinical trials for Core Product in China, including trial preparation, clinical safety management, data management, and report preparation	2,353.5
SMO B	A SMO based in Beijing, providing clinical research outsourcing service	Assist us in implementing and managing clinical trials for Core Product in China, including trial preparation, clinical safety management, data management, and report preparation	586.5
SMO C	A SMO based in Shanghai undertaking SMO projects on clinically valued innovative drugs	Assist us in implementing and managing clinical trials for Core Product in China, including trial preparation, clinical safety management, data management, and report preparation	488.9
SMO D	A SMO based in Anhui Province, providing pharmaceutical technology consulting, pharmaceutical product development and technology transfer, clinical research CRC services, third-party audits, data management and statistics services	Assist us in implementing and managing clinical trials for Core Product in China, including trial preparation, clinical safety management, data management, and report preparation	6.3

Major CROs	Background	Involvement and Contribution	Semi-annual Transaction Amount
<i>(RMB in thousand)</i>			
<i>For the six months ended June 30, 2023</i>			
SMO A	A SMO based in Shanghai, providing all-in-one medical research services	Assist us in implementing and managing clinical trials for Core Product in China, including trial preparation, clinical safety management, data management, and report preparation	327.2

BUSINESS

<u>Major CROs</u>	<u>Background</u>	<u>Involvement and Contribution</u>	<u>Semi-annual Transaction Amount</u>
	<i>(RMB in thousand)</i>		
SMO D.	A SMO based in Anhui Province, providing pharmaceutical technology consulting, pharmaceutical product development and technology transfer, clinical research CRC services, third-party audits, data management and statistics services	Assist us in implementing and managing clinical trials for Core Product in China, including trial preparation, clinical safety management, data management, and report preparation	237.6

CHEMISTRY, MANUFACTURE & CONTROLS (“CMC”)

CMC Team

As of the Latest Practicable Date, our CMC team consisted of six 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 eight years’ experience. Among our CMC team members, over 50% have obtained post-graduate degrees. 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.

Collaboration with CDMO Partners

In terms of the involvement and contributions of each of the major CDMO partners (including CMOs) to the development of our product candidates, we collaborate with our CDMO partners to manufacture a portion of our product candidates to supply for preclinical studies and clinical trials. We did not experience any 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. CIC is of the view that there are alternative CDMOs on comparable terms with similar quality available in the market.

BUSINESS

During the Track Record Period, we engaged four, nine and nine CDMOs in 2021, 2022 and the six months ended June 30, 2023, respectively. The following table sets forth the details of our major CDMOs engaged during the Track Record Period:

Major CDMOs	Background	Involvement and Contribution	Years of Relationship	Annual Transaction Amount
<i>(RMB in thousand)</i>				
<i>For the year ended December 31, 2021</i>				
CDMO A	A leading CDMO headquartered in Zhejiang, providing one-stop customized R&D and commissioned production services for innovative drugs to global pharmaceutical and biotechnology companies	Manufacture active pharmaceutical ingredients of our Core Product	Since 2018	7,059.5
CDMO B	A CDMO based in Shanghai, providing pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	Process development and quality analysis research of drug formulation of our Core Product	Since 2019	1,542.3
CDMO C	A CDMO based in Suzhou, providing integrated, science-driven, product development services throughout the drug discovery and development process to enable life science companies to achieve their drug development goals	Manufacture small-scale drug formulation products of our Core Product	Since 2017	603.3
CDMO D	A CDMO headquartered in Suzhou, providing integrated and specialized services, including API solid-state research, crystallization, preformulation, formulation development, and manufacturing	Crystal morphology research and drug formulation of our Core Product	Since 2015	68.9

BUSINESS

Major CDMOs	Background	Involvement and Contribution	Years of Relationship	Annual Transaction Amount
<i>(RMB in thousand)</i>				
<i>For the year ended December 31, 2022</i>				
CDMO A	A leading CDMO headquartered in Zhejiang, providing one-stop customized R&D and commissioned production services for innovative drugs to global pharmaceutical and biotechnology companies	Manufacture active pharmaceutical ingredients of our Core Product	Since 2018	5,811.3
CDMO E	A CDMO based in Shanghai, providing pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	Manufacture drug formulation of our Core Product	Since 2019	4,526.9
CDMO B	A CDMO based in Shanghai, providing pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	Process development and quality analysis research of drug formulation of our Core Product	Since 2019	4,377.4
CDMO F	A CDMO based in Jiangsu, providing pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	Manufacture drug formulation of our Core Product	Since 2022	1,907.4

BUSINESS

Major CDMOs	Background	Involvement and Contribution	Years of Relationship	Semi-annual Transaction Amount
<i>(RMB in thousand)</i>				
<i>For the six months ended June 30, 2023</i>				
CDMO B	A CDMO based in Shanghai, providing pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	Process development and quality analysis research of drug formulation of our Core Product	Since 2019	1,134.7
CDMO G	A CDMO based in Sichuan, providing manufacture of multi-dose biochemical and chemical drugs	Manufacture drug formulation of Core Product	Since 2022	1,074.3
CDMO D	A CDMO based in Suzhou, providing integrated and specialized services, including API solid-state research, crystallization, preformulation, formulation development, and manufacturing	Crystal morphology research and drug formulation of our Core Product	Since 2015	486.7
CDMO F	A CDMO based in Jiangsu, providing pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	Manufacture drug formulation of our Core Product	Since 2022	478.2

BUSINESS

COMMERCIALIZATION

Our Marketing Strategy

To capture market demand under fierce competition, we will pursue the commercialization strategy of win-win cooperation for future assets to maximize the value of our drug candidates globally. Considering the cost of establishing in-house sales and marketing capabilities, we do not plan to set up a full capacity commercialization team; instead, we will build a small but highly capable marketing team, and an alliance management team to work together with our future commercialization partner(s). Based on the expected approval timeline of each indication of HTD1801 in our pipeline, we expect to file NDA with the NMPA for HTD1801 for T2DM in 2025. In anticipation of the upcoming milestone, we are actively seeking domestic partners with a strong commercialization network and expertise in T2DM. Subject to our global clinical development plan, we also plan to commercialize HTD1801 for MASH, SHTG, PSC and PBC in multiple jurisdictions, including but not limited to the United States, EU and China. We will continue to pursue a flexible strategy to capture the commercial value of HTD1801’s multiple indications in major markets, through the forging synergistic license and collaboration opportunities worldwide. The following table sets forth the details of our commercialization plans for HTD1801 in major global markets in the next five years. We may also consider other global markets subject to our business strategy, clinical development and cash flow. We will formulate a detailed and comprehensive commercialization strategy for additional jurisdictions as our drug candidates continue to progress the clinical development.

Drug Candidate	Indication	Jurisdiction	Commercialization Model
HTD1801	MASH	United States	Commercialization in partnership with pharmaceutical companies in the United States
		Europe	Out-license commercialization right to Hepalink
	T2DM	China	Commercialization in partnership with domestic pharmaceutical companies
		United States	Commercialization in partnership with pharmaceutical companies in the United States
	PSC	United States	Collaboration with pharmaceutical companies with sales network established in the United States
		Europe	Out-license commercialization right to Hepalink
PBC	United States	Collaboration with pharmaceutical companies with sales network established in the United States	

To capture the market demand under existing prevention methods and fierce competition for the Core Product in each targeted jurisdiction, in particular, for MASH and T2DM, we will leverage the expertise and industry connections of our partners. We plan to market the products primarily through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians in the respective therapeutic areas to promote the differentiated clinical aspects of our products. Such marketing efforts are expected to

BUSINESS

commence several months before the expected approval for the commercialization of a drug candidate. In preparation for generating sales of our future approved products, we intend to identify a number of hospitals, clinics and physicians specialized in the metabolic and digestive disease treatment, and visit the sites and physicians in person for pre-launch training and liaison.

We also plan to sponsor numerous investigator-led clinical trials to generate local clinical data and accumulate relevant clinical experience. We believe that these academic-oriented marketing efforts will be beneficial for improving alignment of expert opinions on, and promoting clinical use of, our drug candidates, after they become available for sale. We will also support leading experts to report the results of their researches at international and domestic conventions, symposia and other notable events to promote our brand at the forefront of the industry. Moreover, we will actively organize academic conferences and seminars to publicize the clinical data and research results in relation of our drug candidates in order to raise our brand awareness and recognition.

In the field of MASH, pharmaceutical companies have long seen this as a major drug market opportunity, but there remain no MASH drugs approved despite years of research and trials. This is because clearing fat from the liver efficiently and safely has proven to be much more difficult than first thought, with the MASH pipeline littered with flops and setbacks. Upon our market approval of HTD1801, our marketing will focus on physician acceptance, patient education and drug pricing.

- *Physician acceptance:* Since lifestyle modification is the initial step to manage MASH, physicians might be reluctant to prescribe the drugs for MASH. Hence, targeting and educating physicians will be crucial for the successful market access of products. As physicians are expected to play a key role in this process, not only in administering HTD1801 but also in educating patients about its potential benefits, we intend to design our marketing and academic education strategy for maintaining continued engagement with physicians. We believe that we have already established a rapport with some physicians across China and the United States through the clinical trials that we have conducted, in terms of both gaining recognition of the efficacy and potential benefits of HTD1801 and enhancing physicians' familiarity with HTD1801. In addition, we plan to be pro-actively involved in the policy making framework relating to the HTD1801 therapy by actively participating in consultation sessions with the relevant authorities, particularly on improving medical procedures and standards.
- *Patient education:* Although the prevalence of MASH is high, the diagnosis rate is low since liver biopsy is the commonly used approach to identify the disease. Since liver biopsy is a painful procedure, some patients may opt out of diagnosis, leading to a low diagnosis rate. Hence, patient education on the long-term ill effects of this largely unknown disease is vital for our marketing success. We can work with reputable market research organizations to gather information about patients' daily activities, knowledge, health beliefs and level of understanding. Then we can cooperate with some physical examination centers to hold seminars to educate patients on treatment options, assess patients' ability to carry out treatment plans and identify barriers and individualize treatment plans accordingly.

BUSINESS

- *Drug pricing:* Payers may be reluctant to cover highly-priced MASH drugs, since the drug has to be taken for a longer duration. Payers may also be reluctant to cover potentially expensive medications, in part because lifestyle modification is often the first line treatment for MASH. For pricing in China, we may determine pricing based on the affordability to Chinese patients and the price of comparable products. The pricing in overseas markets may vary according to the specific conditions in each territory, including, among other things, the pricing of multinational competitors in the same market. In order to gain market share against existing and future branded and generic competitors, we will also consider seeking inclusion of our Core Product into the NRDL and other reimbursement programs.

In the field of T2DM, we face fierce competition with approved T2DM drugs, in particular, the GLP-1 inhibitors. Our focus will be physician and patient education to introduce them the differentiated features of our Core Product as compared to GLP-1 inhibitors, such as its favorable safety profiles, oral administration and "pipeline-in-a-product". We also need to increase our market penetration of the Core Product. In China, we plan to adopt a tiered provincial market-entry approach with the goal of achieving nationwide coverage in the medium term. Our priority over the next 12 months upon commercialization is to initially focus on top tier provinces that have favorable reimbursement coverage and high patient volume capture. As we expand into tier 2 and other lower tier provinces, we plan to continue building our on-the-ground presence and coverage. We seek to strengthen our relationship with key stakeholders in each province to drive diagnosis and treatment, and support reimbursement negotiation into provincial formulary.

To capture our market share in Europe for the indication of MASH and PSC, we will leverage Hepalink's strong commercialization capabilities to formulate our marketing strategy by taking into account the features of the European market and adjust marketing strategies and KPIs based on actual sales. In general, we will use a combination of academic marketing with Hepalink's in-house sales and marketing team and collaboration with a network of independent distributors and third-party promoters to generate market demands for HTD1801. To enter into the European market, we will promote HTD1801 through introducing the advantages in quality, supply and price to physicians during its marketing activities in hospitals and academic conferences. We can also leverage Hepalink's capacity to fulfill the orders from hospitals and pharmacies by presenting its integrated supply chain. As HTD1801 for MASH and PSC has not been approved, detailed marketing strategy has not been formulated as of the Latest Practicable Date.

BUSINESS

Pricing

We will determine the prices of our products based on a number of factors, including our costs of production, prices of other similar products, our technology advantages, product quality, health economics, market trends and changes in the levels of supply and demand. We plan to make a detailed pricing strategy when our drug candidates progress toward commercialization.

As of the Latest Practicable Date, there was no pricing guidance or centralized procurement set by the PRC government on our product candidates. In order to gain market share against existing and future branded and generic competitors, we will also consider seeking inclusion of our Core Product into the NRDL and other reimbursement programs. Inclusion into the NRDL is evaluated and determined by the relevant government authorities and we may face significant competition for successful inclusion. If we fail to have our Core Product included in the NRDL after commercialization, our sales channels may be limited and our revenue from commercial sales will be highly dependent on patient self-payments, which could make our products less competitive. We may need to seek alternatives such as commercial private insurance coverage of our Core Product and need to expand our sales channels and explore new collaboration partnerships, such as engaging distribution partners in China, to maximize the sales potential of our products and enhance our commercialization capability.

INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights are central 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 hold 132 patents and patent applications, including 58 patents and patent applications in relation to our Core Product. All the patents and patent applications are inventions. As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that makes us to believe that any of the pending patent applications will be rejected. As we have successfully obtained composition of matter patent for HTD1801 in many countries and regions, including the United States, China, the European Union and Japan, as well as crystalline form patent in the United States and China, to our best knowledge, if any patent is not issued, it will not adversely affect the development and commercialization of our Core Product in the United States, Mainland China and Europe in all material aspects. The following table sets forth an overview of our material granted patents and

BUSINESS

filed patent applications in connection with our clinical and preclinical drug candidates as of the Latest Practicable Date:

Product	Name of patent ⁽¹⁾	Jurisdiction ⁽²⁾	Status	Patent expiration ⁽³⁾	Market commercial rights of the Company	Application date	Approval date
HTD1801 . . .	Berberine Salts,	Australia, Brazil, Mainland	Granted	Australia: 2035/7/28,	Ownership	2015/7/28	Australia: 2019/10/10,
	Ursodeoxycholic Salts and	China, EAPO, EPO, Israel,		2035/7/28			2021/9/2
	Combinations, Methods of	Japan, Korea, Mexico,		Brazil: 2035/7/28			Brazil: 2022/11/29
	Preparation and	Singapore, United States,		Mainland China: 2035/7/28			Mainland China: 2019/5/17
	Application Thereof ⁽⁴⁾	South Africa, Canada, India,		EAPO: 2035/7/28,			EAPO: 2019/8/30, 2023/4/5
		New Zealand		2035/7/28			EPO: 2020/9/2
				EPO: 2035/7/28			Israel: 2021/7/30, 2022/10/2
				Israel: 2035/7/28, 2035/7/28			Japan: 2021/7/21, 2023/5/25
				Japan: 2035/7/28			Korea: 2023/8/29
				Korea: 2035/7/28			Mexico: 2020/3/25,
				Mexico: 2035/7/28,			2023/7/14
				2035/7/28			Singapore: 2020/8/19
				Singapore: 2035/7/28			United States: 2019/5/28,
				United States: 2035/11/12,			2021/4/27, 2023/6/27
				2035/8/25, 2035/12/20			South Africa: 2018/7/25
				South Africa: 2035/7/28			Canada: 2023/5/23
				Canada: 2035/7/28			India: 2023/6/8
				India: 2035/7/28			New Zealand: 2023/7/4
				New Zealand: 2035/7/28			
		Canada, Mainland China,	Pending	-	Ownership		
		EAPO, Israel, Japan, Korea,					
		Mexico, New Zealand,					
		United States					
	Solid Forms of Berberine	Australia, Mainland China,	Granted	Australia: 2038/5/11	Ownership	2018/5/11	Australia: 2022/9/1
	Ursodeoxycholate and	EAPO, United States		Mainland China: 2037/5/12			(2017/5/12
	Compositions and Methods			EAPO: 2038/5/11			EAPO: 2022/9/16
	Thereof ⁽⁵⁾			United States: 2038/6/11			United States: 2021/3/30
		Australia, Canada, EPO, Hong	Pending	-	Ownership		
		Kong, Israel, Japan, Korea,					
		New Zealand, United States					

BUSINESS

Product	Name of patent ⁽¹⁾	Jurisdiction ⁽²⁾	Status	Patent expiration ⁽³⁾	Market commercial rights of the Company	Application date	Approval date
	Compositions of Berberine Ursodeoxycholate and Methods Thereof for Treating Fatty Liver Disease, Diabetes and/or Hyperlipidemia, and Related Diseases and Disorders ⁽⁶⁾	United States, EPO, Mainland China	Pending	-	Ownership	2021/10/22	
	Compositions of Berberine Ursodeoxycholate and Methods for Treating Primary Sclerosing Cholangitis ⁽⁷⁾	United States	Pending	-	Ownership	2022/1/28	
HTD4010 . . .	Compositions and Methods of Using Islet Neogenesis Peptides and Analogs Thereof	Australia, Canada, Mainland China, EPO, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand, Russia, United States, South Africa	Granted	Australia: 2034/3/14, 2034/3/14, 2034/3/14 Canada: 2034/3/14 Mainland China: 2034/3/14, 2034/3/14 EPO: 2034/3/14, 2034/3/14 Hong Kong: 2034/3/14 Israel: 2034/3/14 India: 2034/3/14 Japan: 2034/3/14, 2034/3/14 Korea: 2034/3/14 Mexico: 2034/3/14 New Zealand: 2034/3/14, 2034/3/14 Russia: 2034/3/14 United States: 2034/3/14, 2034/3/14, 2033/3/15 South Africa: 2034/3/14	Ownership	2014/3/14	Australia: 2018/11/1, 2021/1/7, 2022/8/4 Canada: 2022/10/18 Mainland China: 2019/4/16, 2021/4/6 EPO: 2018/10/3, 2022/4/13 Hong Kong: 2022/12/2 Israel: 2021/6/26 India: 2021/10/30 Japan: 2020/3/10, 2022/5/18 Korea: 2021/4/20 Mexico: 2020/12/14 New Zealand: 2020/11/3, 2020/12/1 Russia: 2019/4/23 United States: 2016/7/12, 2017/8/22, 2021/1/26 South Africa: 2016/12/21
		United States	Pending	-	Ownership		
	Conjugates of Islet Neogenesis Peptides and Analogs, and Methods Thereof	Mainland China, United States	Granted	Mainland China: 2037/3/9 United States: 2037/3/9, 2037/3/9	Ownership	2017/3/9	Mainland China: 2022/5/17 United States: 2020/11/10, 2023/1/17
		EPO, United States	Pending	-	Ownership		

BUSINESS

Product	Name of patent ⁽¹⁾	Jurisdiction ⁽²⁾	Status	Patent expiration ⁽³⁾	Market commercial rights of the Company	Application date	Approval date
	Use of Polypeptide Compound in Treatment of Acute Pancreatitis	Japan, United States, Australia	Granted	Japan: 2037/5/11 United States: 2037/5/11, 2034/3/14 Australia: 2037/5/11	Ownership	2017/5/11	Japan: 2022/11/2 United States: 2020/9/15, 2022/12/27 Australia: 2023/7/6
		Australia, Brazil, Canada, Mainland China, EPO	Pending	-	Ownership		
HTD2802	Composition, and Application and Pharmaceutical Preparation Thereof	United States, Australia, Israel	Granted	Australia: 2036/11/10 United States: 2036/11/10 Israel: 2036/11/10	Ownership	2016/11/10	Australia: 2023/4/20 United States: 2022/6/28 Israel: 2023/6/2
		Australia, Canada, Mainland China, EPO, Israel, Japan, Korea, United States	Pending	-	Ownership		
	Methods and Compositions for Treatment of Inflammatory Bowel Disease	Korea, Mainland China	Granted	Korea: 2038/8/8 Mainland China: 2038/8/8	Ownership	2018/8/8	Korea: 2023/11/7 Mainland China: 2022/9/6
		Australia, Canada, EPO, Israel, United States	Pending	-	Ownership		

Abbreviations: EPO = European Patent Office; PCT = Patent Cooperation Treaty; EAPO = Eurasian Patent Organization.

Notes:

- (1) Unless otherwise indicated, the patent for applications within the same family is the same and is therefore disclosed once.
- (2) The reason why a patent has both granted and filed status in a jurisdiction is that we filed a number of divisional, continuation, or other types of derivative patent applications based on the original patent application to provide a boarder scope of patent claims and more extensive protections for our products.
- (3) 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.
- (4) The patents or patent applications direct to compounds, compositions, and methods of use of the Core Product, covering the key characteristics of the Core Product. They provide, jointly with other patents or patent applications in relation to the Core Product, sufficient and prolonged protections by multiple subject matters to the development and commercialisation of the Core Product.
- (5) The patents or patent applications direct to crystalline forms, methods of preparation, methods of use, and compositions of the Core Product, covering the key characteristics of the Core Product. They provide, jointly with other patents or patent applications in relation to the Core Product, sufficient and prolonged protections by multiple subject matters to the development and commercialisation of the Core Product.
- (6) The patent applications direct to compositions and methods of use of the Core Product, covering the key characteristics of the Core Product. They provide, jointly with other patents or patent applications in relation to the Core Product, sufficient and prolonged protections by multiple subject matters to the development and commercialisation of the Core Product.
- (7) The patent application directs to compositions and methods of use of the Core Product, covering the key characteristics of the Core Product. It provides, jointly with other patents or patent applications in relation to the Core Product, sufficient and prolonged protections by multiple subject matters to the development and commercialisation of the Core Product.

BUSINESS

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.

With the support of freedom-to-operate analysis on HTD1801 and HTD4010, we are not aware of any instances of potential or confirmed infringement of third parties’ IP rights in relation to our HTD1801 and HTD4010 in China, the United States, and Europe during the Track Record Period and up to the Latest Practicable Date. Based on the independent due diligence work conducted by the Joint Sponsors, nothing has come to their attention that would reasonably cause them to cast doubt on such view.

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 the paragraphs headed “Risk Factors — Risks Relating to Our Intellectual Property Rights” for a description of risks related to our intellectual property.

We conduct our business under the brand name of “HighTide” or “君圣泰”. As of the Latest Practicable Date, we held 34 trademarks and trademark applications in the United States, Mainland China, Hong Kong, Europe and United Kingdom. We are also the owner of seven domain names.

BUSINESS

We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property or gain access to the intellectual property of others. For details, please see the paragraphs headed “— Collaboration Agreement” in this section.

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.

OUR SUPPLIERS

During the Track Record Period, our major suppliers for our R&D 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, SMOs and CDMOs.

- *Services.* The CRO, SMO or CDMO provides us with services such as implementing a clinical research project, manufacturing products as specified in the master agreement or work order.
- *Term.* The CRO, SMO 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, SMO or CDMO according to the payment schedule agreed by the parties.
- *Confidentiality.* We and the CRO, SMO or CDMO agree to keep confidential any information in relation to the performance of the master agreement.
- *Credit terms.* We usually arrange payment within 30 days of receipt of invoice from CRO, SMO 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.

BUSINESS

- *Liabilities and termination.* The liability of a CRO, SMO 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 2021 and 2022 and the six months ended June 30, 2023, our purchases from our five largest R&D suppliers in each year/period in aggregate amounted to RMB26.9 million, RMB68.7 million and RMB36.4 million, representing 45.5%, 54.4% and 45.7% of our total corresponding purchases, respectively, and our purchases from the largest R&D supplier in each year accounted for 12.0%, 17.9% and 26.5% of our total corresponding purchases, respectively. Our material increase in the expenses attributable to the five largest R&D suppliers during the Track Record Period is in line with the advancement of clinical trials of our Core Product.

BUSINESS

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

Supplier	Background	Major purchases	Commencement of business relationship	Credit terms	Purchase amount	% of total corresponding purchases for the year
					<i>(RMB in thousands)</i>	
<i>For the six months ended June 30, 2023</i>						
Supplier C . . .	A global CRO headquartered in US for drug, biologic, and medical device programs	CRO service	Since 2019	Installment payments will be made within 30 days after receipt of invoices	21,103	26.5%
Supplier A . . .	A global CDMO/CRO which mainly provides pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	CDMO/CRO service	Since 2016	Installment payments will be made within 30 days after receipt of invoices	5,167	6.5%
Supplier E . . .	A meeting planning corporation headquartered in the US, creating communication projects for pharmaceutical companies and a wide range of other sectors	Meeting planning service	Since 2022	Installment payments will be made upon completion of milestones or within five days after the first day of the meeting, as applicable	4,081	5.1%
CRO C	A CRO based in Jiangsu, mainly providing biopharmaceutical technology research and development services, technology transfer services and testing services	CRO service	Since 2013	Installment payments will be made within 10 working days after receipt of invoices	3,124	3.9%
Supplier F . . .	An institution headquartered in the US, mainly providing services for performing clinical trials	Clinical site service	Since 2023	Installment payments will be made within 30 days after receipt of invoices	2,927	3.7%
Total					36,402	45.7%

BUSINESS

Supplier	Background	Major purchases	Commencement of business relationship	Credit terms	Purchase amount	% of total corresponding purchases for the year
					<i>(RMB in thousands)</i>	
<i>For the year ended December 31, 2022</i>						
Supplier A	A global CDMO/CRO which mainly provides pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	CDMO/CRO service	Since 2016	Installment payments will be made within 30 days after receipt of invoices	22,545	17.9%
CRO E	A global CRO headquartered in US for early phase research, delivering translational medicine	CRO service	Since 2022	Installment payments will be made within 30 days after receipt of invoices	14,283	11.3%
Supplier C	A global CRO headquartered in US for drug, biologic, and medical device programs	CRO service	Since 2019	Installment payments will be made within 30 days after receipt of invoices	13,160	10.4%
Supplier B*	A global CDMO/CRO headquartered in Hangzhou, providing innovative clinical research solutions across the full life cycle of biopharmaceutical and medical device products	CDMO/CRO service	Since 2016	Installment payments will be made within 30 days after receipt of invoices	12,919	10.2%
CDMO A	A leading CDMO headquartered in Zhejiang, providing one-stop customized R&D and commissioned production services for innovative drugs to global pharmaceutical and biotechnology companies	CDMO service	Since 2018	Installment payments will be made within 30 days after receipt of invoices	5,811	4.6%
Total					68,718	54.4%

Note: One of our [REDACTED] investors is the subsidiary of Supplier B.

BUSINESS

Supplier	Background	Major purchases	Commencement of business relationship	Credit terms	Purchase amount <i>(RMB in thousands)</i>	% of total corresponding purchases for the year
<i>For the year ended December 31, 2021</i>						
CDMO A	A leading CDMO headquartered in Zhejiang, providing one-stop customized R&D and commissioned production services for innovative drugs to global pharmaceutical and biotechnology companies	CDMO service	Since 2018	Installment payments will be made within 30 days after receipt of invoices	7,059	12.0%
Supplier C	A global CRO headquartered in US for drug, biologic, and medical device programs	CRO service	Since 2019	Installment payments will be made within 30 days after receipt of invoices	6,836	11.6%
Supplier B*	A global CDMO/CRO headquartered in Hangzhou, providing innovative clinical research solutions across the full life cycle of biopharmaceutical and medical device products	CDMO/CRO service	Since 2016	Installment payments will be made within 30 days after receipt of invoices	6,502	11.0%
Supplier A	A global CDMO/CRO which mainly provides pharmaceutical and medical device companies with a full range of integrated laboratory R&D and production services from drug discovery, development to marketization	CDMO/CRO service	Since 2016	Installment payments will be made within 30 days after receipt of invoices	3,621	6.1%
Supplier D	A compliance consultant responsible for filing of reports related to FDA certification	Consulting service	Since 2020	Payments will be made within 30 days after receipt of invoices	2,868	4.8%
Total					26,886	45.5%

Note: One of our [REDACTED] investors is the subsidiary of Supplier B.

BUSINESS

All of our five largest suppliers 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 during the Track Record Period.

COMPETITION

Our industry is highly competitive and subject to rapid and significant change. While we believe that our differentiated development approach, our pipeline of drug candidates in clinical and preclinical trials and our experienced management team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications against which we are developing our drug candidates. These include major pharmaceutical companies, academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future.

We face fierce competition from existing products and product candidates under development in the entire MASH, T2DM, SHTG, PSC and PBC market. In addition to approved therapies, there are a large number of competing drug candidates currently under different clinical stages. We may also face potential competition from existing products used off-label for MASH and PSC. Those existing products may also be developed to expand their indications targeted by the Core Product. As multiple product candidates are currently in Phase III clinical trials for each of the targeted indications of the Core Product, our development and commercialization of Core Product may be adversely affected some or all of such product candidates receive NDA approval prior to the Core Product. For example, the FDA would request head-to-head studies for HTD1801 before the granting of the approval, which may impose higher risk of clinical failure and also delay the original development plan. 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.

BUSINESS

AWARDS AND RECOGNITION

The table below sets forth an indicative list of some of the awards and recognitions we have received as of the Latest Practicable Date.

Award/Project	Year	Award/Grant Authority
OASE Partner (重點企業夥伴)	2023	Office for Attracting Strategic Enterprises of Hong Kong (香港引進重點企業辦公室)
Specialized, Excellent, Featured and Innovative Small and Medium Enterprise (專精特新中小企業)	2023	Industry and Information Technology Bureau of Shenzhen Municipality (深圳市工業和信息化局)
Small and Medium Innovative Enterprises of Shenzhen (深圳市創新型中小企業)	2022	Shenzhen Small and Medium Enterprise Service Bureau (深圳市中小企業服務局)
Guangdong Provincial Engineering Research Center of Multifunctional Innovative Drug Development based on Natural Products (廣東省基於天然產物的多功能創新藥物研發工程技術研究中心)	2022	Department of Science and Technology of Guangdong Province (廣東省科學技術廳)
High-tech Enterprise (高新技術企業)	2022	Shenzhen High-tech Innovation Committee (深圳市科技創新委員會), Shenzhen Municipal Department of Finance (深圳市財政局), National Department of Taxation, Shenzhen Taxation Bureau (國家稅務總局深圳市稅務局)
Director of HK Bio-Med Innotech Association (香港生物醫藥創新協會會董)	2022	HK Bio-Med Innotech Association (香港生物醫藥創新協會)
Member of the third council of Shenzhen Life Science and Biotechnology Association (深圳市生命科學與生物技術協會第三屆理事會理事單位)	2021	Shenzhen Life Science and Biotechnology Association (深圳市生命科學與生物技術協會)
Top 50 Small and Medium Innovative Enterprises of Longgang District (龍崗區中小創新企業50強)	2020	Science and Technology Innovation Bureau of Longgang District, Shenzhen (深圳市龍崗區科技創新局)

BUSINESS

Award/Project	Year	Award/Grant Authority
Director Unit of Guangdong Biomedical Innovation Technology Association (廣東省生物醫藥創新技術協會理事單位)	2020	Guangdong Biomedical Innovation Technology Association (廣東省生物醫藥創新技術協會)
Member Unit of Shenzhen Biomedicine Promotion Association (深圳市生物醫藥促進會會員單位)	2020	Shenzhen Biomedicine Promotion Association (深圳市生物醫藥促進會)
Shenzhen Peacock Plan Team (深圳市孔雀計劃團隊)	2012	Shenzhen Science and Technology Innovation Committee (深圳市科技創新委員會)

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover employee benefits liability and adverse events in clinical trials. We currently do not maintain insurance for environmental liability or property loss. Please refer to the section headed “Risk Factors — Risks Relating to our Business and Industry — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.” in this document.

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

EMPLOYEES

As of the Latest Practicable Date, we had 66 employees in total, and 47 employees are stationed in our headquarters in Shenzhen. The following table sets forth the number of our employees categorized by function and location as of the Latest Practicable Date.

	Number of employees by functions	Percentage
Discovery and Clinical Development	34	52%
CMC	6	9%
Regulatory Affairs	5	8%
Management Operations	21	32%
Total	66	100%

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.

BUSINESS

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. Please refer to the section headed “Risk Factors — Risks Relating to Our Business and Industry — Failure to make social insurance and housing provident fund contributions for some of our employees timely as required by PRC laws and regulations may subject us to late payments and fines imposed by relevant governmental authorities.” in this document.

During the Track Record Period, we had not made full contributions to the social insurance premium and housing provident fund based on the actual salary level of some of our employees as prescribed by relevant laws and regulations.

As advised by our PRC Legal Advisor, pursuant to relevant PRC laws and regulations, if we fail to pay the full amount of social insurance contributions as required, we may be ordered to pay the outstanding social insurance contributions within a prescribed period and may be subject to an overdue fine of 0.05% of the delayed payment per day from the date on which the payment is payable. If such payment is not made within the prescribed period, the competent authorities may further impose a fine from one to three times the amount of any overdue payment. In view of the above and based on the estimation of our Directors, the potential maximum penalty with respect to fines that our Group may be exposed to during the Track Record Period, would be less than RMB15,000, nil and nil in 2021 and 2022 and the six months ended June 30, 2023, respectively.

Our Directors believe that such non-compliance would not have a material adverse effect on our business and results of operations, considering that: (i) as advised by our PRC Legal Advisor and based on the written confirmations issued by the competent government authorities of our Company and its subsidiaries, we had not been subject to any administrative penalties during the Track Record Period and up to the Latest Practicable Date; (ii) we were neither aware of any employee complaints filed against us nor involved in any labor disputes with our employees with respect to social insurance and housing provident funds during the Track Record Period and up to the Latest Practicable Date; (iii) as of the Latest Practicable Date, we had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing provident funds; and (iv) the amount of shortfalls is low and such non-compliance will not have a material adverse effect on our financial condition or results of operations taken as a whole. As a result, we did not make any provisions in connection with these non-compliances during the Track Record Period and up to the Latest Practicable Date.

BUSINESS

During the Track Record Period, Shenzhen HighTide engaged a third-party human resource agency to pay social insurance premium and housing provident funds for three of our employees. As advised by our PRC Legal Advisor, the engaging of third-party human resources agencies is not in compliance with the applicable PRC rules and regulations. We terminated our contract with the third-party human resource agency in September 2021.

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), each employer shall declare on its own and pay on time and in full social insurance contributions. Thus, if an employer engages third-party human resource agencies to pay the social insurance, the relevant authorities could order the employer to pay, within a prescribed time limit, the outstanding amount with an additional late payment penalty at the daily rate of 0.05%, and if the employer fails to make the overdue contributions within such time limit, a fine equal to one to three times the outstanding amount may be imposed. According to the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), each employer shall apply to the housing provident fund management center for registration of payment and deposit of the housing provident fund and go through the formalities of opening housing provident fund accounts on behalf of its employees. Thus, if the employer engages third-party human resource agencies to pay the housing provident funds, the authority could order the employer to correct it within a prescribed time limit, where failure to do so at the expiration of the time limit shall result in a fine of not less than RMB10,000 nor more than RMB50,000 being imposed.

Our Directors believe that such non-compliance would not have a material adverse effect on our business and results of operations, considering that: during the Track Record Period and up to the Latest Practicable Date, (i) based on the written confirmations issued by the competent government authorities of Shenzhen HighTide and advised by our PRC Legal Advisor, we had not been subject to any administrative penalties relating to the engagement of the third-party human resource agency; (ii) we were neither aware of any employee complaints filed against us nor involved in any labor disputes with our employees relating to the engagement of the third-party human resource agency; and (iii) we had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges relating to the engagement of the third-party human resource agency.

In light of the foregoing, we have also adopted internal policies in relation to social insurance and housing provident funds, which include the following on-going measures:

- we have issued an internal notice to our senior management and human resources department in respect of the prohibition of the arrangement of third-party human resources agencies for the newly employed employees to ensure that they are informed of the new policy of such prohibition;
- our human resources department is responsible for conducting monthly review on payment records of social insurance and housing provident funds to ensure that there are no incidents of the arrangement of third-party human resources agencies. If any incident of such arrangement is identified, the manager of our human resources department will report to our Directors for further actions;
- we will continue to provide trainings to our employees in relation to the relevant laws and regulations on social insurance and housing provident funds and the compliance requirements from time to time;

BUSINESS

- we will continue to consult our PRC legal counsel on a regular basis for advice on relevant PRC laws and regulations to enhance our awareness and to keep us abreast of relevant regulatory developments.

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 13 properties in Mainland China and Hong Kong with an aggregate GFA of approximately 2,809.4 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. We will negotiate with our landlord for the renewal of the lease agreement that will expire within three months and we do not anticipate undue difficulty in renewing our leases upon their expiration.

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

Usage	Location	GFA (sq.m)	Expiry Date
Employee Dormitory	Shenzhen, Mainland China	76	April 4, 2024
Office, R&D	Shenzhen, Mainland China	1,315.7	December 31, 2023
Office	Shenzhen, Mainland China	435.3	March 31, 2026
Employee Dormitory	Shenzhen, Mainland China	88.6	October 31, 2024
Employee Dormitory	Shenzhen, Mainland China	72.2	November 30, 2023
Employee Dormitory	Shenzhen, Mainland China	125.6	August 31, 2027
Office	Nanchang, Mainland China	100	September 16, 2025
Employee Dormitory	Shenzhen, Mainland China	62.7	February 29, 2024
Office, R&D	Shanghai, Mainland China	25	December 31, 2023
Office	Shanghai, Mainland China	1.6	Automatically renewed each three months since August 1, 2019
Office, R&D	Shanghai, Mainland China	333.5	May 16, 2024
Office	Shanghai, Mainland China	100.4	March 14, 2025
Office	Hong Kong	72.8	June 18, 2026

BUSINESS

As of June 30, 2023, no single property interest that forms part of non-property activities has a carrying amount of 15%, and no single property interest that forms part of property activities has a carrying amount of 1%, of our total assets. Therefore, according to Chapter 5 of the [REDACTED] Rules and section 6(2) of the Companies (Exemption of Companies and Documents 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.

As of the Latest Practicable Date, the actual usage of one leased property was inconsistent with the usage set out in its title certificate but in compliance with the usage agreed in the lease agreement. The usage in the title certificate is factory while our actual usage is office. As advised by our PRC Legal Advisor, it is primarily the lessor's responsibility to ensure the actual usage is consistent with the approved usage, and to the extent necessary, to complete the relevant "change of registration" procedures with the competent authorities to register the changed usage; we as the tenant will not be subject to any administrative punishment or penalties because of the lessors' failure to complete such procedures, but our use of this leased property may be affected by third party claims or challenges against the lease. If the lessor does not have the requisite rights to lease the defective leased property to us for our intended usage, the relevant lease agreement may be deemed invalid, and as a result we may be required to vacate the defective leased property. Our PRC Legal Advisor believes that there is a likelihood that we will be asked to vacate the non-compliant leased property. We may incur substantial reinstatement, relocation and renovation costs with an estimated relocation cost of no more than RMB10,000. Our Directors are of the view that the relocation would not materially and adversely affect our business operations, considering that (i) the leased property is highly substitutable and there is no difficulty in obtaining an alternative property in a timely manner with the same conditions; (ii) we would be able to relocate to a different site easily should we be required to do so given that the leased property is not material to our operation nor used for manufacturing; (iii) the lease market in the vicinity of such leased property is active; and (iv) the relocation cost is low.

We have enhanced our internal control measures in connection with property rentals. Before entering into any new lease agreements, we will obtain the valid title certificates and other necessary documentation from all of our lessors and carefully review the relevant documents provided by the lessors, to ensure that we will not inadvertently lease any property with title defects. All the lease agreements as well as the relevant documents provided by the lessors need to be approved by our legal department. Our internal control consultant is of the view that our enhanced internal control measures are effective.

Moreover, ten of our lease agreements for properties in China have not been registered with relevant authorities in China. As advised by our PRC Legal Advisor, according to the PRC Civil Code, failure to complete the registration and filing of lease agreements will not affect the validity of the lease agreements. However, the relevant PRC authorities may impose a fine on us ranging from RMB1,000 to RMB10,000 for each unregistered lease.

We have enhanced our internal control measures in connection with property rentals. We will require all of our lessors to provide the necessary documentation before we enter into lease agreements with them, and to cooperate with us in completing the registration of the lease agreements. Designated staff from our legal department will conduct self-inspections from time to time on whether the lease agreements are properly registered.

BUSINESS

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 United States, PRC, Australia and Hong Kong 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 “Regulatory Overview” in this document. We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. There is no material legal impediment in renewing such licenses, permits, approvals and certificates as they expire in the future as long as we are in compliance with applicable laws, regulations and rules. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates.

The following table sets forth the details of our 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>
Notice of Approval for Clinical Drug Trial (No. 2023LP01784) (藥物臨床試驗批准通知書 (編號: 2023LP01784))	NMPA	Shenzhen HighTide	September 8, 2023	N/A
Certificate for Clinical Trial/Medicinal Test (No. 200213, 200214) ((臨床試驗/藥物測試證明書) (編號: 200213, 200214))	The Department of Health of Hong Kong	Australia HighTide	August 24, 2023	N/A
Decision on Approval of International Cooperative Scientific Research on Human Genetic Resources in China (No. (2022) GH0605) ((中國人類遺傳資源國際合作科學研究審批決定書) (編號: (2022) GH0605))	Administration Office of China Human Genetic Resources	Shenzhen HighTide	February 21, 2022	N/A
Notice of Approval for Clinical Drug Trial (No. 2021LP00748) ((藥物臨床試驗批准通知書) (編號: 2021LP00748))	NMPA	Shenzhen HighTide	May 21, 2021	N/A
Approval for HTD1801.PCT013 Clinical Trial for Primary Biliary Cholangitis	FDA	Australia HighTide	January 26, 2021	N/A
Notice of Approval for Clinical Drug Trial (藥物臨床試驗批准通知書)	NMPA	Shenzhen HighTide	October 25, 2019	N/A
Fast Track Designation of HTD1801 for Nonalcoholic Steatohepatitis	FDA	Australia HighTide	November 23, 2018	N/A
Approval for HTD1801.PCT012 Clinical Trial for Nonalcoholic Steatohepatitis and Type 2 Diabetes Mellitus	FDA	Australia HighTide	October 24, 2018	N/A

BUSINESS

License/Permit	Issuing Authority	Holder	Grant date	Expiration date
Fast Track Designation of HTD1801 for Primary Sclerosing Cholangitis	FDA	Australia HighTide	September 25, 2018	N/A
Registration for HTD1801.PCT004 Clinical Trial for Hypercholesterolemia	TGA	Australia HighTide	January 18, 2018	N/A
Approval for HTD1801.PCT003 Clinical Trial for Primary Sclerosing Cholangitis	FDA	Australia HighTide	December 8, 2017	N/A
Registration for HTD1801.PCT002 Clinical Trial for Primary Sclerosing Cholangitis	TGA	Australia HighTide	March 23, 2017	N/A
Orphan Drug Designation of HTD1801 for Primary Sclerosing Cholangitis	FDA	Australia HighTide	August 29, 2016	N/A
Acknowledgement of HTD4010.PCT001 Clinical Trial for Type 2 Diabetes Mellitus	TGA	Australia HighTide	October 8, 2015	N/A

ENVIRONMENTAL, SOCIAL, AND GOVERNANCE

Governance

We acknowledge our environmental protection and social responsibility, and realize that climate-related issues may affect our business operations. We are committed to, after [REDACTED], complying with the reporting requirements related to environmental, social and governance (“ESG”). We understand the environmental and social-related risks that will affect our business and we, therefore, established an ESG working group for addressing such risks and formulated not only corresponding working rules to supervise our corporate social responsibility but also measures for sustainable development. The working group is responsible for (i) assessing and managing our ESG-related risks and opportunities, and deliberating on the formulation of, among others, our ESG strategic plans, management structure, systems, strategies and implementation rules so as to ensure the continuous execution and implementation of our ESG policies; (ii) making guidelines for and reviewing the identification and ranking of our important ESG issues; (iii) determining our key ESG issues; (iv) reviewing our ESG work and internal monitoring systems, and making recommendations on their appropriateness and effectiveness; (v) reviewing our ESG-related disclosure documents, including but not limited to the annual ESG reports; (vi) monitoring our ESG-related risks and making inquiries on and formulating corresponding measures for major issues that affect our performance of ESG-related work, and reviewing and supervising how such issues are handled; and (vii) providing ESG-related training and materials to the Board of Directors.

BUSINESS

The Board has collective responsibility for managing the impact of the material ESG risks and opportunities affecting the Group, formulation and establishment the Group's ESG-related mechanisms, policies and objectives, and reviewing the Group's performance against the ESG objectives on an annual basis and revising the ESG policy as appropriate if significant deviations from the objectives are identified.

The Board has engaged an independent ESG consultant to assess ESG risks and review the Group's existing strategies, objectives and internal controls, and will implement necessary improvements to mitigate the risks. The Board, ESG working group will continue to monitor the Group's strategic planning for risk management, including climate-related risks and those risks that were monitored as part of standard operating procedures, to ensure that appropriate mitigation measures are implemented as part of regular management reviews. Our ESG working group consists of nine members, including our Director, senior managements and department heads who will gain experience for monitoring ESG-related matters with the assistance of our independent ESG consultant.

For the board governance structure for overseeing the ESG risks, the Group has established three-level ESG management structure consisting of the Board, the ESG working group and the departments. The Board will be informed of the ESG working group's assessment on ESG matters through regular reports, which include quarterly reports, interim reports and annual reports. When there are important changes in the external ESG environment or policies, ESG working group will report to the Board through special ESG reports. ESG working group meetings are divided into regular and ad hoc meetings. Regular meetings are held at least twice a year, and ad hoc meetings are held at the initiative of ESG working group members.

Materiality Assessment

In order to identify the scope of the Group's ESG practices and disclosure priorities, we commissioned an independent ESG consultant to conduct an ESG materiality analysis. This aims to identify the ESG issues that are most relevant to the Group. After careful analysis, we have identified following ESG material issues that are applicable to the Group's business, taking into account the Group's business development direction and actual operating conditions, with reference to the disclosure responsibilities as set out in the Appendix 27 of the Environmental, Social and Governance Reporting Guidelines of the Main Board Listing Rules of the Stock Exchange, the trends of the peers, and the material issues of the Sustainability Accounting Standards Board.

BUSINESS

Materiality	Substantive Issues	Quantified Disclosures	Unit
Highly material	Product quality and safety	Pass rate for official inspection/audit	%
	Product innovation and research and development	Expenses on research and development to operation revenue	%
	Protecting customer privacy and data security	Cases of data breach	case
	Protecting intellectual property rights	Number of intellectual property applications	item
	Employee health and safety	Lost days due to work injury per capita	day/person
	Compliant operations	Training hours completed per employee for compliance	hour/person
Moderately material . . .	Business ethics and anti-corruption	Number of concluded proceeding for corruption	case
		Training hours completed per employee for anti-corruption	hour/person
	Employee training and development	Average training hours completed per employee	hour/person
	Employee benefits and protection	Percentage of labor contract signed	%
		Investment in employees' benefits	monetary unit
	Employee Diversity	Workforce by gender	—
	Waste discharge management	General waste discharge per capita	ton/person
	Energy consumption	Comprehensive energy consumption per capita	kWh/person
Water consumption	Water consumption per capita	m ³ /person	

BUSINESS

Materiality	Substantive Issues	Quantified Disclosures	Unit
	Response to climate change	Greenhouse gas emissions per capita	CO ₂ -e /person
	Sustainability management of supply chains	Percentage of employees trained for quality management, environment management and safety management	%
	Risk management	Number of suppliers Number of events of significant risk Training hours completed per employee for risk management	unit case hour/person
	Responsible marketing	Percentage of employees trained	%
General material	Drug and antibiotic resistance in the environment	—	N/A

Risk Management

We have adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. The following internal policies and programs outline our approach to risk management:

- The relevant departments in our Company are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. Each department is responsible for identifying and evaluating risks associated with its working scope. In order to standardize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) identify the source of the risks and potential impact, (ii) monitor the development of such risks, and (iii) prepare risk management reports periodically for ESG working group’s review.
- Our ESG working group will coordinate, oversee and manage the overall risks associated with our business operations and quality control, respectively, mainly including (i) reviewing our corporate risk in light of our corporate risk tolerance, (ii) maintaining a key risk list and leading corresponding risk management activities, and (iii) organizing revision and update of the key risk list. Our ESG working group will be responsible for carrying out the risk prevention and management activities with relevant department and conduct irregular reviews.
- Our Board will be responsible for (i) reviewing the risk management information, (ii) reviewing annual risk management report of the Group, and (iii) overseeing ESG working group to promulgating annual risk evaluations.

BUSINESS

- We will carry out a corporate risk assessment at least once a year which covers current and potential risks that the Group faces, including but not limited to ESG risks and strategic risks from disruptive forces (such as climate change). The Board of Directors will, by themselves or by engaging external experts to, assess such risks, review our existing strategies, objectives and internal control, and make necessary improvements to reduce the risks. The Board and the ESG working group will keep monitoring our approaches to risk management, including climate-related risks and risks monitored as part of standard operation procedures, to ensure that appropriate mitigation measures are implemented in regular management reviews.
- The decisions on the reduction, transfer, acceptance or control of the risks are affected by various factors. We will incorporate climate-related issues, including the analysis on physical and transition risks, into its risk assessment process and risk appetite setting. We will consider the risks and opportunities in its strategic and financial planning process if such risks and opportunities are deemed to be material. After reviewing the environmental, social and climate-related risks and our performance in response to such risks each year, we may revise and alter our ESG strategies as appropriate.

We are adopting various strategies and measures to identify, assess, manage and mitigate ESG and climate-related risks, including but not limited to:

- Reviewing and evaluating ESG reports of comparable companies in the industry so as to ensure timely identification of all ESG-related risks.
- Discussing with the management from time to time so as to ensure that all material ESG areas are identified and reported.
- Discussing key ESG principles and practices with key stakeholders to ensure that important aspects are covered.
- Formulating specific ESG risk management approaches and quantified performance indicators so as to identify and consider ESG risks and opportunities and separate ESG risks and opportunities from other business risks and opportunities.
- Setting targets for environmental KPIs, including emissions, pollution and other impacts on the environment, so as to reduce emissions and consumption of natural resources.

We will review the ESG-related progress and risks made on a regular basis through direct supervision by the Board and senior management, as well as with the assessment by our external independent ESG consultant.

BUSINESS

We have carried out the following analysis on the ESG-related risks and actual and potential impact of such risks on business, strategy and financial performance:

		Type of Risks	Potential Impact
Physical risks	Acute risks	Frequent occurrence of typhoons, floods, droughts and other extreme weather	<ul style="list-style-type: none"> Supplies/business interruption resulting in loss of sales
	Chronic risks	Rising average temperature	<ul style="list-style-type: none"> Increased energy consumption in laboratories, factories and offices resulting in higher energy costs Decreased employees’ productivity and increased labor costs
Transition risks	Policy and legal risks	Industry low-carbon policy requirements	<ul style="list-style-type: none"> Government’s quotas allocation on carbon emission and pressure on carbon costs
		Tightening regulatory requirements	<ul style="list-style-type: none"> Fines, loss of business, closure of business, and negative publicity on the brand and its reputation Stricter supply chain compliance requirements
		Litigation risk	<ul style="list-style-type: none"> Litigation risk brought from the interruption of supply chain, resulting in our failure to perform the contract(s) on time
	Market and technology risk	Costs for transition to low-carbon emission technology	<ul style="list-style-type: none"> Increased investment on R&D on the new technology such as green biocatalysis Increased cost on upgrading facilities for energy saving and high efficiency
		Changes in customers’ behavior and preferences	<ul style="list-style-type: none"> Loss of orders and decreased revenue resulting from insufficient disclosure of carbon neutrality goals and data

BUSINESS

Type of Risks		Potential Impact
		<ul style="list-style-type: none"> • Demand from downstream corporate customers to upstream suppliers to provide green and low-carbon biomedical products and to formulate carbon-neutral strategic goals
	Rising raw material costs	<ul style="list-style-type: none"> • Decreasing quantity and quality of raw materials • Increased R&D costs resulting from insufficient resources of laboratory supplies
	Uncertain demand	<ul style="list-style-type: none"> • Possible increased demand for medicines and other pharmaceutical products resulting from the emergence of new chronic diseases and other diseases
Reputation risk	Negative publicity	<ul style="list-style-type: none"> • Negative publicity on our reputation resulting from its inability to respond to shareholders’ expectation caused by insufficient disclosure on the reduction targets and information on emission

In addition, we shall take comprehensive measures to mitigate, adapt and build resilience to the impact of the environment on our business, strategies and financial performance, as summarized below:

Important Areas	Key Measures
Solid Waste Management	<ul style="list-style-type: none"> • Requiring proper handling and disposal of solid waste • Carrying out hazardous waste storage in accordance with relevant standards, and establishing a system for standardized management of hazardous waste
Energy and resources saving	<ul style="list-style-type: none"> • Establishing a “Green Office Management System” • Replacing with energy-saving equipment in offices

BUSINESS

Goals, Targets and Policies

We monitor the following indicators to assess and manage our environmental and climate-related risks arising from our business and production activities:

- Power consumption. We regularly monitor our electricity consumption levels and implement measures to improve energy efficiency. For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, our electricity consumption levels were 152.9 MWh, 186.3 MWh and 109.2 MWh, respectively.
- Water consumption. We regularly monitor our water consumption levels and implement measures to promote water conservation. For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, our water consumption levels were 2,121.1 tons, 2,307.4 tons and 2,017.2 tons, respectively.
- Emission of greenhouse gases. We regularly monitor the level of greenhouse gas (“GHG”) emissions. For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, our greenhouse gas emissions were 87.2 tonnes of CO₂-e, 106.2 tonnes of CO₂-e, and 62.3 tonnes of CO₂-e respectively. The waste gas is properly treated before discharge.
- Discharge of hazardous waste. We regularly monitor the level of our hazardous waste discharge. For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, our hazardous waste discharge levels were 0.5 tonnes, 0.7 tonnes and 0.3 tonnes, respectively.

We have in place a set of environmental, social and governance policies (“ESG Policy”) which are in line with relevant international standards. We strive to reduce the negative impact on the environment through our commitment to energy conservation and sustainable development. We intend to adopt governance measures which are in compliance with all ESG-related laws and regulations, and to monitor and collect ESG-related data so as to prepare our disclosure report after [REDACTED] and in accordance with the Environmental, Social and Governance Reporting Guide, Appendix 27 of the Listing Rules in due course. We are preparing and shall formulate our ESG policies in accordance with the standards under Appendix 27 of the Listing Rules, which outlines, among other things, (i) establishment of a green management system; (ii) strict rules on waste disposal; (iii) resources efficiency; and (iv) responses to climate change. We believe that employees are the most valuable resource to us, and are committed to respecting their dignity and treating them with respect. We shall continue to promote work-life balance and create a positive workplace for all of our employees. With regard to the issues in our society and our communities, we adopted the following policies relating to: (i) product quality and safety; (ii) employee’s compensation and fringe benefits; and (iii) training, health, and professional and personal development for our employees. The Board takes full responsibility for monitoring and identifying the risks and opportunities related to our environment, society and climate, establishing and adopting our ESG policies and objectives, and reviewing our performance based on its ESG objectives annually. If material deviations from the objectives are found, our ESG strategies will be revised accordingly.

BUSINESS

The ESG working group will set targets for each material key performance indicator at the beginning of each financial year in accordance with the disclosure requirements under Appendix 27 of the Listing Rules and any other relevant rules and regulations after [REDACTED]. Relevant targets of the material key performance indicators will be reviewed annually to ensure that they are still suitable for our needs. When setting the targets for environment-related KPIs, we shall take into account our respective consumption or emission levels during the Track Record Period, and consider our future business expansion in a comprehensive and prudent manner, with a view to crafting a balance between business growth and environmental protection and achieving sustainable development. We promote a low-carbon office and low-carbon travel, and implement a number of measures including: (i) low-carbon use of electric lights and electrical equipment; (ii) low-carbon use of ventilation equipment and air conditioners; (iii) water saving; (iv) paperless office; (v) recycling and reuse of office supplies; (vi) improving the working environment in the office; (vii) green travel; (viii) purchasing environmentally friendly products; and (ix) cherishing food and avoiding food wastage. Considering that our production activities will be increased this year, and referencing to the average of industry peers, international standards and our indicators during the Track Record Period, we shall continue to put effort into achieving our goal of reducing per capita water and electricity consumption and gas emissions by 3% in 2023, which may lead to 3% increase in our operation cost in 2023.

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 operations. Our Directors confirmed that we had complied with all material applicable laws and regulations for our operations in the United States and Australia and we were not involved in any material or systemic non-compliance incidents in the United States, PRC and Australia.

Our legal team is responsible for building, developing and improving our compliance management system to ensure our compliance culture is embedded into our everyday workflow. The legal team conducts compliance training for our employees and identifies, assesses, and reports compliance risks and expectations in a timely manner. Our legal team will also work with the senior management team to monitor and evaluate the effectiveness of our compliance function and structure to ensure that we comply with applicable laws and regulations.

BUSINESS

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 Business and Industry”. 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 14 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.

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

BUSINESS

We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant laws and regulations regularly to proactively identify any concerns and issues relating to any potential non-compliance.

Anti-bribery

We maintain a strict code of conduct and anti-corruption policies among our employees and distributors. We believe we will be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses should be rejected and promptly reported. Misleading, incomplete or false entries in our books and records are never acceptable. We will also ensure that future commercialization team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

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.

Our employee agreements have included non-competition clauses, which prohibit employees from engaging in or directly or indirectly assisting any third party to engage in the same, similar and competitive business activities as our Company for a period of two years from the date of termination of employment. 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.

BUSINESS

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.

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.

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, had not been involved in any accident or fatality and had been in compliance with the relevant PRC laws and regulations in all material aspects.

DIRECTORS AND SENIOR MANAGEMENT

DIRECTORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board of Directors comprises nine Directors, including two executive Directors, four non-executive Directors and three independent non-executive Directors. The following table sets out information in respect of the Directors of the Company:

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Date of joining our Group</u>	<u>Date of appointment as a Director</u>	<u>Roles and responsibilities</u>
Dr. LIU Liping (劉利平)	54	Executive Director	November 15, 2011	February 28, 2018	Overall management of the business strategy, corporate development and research and development of our Group
Ms. YU Meng (于萌)	42	Executive Director	May 4, 2015	May 11, 2023	Assisting the chief executive officer in management of business strategy, corporate development and research and development of our Group
Mr. LI Li (李鏗) ...	59	Non-executive Director	November 15, 2011	October 16, 2018	Providing guidance and advice on the corporate and business strategies of our Group
Dr. ZHU Xun (朱迅)	65	Non-executive Director	November 30, 2020	November 30, 2020	Providing guidance and advice on the corporate and business strategies of our Group
Mr. MA Lixiong (馬立雄)	49	Non-executive Director	November 16, 2021	November 16, 2021	Providing guidance and advice on the corporate and business strategies of our Group
Mr. JIANG Feng (江峰)	44	Non-executive Director	November 16, 2022	November 16, 2022	Providing guidance and advice on the corporate and business strategies of our Group

DIRECTORS AND SENIOR MANAGEMENT

Name	Age	Position	Date of joining our Group	Date of appointment as a Director	Roles and responsibilities
Mr. TAN Bo (譚肇)	50	Independent non-executive Director	[REDACTED]	[REDACTED]	Supervising and providing independent recommendations to our Board
Dr. Jin LI (李靖) ...	58	Independent non-executive Director	[REDACTED]	[REDACTED]	Supervising and providing independent recommendations to our Board
Mr. HUNG Tak Wai (孔德偉).....	65	Independent non-executive Director	[REDACTED]	[REDACTED]	Supervising and providing independent recommendations to our Board

Executive Directors

Dr. LIU Liping (劉利平), aged 54, founder of our Group, was appointed as a Director on February 28, 2018 and redesignated as an executive Director on May 15, 2023. Dr. Liu is primarily responsible for overall management of the business strategy, corporate development and research and development of our Group.

In addition to our Company, Dr. Liu has served the following positions in our Group:

- a director (and an executive director since October 2020) and chief executive officer of Shenzhen HighTide since November 2011;
- a director of Shanghai HighTide from March 2014 to October 2020; and an executive director and chief executive officer of Shanghai HighTide since October 2020;
- a director (and an executive director since October 2020) and chief executive officer of JSK Healthcare since July 2015;
- an executive director and the chief executive officer of Australia HighTide since August 2015;
- an executive director and the chief executive officer of HighTide Therapeutics, Ltd. since March 2018;
- an executive director and the chief executive officer of U.S. HighTide since November 2019;
- an executive director and the chief executive officer of HK HighTide since April 2018;

DIRECTORS AND SENIOR MANAGEMENT

- an executive director and the chief executive officer of Shanghai Fusion since May 2021;
- an executive director and the chief executive officer of Nanchang Fusion since November 2021; and
- an executive director of Hebei Puhui since September 2023.

Dr. Liu has over 20 years of experience in the R&D of new drugs. Prior to founding our Group, Dr. Liu worked as a postdoctoral researcher in the Hospital for Sick Children in Canada from March 1995 to April 2000. From April 2000 to December 2002, she served as a director of antigen discovery of CTL ImmunoTherapies Corporation. From January 2003 to September 2005, she served as a group leader in chemistry department of MannKind Corporation. From September 2005 to May 2008, Dr. Liu worked in the translational research department of American Type Culture Collection where she was primarily responsible for biomarker discovery, translational research and drug discovery. Dr. Liu served as a senior director of R&D of Stealth Peptide Inc. from May 2008 to August 2010. From February 2011 to April 2011, she served as the managing director of ABLE BioGroup LLC. On November 15, 2011, Dr. Liu established Shenzhen HighTide together with Hepalink. For details, please see “Our Group — Shenzhen HighTide” in the section headed “History”.

Dr. Liu obtained her bachelor’s degree in chemistry and doctoral degree in physics of polymers from Nankai University (南開大學) in the PRC in July 1990 and December 1994, respectively. Dr. Liu obtained a master of business administration from Johns Hopkins University Carey Business School in May 2009 in the United States. Dr. Liu was awarded Technology Innovation and Entrepreneurial Talent by the Ministry of Science and Technology of the PRC in March 2014 and Distinguished Expert in Longgang District by the People’s Government of Longgang District, Shenzhen in November 2017. She was also regarded as Top 10 Drug Innovative Scientist by Securities Times in May 2021. Dr. Liu was awarded the EY Entrepreneurial Winning Women Asia-Pacific in 2023.

Dr. Liu was a director, general manager and legal representative of Changzhou Aibo Biotechnology Co., Ltd.* (常州愛博生物技術有限公司), a PRC incorporated company, which was dissolved on January 5, 2012 because it had not been in operations for a long time. Dr. Liu confirmed that, Changzhou Aibo Biotechnology Co., Ltd was solvent before it was dissolved. Dr. Liu also confirmed that, there was no wrongful act on the part of Dr. Liu leading to the dissolution of Changzhou Aibo Biotechnology Co., Ltd. and that as of the Latest Practicable Date, no claims have been made against Dr. Liu and she was not aware of any threatened or potential claims made against her and there are no outstanding claims and/or liabilities as a result of the dissolution of Changzhou Aibo Biotechnology Co., Ltd..

Ms. YU Meng (于萌), aged 42, joined our Group on May 4, 2015 and was appointed as a director on May 11, 2023. She was redesignated as an executive Director on May 15, 2023. Ms. Yu Meng is primarily responsible for assisting Dr. Liu in management of business strategy, corporate development and research and development of our Group.

DIRECTORS AND SENIOR MANAGEMENT

Ms. Yu Meng joined our Group on May 4, 2015 as a senior manager in Shenzhen HighTide, and was the R&D director in Shenzhen HighTide from June 2017 to July 2021, where she was primarily responsible for overall monitoring of CMC and pre-clinical activities of Shenzhen HighTide. From August 2021 to September 2022, Ms. Yu Meng was the head of R&D operations of our Group. From November 2022 to present, Ms. Yu Meng is the deputy general manager and vice president of Shenzhen HighTide, primarily responsible for overall management and monitoring of the research and development of the Group in China.

From September 2008 to September 2009, Ms. Yu Meng worked in Asymchem Laboratories (Tianjin) Co., Ltd. (凱萊英醫藥集團(天津)股份有限公司), a pharmaceutical company whose shares are listed on Shenzhen Stock Exchange (stock code: 002821). From December 2009 to April 2015, Ms. Yu Meng served as a scientific liaison manager of Huya Biological Medicine Technology (Shanghai) Co., Ltd. (滬亞生物醫藥技術(上海)有限公司).

Ms. Yu Meng obtained her bachelor's degree in chemistry from University of Science and Technology of China (中國科學技術大學) in July 2004 in the PRC. Ms. Yu Meng obtained her master of science degree in chemistry from University of Nevada, Reno in August 2008 in the United States.

Non-executive Directors

Mr. LI Li (李鏗), aged 59, joined our Group on November 15, 2011 as a director of Shenzhen HighTide when Dr. Liu established Shenzhen HighTide together with Hepalink and was appointed as a Director on October 16, 2018. He was redesignated as a non-executive Director on May 15, 2023. Mr. Li is primarily responsible for providing guidance and advice on the corporate and business strategies of our Group.

Mr. Li has served the following positions outside our Group:

- the chairman of the board of Hepalink since April 1998;
- a director of Shenzhen Topknow Industrial Development Co., Ltd. (深圳市多普樂實業發展有限公司) since May 2000;
- a director of Shenzhen Techdow Pharmaceutical Co., Ltd. (深圳市天道醫藥有限公司) since November 2010;
- a director of Urumchi Feilaishi equity investment partnership (limited partnership) (烏魯木齊飛來石股權投資有限公司) since June 2008;
- a director of Shenzhen Leren Technology Co., Ltd (深圳市樂仁科技有限公司) since August 2007;
- a director of Hepalink Europe AB since February 2010;
- a director of Techdow (Hong Kong) Limited since May 2013;
- a director of HEPALINK USA INC. since April 2014;
- a director of Hepalink (Hong Kong) Limited since June 2014;

DIRECTORS AND SENIOR MANAGEMENT

- a director of Shenzhen Dekang investment development co. Ltd (深圳市德康投資發展有限公司) since March 2015;
- the chairman of the board of Shenzhen Fanpu Biological Technology Co., Ltd. (深圳市返璞生物技術有限公司) since April 2015;
- a director of Cytovance Biologics, Inc. since October 2015;
- the chairman of the board of Shenzhen Oncovent Biopharmaceuticals Co., Ltd. (深圳昂瑞生物醫藥技術有限公司) since July 2016;
- a director of Shenzhen Arimab Biopharmaceuticals Co., Ltd. (深圳市瑞迪生物醫藥有限公司) since July 2018;
- a director of Hepalink Investment Limited since August 2019;
- a director of Hepalink Pharmaceutical (Hong Kong) Limited since August 2019;
- a director of Cytovance Cayman Inc. since August 2019;
- a director of Hepalink Capital I Inc, Hepalink Capital II Inc, Hepalink Healthcare Partners I L.P, Hepalink Healthcare Partners II L.P, Hepalink Biotechnology I Limited, Hepalink Biotechnology II Limited and Hepalink Biotechnology III Limited since September 2021.

Mr. Li graduated in physics and chemistry from Chengdu University of Science and Technology (成都科學技術大學), which later merged with Sichuan University (四川大學), in July 1987 in the PRC. He won many prizes as a successful entrepreneur, including the Second Prize of Chengdu Science Technology Progress granted by Chengdu Municipal People's Government in March 1991 and the Chengdu Advanced Professional and Technical Individual granted by Organization Department of the CPC Chengdu Committee in December 1990, 100 Shenzhen Industry Leaders granted by Shenzhen Entrepreneurs Association in December 2011 and Shenzhen Mayor Award granted by Shenzhen Municipal People's Government in September 2012.

Since April 1998, Mr. Li has been the chairman of the board and an executive director of Hepalink, a leading China-based pharmaceutical company with global pharmaceutical, innovative biotech and CDMO businesses. As (i) Mr. Li is not involved in the daily management and operation of our Company given his non-executive role in our Company, (ii) Hepalink is currently not engaged in the development of the HTD1801, which is the Core Product of the Company; and (iii) there is no other overlapping product between the Group and Hepalink, the roles held by Mr. Li in Hepalink would not give rise to any material competition issue under Rule 8.10 of the Listing Rules.

Notwithstanding that Mr. Li holds a number of company directorships, the Board believes that he will still be able to devote sufficient time to our Board because (i) except for Hepalink, none of the companies that Mr. Li holds a directorship is a listed Company that will require his devotion as much as a director in a listed company; (ii) Mr. Li has demonstrated that he is able to properly discharge his duties owed to multiple companies including Hepalink and has attended nearly all of

DIRECTORS AND SENIOR MANAGEMENT

the required board meetings as well as committee meetings of Hepalink; (iii) Mr. Li has been our director since 2011 and he has demonstrated he has devoted sufficient time to our Company by attending nearly all of the board meetings in our Company either in person or via his proxy; (iv) Mr. Li’s experience as a director of Hepalink, a company listed in both Hong Kong and the PRC would facilitate his understanding of corporate governance and his proper discharge of responsibilities as a director of our Company; and (v) Mr. Li has undertaken to devote sufficient time to attending to the management of our Company.

On December 19, 2019, the Shenzhen Securities Regulatory Bureau (the “**Shenzhen Bureau**”) of the China Securities Regulatory Commission (the “**CSRC**”) issued a letter of caution (“**Caution Letter**”) to Hepalink which identified three issues of concern, being (i) irregular accounting treatment of Hepalink’s equity investment in Resverlogix Corp. (a company whose shares are listed on the Toronto Stock Exchange (stock code: RVX)); (ii) Hepalink’s internal approval process discrepancies with respect to certain related party transactions and other related pricing policy disclosure discrepancies; and (iii) Hepalink’s inadequate registration of insiders (the “**Concerned Matters**”). Mr. Li, as a director of Hepalink, was subject to a regulatory interview conducted with the CSRC in 2019 (the “**Regulatory Interview**”). As at the Latest Practicable Date and to our best knowledge, there has not been any further correspondence between Hepalink and the Shenzhen Bureau of the CSRC since Mr. Li completed the Regulatory Interview in 2019, and Mr. Li has not been imposed any penalties by the Shenzhen Bureau of the CSRC relating to the Concerned Matters.

Based on the inquiries with Mr. Li and the information available to the Company up to the Latest Practicable Date, and on the basis that (i) Mr. Li has been the executive director of Hepalink since its listing on the Main Board of the Hong Kong Stock Exchange Limited in 2020 and Mr. Li remained the executive director of Hepalink as at the Latest Practicable Date; (ii) our PRC Legal Advisor is of the view that the Caution Letter and the Regulatory Interviews are administrative regulatory measures that do not constitute administrative penalties; (iii) Mr. Li confirmed that (a) since he completed the Regulatory Interview in 2019, he has not been informed of any further update of the status of the regulatory review of the Concerned Matters, nor has he been requested to provide any further cooperation with any regulatory authorities in relation to the Concerned Matters; and (b) he has not been punished or investigated by any regulatory authority in relation to the Concerned Matters; and (iv) based on our due enquiry and review of related documents and disclosure, to the best knowledge of our Company, we are not aware of any specific facts against Mr. Li which would lead us to believe that Mr. Li is unsuitable to act as a director of a [REDACTED] company, the Directors are of the view that the Caution Letter and the Regulatory Interview do not affect Mr. Li’s suitability as a Director under Rules 3.08 and 3.09 of the Listing Rules.

Dr. ZHU Xun (朱迅), aged 65, joined our Group and was appointed as a Director on November 30, 2020, and was redesignated as a non-executive Director on May 15, 2023. Dr. Zhu was appointed as the chairman of the Board on December 17, 2020*. Dr. Zhu is primarily responsible for providing guidance and advice on the corporate and business strategies of our Group.

* Dr. Zhu was appointed as the chairman of the Board as an administrative role to chair the board meetings from December 17, 2020 till the [REDACTED], but he did not and will not involve in the day-to-day management of our Company. Since the day-to-day management and operation of the Group has been and will remain to be driven by the executive Directors and the senior management under Dr. Liu’s leadership, Dr. Liu will be appointed as the chairwoman of the Board upon [REDACTED].

DIRECTORS AND SENIOR MANAGEMENT

Dr. Zhu has served the following positions outside our Group:

- an independent non-executive director of Sihuan Pharmaceutical Holdings Group Ltd. (四環醫藥控股集團有限公司), a pharmaceutical company whose shares are listed on the Stock Exchange (stock code: 0460), since February 2014;
- a director of Changchun Yinuoke Pharmaceutical Technology Co., Ltd. (長春億諾科醫藥科技有限責任公司) since July 2016;
- a director of Beijing Dingchi Biotechnology Co., Ltd. (北京鼎持生物技術有限公司) since December 2016;
- a director of Jianaishi Biomedical Technology (Hangzhou) Co., Ltd. (健艾仕生物醫藥科技(杭州)有限公司) since March 2018;
- an independent director of Shenzhen Chipscreen Biosciences Co., Ltd. (深圳微芯生物科技股份有限公司), a technology company whose shares are listed on the Shanghai Stock Exchange (stock code: 688321), since March 2018;
- a legal representative of Shenzhen Saibao Pengsheng Investment Co., Ltd. (深圳市賽寶鵬盛投資有限公司) since November 2021; and
- an independent non-executive director of Lansan Pharmaceutical Holdings Limited (朗生醫藥控股有限公司), a pharmaceuticals and biotechnology company whose shares are listed on the Stock Exchange (stock code: 503), since September 2022.

Dr. Zhu served several positions in Norman Bethune Medical University (白求恩醫科大學) (currently known as Norman Bethune Health Science Center of Jilin University (吉林大學白求恩醫學部)), including lecturer, professor and doctoral supervisor in the immunological department, dean of the department and vice president of the University from December 1985 to June 2018. From April 2004 to September 2011, he served as the vice chairman of the board of directors and the general manager in Changchun Botai Medicine Biology Technology Co., Ltd. (長春博泰醫藥生物技術有限責任公司).

Dr. Zhu graduated in medicine from Jilin Medical College (吉林醫學院) (currently known as Beihua University (北華大學)) in December 1982 in the PRC and obtained his doctoral degree in medicine from Norman Bethune Medical University (白求恩醫科大學) in April 1989 in the PRC.

Notwithstanding that Dr. Zhu holds a number of listed company directorships, the Board believes that he will still be able to devote sufficient time to our Board because (i) none of his commitments to such other listed companies are of an executive nature and none of them require his full-time involvement; (ii) Dr. Zhu has demonstrated that he is able to properly discharge his duties owed to multiple listed companies and has attended nearly all of the required board meetings as well as committee meetings of these listed companies; (iii) Dr. Zhu has joined our Group since 2020 and he has demonstrated he has devoted sufficient time to our Company by attending nearly all of the required meetings in our Company; (iv) Dr. Zhu's experience as a director of listed companies in both Hong Kong and the PRC would facilitate his understanding of corporate

DIRECTORS AND SENIOR MANAGEMENT

governance and his proper discharge of responsibilities as a director of our Company; and (v) Dr. Zhu has undertaken to devote sufficient time to attending to the management of our Company.

Dr. ZHU was a director of Beijing Yitang Biotechnology Co., Ltd.* (北京怡唐生物科技有限公司), a PRC incorporated company, which was dissolved in June 2022 because it had not been in operations for a long time. Dr. Zhu was a director of Shenzhen Zhongke Hui'erli Biotechnology Co., Ltd.* (深圳中科卉尔立生物科技有限公司), a PRC incorporated company, which was wound up due to bankruptcy on December 15, 2020. Dr. Zhu confirmed that, Beijing Yitang Biotechnology Co., Ltd. was solvent before it was dissolved. Dr. Zhu also confirmed that, there was no wrongful act on the part of Dr. Zhu leading to the dissolution of Beijing Yitang Biotechnology Co., Ltd. or the winding-up of Shenzhen Zhongke Hui'erli Biotechnology Co., Ltd. and that as of the Latest Practicable Date, no claims have been made against Dr. Zhu and he was not aware of any threatened or potential claims made against him and there are no outstanding claims and/or liabilities as a result of the dissolution of Beijing Yitang Biotechnology Co., Ltd. or the winding-up of Shenzhen Zhongke Hui'erli Biotechnology Co., Ltd..

Mr. MA Lixiong (馬立雄), aged 49, joined our Group and was appointed as a Director on November 16, 2021 and was re-designated as a non-executive Director on May 15, 2023. Mr. Ma is primarily responsible for providing guidance and advice on the corporate and business strategies of our Group.

Mr. Ma mainly holds the current directorship and management positions in the following companies:

- an executive director and general manager in Yuthai Investment Management Co., Ltd. (昱烽晟泰投資管理有限公司) since April 2015;
- an executive director and general manager in Shenzhen AIH Capital Management Co., Ltd. (深圳市德正嘉成投資管理有限公司) since October 2015; and
- a director in Qide Technology Group Ltd. (啟德科技集團有限公司) since February 2021.

Mr. Ma served as a senior auditor at the PWC from 1998 to 2003. He served as a vice president at the Hong Kong First Investment Group Limited from 2004 to 2015.

Mr. Ma obtained his bachelor's degree in international accounting from Shenzhen University (深圳大學) in June 1998 in the PRC. He obtained the professional qualification in fund in December 2016.

Mr. MA was a supervisor of Foshan Boshen Investment Consulting Co., Ltd.* (佛山市博申投資顧問有限公司), a PRC incorporated company, which was dissolved on April 22, 2013 because it had not been in operations for a long time. Mr. Ma was a supervisor of Shenzhen Kaimen Seven Things Green Food Co., Ltd.* (深圳市開門七件事綠色食品有限公司), a PRC incorporated company, which was dissolved because it had not been in operations for a long time. Mr. Ma confirmed that, each of Foshan Boshen Investment Consulting Co., Ltd. and Shenzhen Kaimen Seven Things Green Food., Ltd. was solvent before they were dissolved. Mr. Ma also confirmed that, there was no wrongful act on the part of Mr. Ma leading to the dissolution of Foshan Boshen

DIRECTORS AND SENIOR MANAGEMENT

Investment Consulting Co., Ltd. or Shenzhen Kaimen Seven Things Green Food Co., Ltd. and that as of the Latest Practicable Date, no claims have been made against Mr. Ma and he was not aware of any threatened or potential claims made against him and there are no outstanding claims and/or liabilities as a result of the dissolution of Foshan Boshen Investment Consulting Co., Ltd. or Shenzhen Kaimen Seven Things Green Food Co., Ltd..

Mr. JIANG Feng (江峰), aged 44, joined our Group and was appointed as a Director on November 16, 2022, and was redesignated as a non-executive Director on May 15, 2023. Mr. Jiang is primarily responsible for providing guidance and advice on the corporate and business strategies of our Group.

Since January 2021, Mr. Jiang has been serving as a vice general manager of Guangdong Kaiheng Private Equity Investment Fund Management Co., Ltd. (廣東開恒私募股權投資基金管理有限公司).

Mr. Jiang worked as a senior manager in the bureau of retired cadres of China Development Bank from October 2016 to February 2018. From February 2018 to January 2021, Mr. Jiang worked as a senior manager in the party committee office of China Development Bank Capital Co., Ltd.

Mr. Jiang obtained his bachelor’s degree in wireless communication from Chinese People’s Liberation Army Communication Command College (中國人民解放軍通信指揮學院) in June 2002 in the PRC and his master’s degree in military history from PLA Nanjing Institute of Politics (中國人民解放軍南京政治學院) in March 2005 in the PRC.

Independent Non-executive Directors

Mr. TAN Bo (譚孳), aged 50, was appointed as an independent non-executive Director with effect from the [REDACTED]. He is responsible for supervising and providing independent recommendations to our Board.

Mr. Tan has served as an independent non-executive director of Globe Metals & Mining, a company whose shares are listed on the Australian Securities Exchange (stock code: GBE), since October 2013, and an independent non-executive director of Akeso, Inc., a company whose shares are listed on the Stock Exchange (stock code: 9926), where he has served as the chairman of the audit committee, since April 2020.

Mr. Tan has extensive experience within the financial and pharmaceutical industries, and has worked in private equity, equity research and commercial sectors for over 15 years. He worked in Macquarie Capital Limited in Hong Kong from November 2004 to February 2006. From March 2006 to March 2007, he worked in the equity research division of Lehman Brothers Asia Limited. From February 2009 to December 2019, Mr. Tan worked at 3SBio Inc., a company whose shares are listed on the Stock Exchange (stock code: 1530), and served as its executive vice president, executive director and chief financial officer (“CFO”), being primarily responsible for the finance management of the company. From September 2020 to January 2023, Mr. Tan served as an independent non-executive director of Everest Medicines Limited, a company whose shares are listed on the Stock Exchange (stock code: 1952).

DIRECTORS AND SENIOR MANAGEMENT

Mr. Tan obtained his bachelor’s degree in economics from Renmin University of China (中國人民大學) in July 1994 in the PRC, master’s degree in economics from the University of Connecticut in December 1996 and a master of international management from American Graduate School of International Management (now known as Thunderbird School of Global Management) in August 1998 in the United States.

Dr. Jin LI (李靖), aged 58, was appointed as an independent non-executive Director with effect from the [REDACTED]. He is responsible for supervising and providing independent recommendations to our Board.

Since August 2015, Dr. Li has served as the chairman of the board and general manager of Beijing Orbiopharm Co., Ltd. (北京歐博方醫藥科技有限公司). Since December 2018, he has served as an independent director at Chengdu Easton Biopharmaceuticals Co., Ltd (成都苑東生物製藥股份有限公司), a company whose shares are listed on the Shanghai Stock Exchange (stock code: 688513).

Dr. Li also holds a series of other positions outside our Group, including a director of Huaqing Bencao Investment Arrangement Limited Company (華清本草投資管理南通有限公司) since May 2015, a director of Yaodu (Beijing) Medical Information Consulting Co., Ltd. (藥渡(北京)醫藥信息諮詢有限公司) (currently known as Pharmacodia Pharma Intelligence (Beijing) Technology Co., Ltd. (藥渡智慧(北京)醫藥科技有限公司) since July 2017, the chairman of the board of Qingdao Orbiopharm Co., Ltd. (青島歐博方醫藥科技有限公司) from November 2013 to April 2022, the chairman of the board of director of Qingdao Pet Love Animal Hospital Management Co., Ltd. (青島寵之愛動物醫院管理有限公司) since August 2018, a director of Beijing Zhongguancun Shangdi Biotechnology Development Co., Ltd. (北京中關村上地生物科技發展有限公司) since September 2021, an independent non-executive Director of 3D Medicines Inc., a company whose shares are listed on the Stock Exchange (stock code: 1244) since December 2022 and a director of Beijing Konruns Pharmaceutical Co., Ltd. (北京康辰藥業股份有限公司), a company whose shares are listed on the Shanghai Stock Exchange (stock code: 603590) since January 2023.

Dr. Li obtained his Ph.D. in chemistry from the University of Wisconsin-Milwaukee in the United States in May 1999. He has published more than 25 papers and 14 book chapters in the chemistry field, and is the inventor of more than 30 patents. He also obtained the Fund Practicing Qualification Certificate in September 2018 from the Asset Management Association of China, and the independent director certificate issued by the Shanghai Stock Exchange in November 2018.

Notwithstanding that Dr. Li holds a number of listed company directorships, the Board believes that he will still be able to devote sufficient time to our Board because (i) none of his commitments to such other listed companies are of an executive nature and none of them require his full-time involvement; (ii) Dr. Li has demonstrated that he is able to properly discharge his duties owed to multiple listed companies and has attended nearly all of the required board meetings as well as committee meetings of these listed companies, (iii) Dr. Li’s experience as a director of listed companies in both Hong Kong and the PRC would facilitate his understanding of corporate governance and his proper discharge of responsibilities as a director of our Company, and (iv) Dr. Li has undertaken to devote sufficient time to attending to the management of our Company.

Mr. HUNG Tak Wai (孔德偉), aged 65, was appointed as an independent non-executive Director with effect from the [REDACTED]. He is responsible for supervising and providing independent recommendations to our Board.

DIRECTORS AND SENIOR MANAGEMENT

Mr. Hung worked at UBS AG, Hong Kong from October 2001 to March 2009. Mr. Hung was the project director in the equity & derivatives department of BNP Paribas Hong Kong Branch from November 2009 to August 2011, a managing director in UBS Corporate Management (Shanghai) Co. Ltd. from October 2011 to September 2012, an assistant president in China Merchant Securities Co. Limited from November 2012 to October 2018, a senior adviser in Macquarie Capital Limited from June 2019 to June 2020 and a senior adviser in Expecta Capital Limited since May 2022.

Mr. Hung obtained the senior management qualification for securities companies issued by the CSRC in June 2007. He was a vice-chair of the Asset Securitization and Structured Financing Professional Committee (資產證券化暨結構化融資專業委員會委員) in National Association of Financial Market Institutional Investors (中國銀行間市場交易商協會) from April 2018 to September 2022.

Mr. Hung obtained his bachelor degree of science in industrial chemistry in the City University in London in June 1981 and his master degree of science in chemical engineering in Columbia University in the USA in January 1983.

Having considered the nature and reasons of the aforementioned dissolution or winding-up of companies that Dr. Liu, Dr. Zhu Xun and Mr. Ma Lixiong used to hold a position in, our Directors are of the view that such dissolution or winding-up would not affect the suitability of Dr. Liu, Dr. Zhu Xun and Mr. Ma Lixiong to act as the Company's directors under Rules 3.08 and 3.09 of the Listing Rules based on the following reasons: (i) the dissolution or winding-up of the aforementioned companies was not due to the dishonesty, gross negligence or recklessness of Dr. Liu, Dr. Zhu Xun and Mr. Ma Lixiong; and (ii) each of Dr. Liu, Dr. Zhu Xun and Mr. Ma Lixiong has attended the relevant training provided by our Hong Kong legal counsel and is aware of the requirements and obligations as directors of a [REDACTED] company pursuant to the Listing Rules and has undertaken to observe and comply with all the relevant rules and regulations. Based on the independent due diligence work conducted by the Joint Sponsors, nothing has come to their attention that would reasonably cause them to cast doubt on such view.

COMPETITION

As of the Latest Practicable Date, none of our Directors has any interests in any business, which competes or is likely to compete, either directly or indirectly, with our business which would require disclosure under Rule 8.10 of the Listing Rules.

DIRECTORS AND SENIOR MANAGEMENT

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management of our business. The table below shows certain information in respect of the senior management of our Company:

Name	Age	Position	Date of joining our Group	Date of appointment as a senior management	Roles and responsibilities
Dr. LIU Liping (劉利平)	54	Chief executive officer	November 15, 2011	February 28, 2018	Overall management of the business strategy, corporate development and research and development of our Group
Dr. Leigh Anne MACCONELL	57	Chief development officer	February 1, 2021	February 1, 2021	Leading and overseeing global clinical and non-clinical development, CMC, drug safety and project management activities of our Group
Mr. SIM Koon Yin Edmund (沈觀賢)	54	Chief financial officer	December 1, 2022	December 1, 2022	Overseeing management of the Group’s capital market activities, finances and legal affairs
Ms. YU Meng (于萌)	42	Deputy general manager	May 4, 2015	June 1, 2017	Assisting the chief executive officer in management of business strategy, corporate development and research and development of our Group
Dr. MA Tianwei (馬天偉)	56	Vice president of discovery research	February 1, 2023	February 1, 2023	Overseeing management of the discovery research of our Group
Ms. YU Li (于莉)	47	Vice president	November 15, 2011	February 28, 2018	Overseeing management of administration of our Group
Ms. BAI Ru (白茹)	38	Director of non-clinical development	February 6, 2012	November 1, 2020	Management of the preclinical pharmacology, pharmacokinetics and toxicology of our Group

DIRECTORS AND SENIOR MANAGEMENT

Dr. LIU Liping (劉利平), aged 54, was appointed as the chief executive officer of our Company on February 28, 2018. For details of her biography, please see “— Board of Directors — Executive Directors” in this section.

Dr. Leigh Anne MACCONELL, aged 57, joined our Group as the chief development officer on February 1, 2021. Dr. MacConell is primarily responsible for leading and overseeing global clinical and non-clinical development, CMC, drug safety and project management activities of our Group.

From October 1998 to March 2003, Dr. MacConell served as a postdoctoral research associate of The Salk Institute. From March 2003 to February 2013, Dr. MacConell served in Amylin Pharmaceuticals Inc. including medical research and clinical scientist with her last position being a senior director. From June 2013 to May 2020, Dr. MacConell served in various positions, the latest position having served as a senior vice president of clinical development and cholestasis programme head in Intercept Pharmaceuticals Inc., a pharmaceutical company whose shares are listed on NASDAQ Global Market (stock symbol: ICPT). Dr. MacConell has been the chief development officer of U.S. HighTide since February 2021.

Dr. MacConell obtained her bachelor’s degree in biopsychology from University of California, Santa Barbara in December 1989 in the United States and her master’s and doctoral degree in neuroscience from University of California, San Diego in June 1994 and December 1998 in the United States, respectively.

Mr. SIM Koon Yin Edmund (沈觀賢), aged 54, joined our Group as the chief financial officer on December 1, 2022. Mr. Sim is primarily responsible for overseeing the Group’s management of the capital market activities, finances and legal affairs.

Mr. Sim has over 18 years of experience in the investment banking industry. From March 2004 to June 2008, Mr. Sim served as a director in equity capital markets in Citigroup Global Markets Asia Limited where he was responsible for Hong Kong equity markets offerings. Mr. Sim worked in Goldman Sachs (Asia) L.L.C. and Goldman Sachs Gao Hua Securities Company Limited from June 2008 to May 2010 as an executive director in the financing group department. From May 2010 to July 2012, Mr. Sim served as a managing director and co-head of the China equity markets department in Merrill Lynch (Asia Pacific) Limited. Mr. Sim served as a managing director and head of global capital markets from October 2012 to May 2017 and a managing director and head of equities division from May 2017 to October 2018 in China Merchants Securities International Company Limited, where he was primarily responsible for the equity and debt capital market offering as well as the overall management of the institutional equities, investment research, and financial products department as being the head of the equities division. From November 2019 to November 2022, Mr. Sim served as a vice president of Vitasky Research Holdings Co. Limited where he was primarily responsible for international business development and capital markets activities. Mr. Sim has been the chief financial officer of HK HighTide since December 2022.

Mr. Sim obtained his bachelor of business degree in accountancy from Queensland University of Technology in August 1996 in Australia and his master of science degree in financial management from University of London in December 2000 in the United Kingdom through long distance learning. In May 1999, Mr. Sim was admitted as a certified practising accountant of the

DIRECTORS AND SENIOR MANAGEMENT

Australian Society of Certified Practising Accountants. Mr. Sim has been a Certified Public Accountant of the Hong Kong Institute of Certified Public Accountants (“HKICPA”) since March 2000.

Ms. YU Meng (于萌), aged 42, was appointed as the deputy general manager of our Group on June 1, 2017. For details of her biography, please see “— Board of Directors — Executive Directors” in this section.

Dr. MA Tianwei (馬天偉), aged 56, was appointed as the vice president of discovery research of our Group on February 1, 2023. Dr. Ma is primarily responsible for leading and overseeing the discovery research of our Group.

From March 2000 to March 2018, Dr. Ma worked in Eli Lilly China. From April 2011 to December 2017, Dr. Ma served as a R&D pharmaceutical director in Lilly China Research and Development Center. From July 2018 to August 2019, Dr. Ma served as a vice president in PegBio Co., Ltd. From September 2019 to January 2023, Dr. Ma served as a vice president and the head of chemistry in BioFront Therapeutics, Beijing. Dr. Ma has been the vice president of Shanghai Fusion since February 2023.

Dr. Ma obtained his bachelor of science degree in organic chemistry from Nankai University (南開大學) in July 1989 in the PRC and his master of science degree in medicinal chemistry from Beijing Medical Sciences University in July 1992 in the PRC, which was later merged into Peking University (北京大學) in April 2000 in the PRC. Dr. Ma obtained his doctorate degree from University of Georgia in June 1997.

Ms. YU Li (于莉), aged 47, was appointed as the vice president of our Group on February 28, 2018. Ms. Yu Li joined our Group on November 15, 2011 as a vice general manager of Shenzhen HighTide. Ms. Yu Li is primarily responsible for the management of administration of our Group.

Ms. Yu Li served as an engineer of Shandong Xinhua Pharmaceutical Co., Ltd. (山東新華製藥股份有限公司), a pharmaceutical company whose shares are listed on Shenzhen Stock Exchange (stock code: 000756) from July 1998 to February 2003, where she was mainly responsible for supervising production. From May 2003 to December 2007, Ms. Yu Li served in Shanghai Yoseen New Drug R&D Co., Ltd. (上海玉森新藥開發有限公司) with her last position being a senior manager of registration department, where she was mainly responsible for development and regulatory affairs of new drugs. From July 2009 to February 2010, Ms. Yu Li served as a regulatory affairs manager of Stealth Peptides International (Shanghai) Inc. (康肽德生物醫藥技術(上海)有限公司) (currently known as Tealth Peptides International (Shanghai) Inc. (世耀生物醫藥技術(上海)有限公司)). From March 2010 to August 2011, Ms. Yu Li served as a regulatory affairs manager of All Pharma (Shanghai) Trading Co., Ltd. (阿樂濱度(上海)貿易有限公司). Ms. Yu Li has been the vice president of Shenzhen HighTide since November 2011, the vice president of Australia HighTide since August 2015 and the manager of Hebei Puhui since September 2023.

Ms. Yu Li obtained her bachelor’s degree in traditional Chinese medicine from Shandong University of Traditional Chinese Medicine (山東中醫藥大學) in July 1998 in the PRC. Ms. Yu Li obtained her master’s degree in traditional Chinese medicine from Shanghai University of Traditional Chinese Medicine (上海中醫藥大學) through on-the-job learning in July 2007 in the PRC.

DIRECTORS AND SENIOR MANAGEMENT

Ms. BAI Ru (白茹), aged 38, was appointed as the director of non-clinical development of our Group on November 1, 2020. Ms. Bai joined our Group on February 6, 2012 as a project manager of pharmacology. Ms. Bai is primarily responsible for management of the preclinical pharmacology, pharmacokinetics and toxicology of our Group.

Ms. Bai served in Shenzhen Dong Yangguang Industrial Development Co., Ltd. (深圳市東陽光實業發展有限公司) from July 2011 to February 2012. Ms. Bai has been the non-clinical development director of Shenzhen HighTide since November 2020.

Ms. Bai obtained her bachelor’s degree in biotechnology from China Pharmaceutical University (中國藥科大學) in July 2008 in the PRC. Ms. Bai obtained her master’s degree in chemical biology from Nankai University (南開大學) in June 2011 in the PRC. She was qualified as an intermediate pharmaceutical manufacturing engineer by Shenzhen Pharmaceutical Senior Professional Title Review Committee in May 2022.

Other than the information disclosed above and the information as set out in the section headed “Statutory and General Information — F. Miscellaneous information in relation to Rule 13.51(2) of the Listing Rules” in Appendix IV to this document, none of the Directors or senior management of the Company held position of director in any other listed companies during the Track Record Period, and no other information relating to Directors is required to be disclosed pursuant to Rule 13.51(2) of the Hong Kong Listing Rules, and no other matters are required to be brought to the attention of Shareholders. As of the Latest Practicable Date, none of our Directors or senior management is related to other Directors or senior management of our Company.

JOINT COMPANY SECRETARIES

Ms. YU Li (于莉), aged 47, one of our joint company secretaries, was appointed on May 15, 2023. See her biography under “— Senior Management” for details.

Ms. CHU Pik Man (朱璧敏), aged 27, one of our joint company secretaries, was appointed on [●], 2023. Ms. Chu is an assistant manager of SWCS Corporate Services Group (Hong Kong) Limited.

Ms. Chu obtained her bachelor’s degree of business administration (honours) in corporate governance concentration from Hong Kong Shue Yan University in July 2018. Ms. Chu is an associate member of The Hong Kong Chartered Governance Institute (formerly known as The Hong Kong Institute of Chartered Secretaries) and The Chartered Governance Institute (formerly known as the Institute of Chartered Secretaries and Administrators).

BOARD COMMITTEES

Our Company has established three committees under the Board pursuant the corporate governance practice requirements under the Hong Kong Listing Rules, including the Audit Committee, Remuneration Committee and Nomination Committee.

DIRECTORS AND SENIOR MANAGEMENT

Audit Committee

We have established an Audit Committee in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code set out in Appendix 14 to the Listing Rules. The primary duties of the Audit Committee are to review and supervise the financial reporting process and internal controls system of the Group, review and approve connected transactions and to advise the Board. The Audit Committee comprises three independent non-executive Directors, namely Mr. TAN Bo (譚肇), Dr. Jin LI (李靖) and Mr. HUNG Tak Wai (孔德偉). Mr. TAN Bo (譚肇) being the chairman of the committee, is appropriately qualified as required under Rules 3.10(2) and 3.21 of the Listing Rules.

Remuneration Committee

We have established a Remuneration Committee in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code set out in Appendix 14 to the Listing Rules. The primary duties of the Remuneration Committee are to review and make recommendations to the Board regarding the terms of remuneration packages, bonuses and other compensation payable to our Directors and senior management. The Remuneration Committee comprises one executive Director and two independent non-executive Directors, namely Dr. LIU Liping (劉利平), Mr. TAN Bo (譚肇) and Dr. Jin LI (李靖). Dr. Jin LI (李靖) is the chairman of the committee.

Nomination Committee

We have established a Nomination Committee in compliance with with Rule 3.27A of the Listing Rules and the Code on Corporate Governance set out in Appendix 14 to the Listing Rules. The primary duties of the Nomination Committee are to make recommendations to our Board regarding the appointment of Directors and Board succession. The Nomination Committee comprises one executive Director and two independent non-executive Directors, namely Dr. LIU Liping (劉利平), Dr. Jin LI (李靖) and Mr. HUNG Tak Wai (孔德偉). Dr. LIU Liping (劉利平) is the chairwoman of the committee*.

BOARD DIVERSITY POLICY

In order to enhance the effectiveness of our Board and to maintain the high standard of corporate governance, 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. Pursuant to the Board Diversity Policy, we seek to achieve the diversity of the Board through the consideration of a number of factors when selecting the candidates to our Board, including but not limited to gender, skills, age, professional experience, knowledge, cultural, education background, ethnicity and length of service. The ultimate decision of the appointment will be based on merit and the contribution which the selected candidates will bring to our Board.

Our Directors have a balanced mix of knowledge and skills, including in biochemistry, pharmaceuticals, business development, research and development, investment management and corporate finance. They obtained degrees in various majors including biology, pharmaceuticals,

* effective upon [REDACTED]

DIRECTORS AND SENIOR MANAGEMENT

economics and business development, among others. We have three independent non-executive Directors with different industry backgrounds, representing at least one third of the members of our Board. Furthermore, In respect of gender diversity, we recognize the particular importance of gender diversity. Our Board currently comprises two female Directors and seven male Directors. We have taken and will continue to take steps to promote and enhance gender diversity at all levels of our Company, including but without limitation at our Board and senior management levels. After the [REDACTED], we expect to maintain such gender ratio at the Board level going forward. In particular, we will actively identify female individuals suitably qualified to become our Board members. We will ensure that there is gender diversity when recruiting staff at mid to senior level so that we will have a pipeline of female senior management and potential successors to our Board in due time to ensure gender diversity of the Board. Our Group will continue to emphasize training of female talent and providing long-term development opportunities for our female staff.

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After the [REDACTED], our Nomination Committee will monitor the implementation of the Board Diversity Policy and review 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.

CODE PROVISION C.2.1 OF THE CORPORATE GOVERNANCE CODE

Under paragraph C.2.1 of the Corporate Governance Code, the roles of the chairman and chief executive officer should be separate and should not be performed by the same individual. Dr. Liu will be our chairwoman of the Board and the chief executive officer of our Company after the [REDACTED]. With extensive experience in the pharmaceutical industry and having served in our Company since its establishment, Dr. Liu is in charge of overall strategic planning, business direction and operational management of our Group. Our Board considers that vesting the roles of chairwoman and chief executive officer in the same person is beneficial to the management of our Group. The balance of power and authority is ensured by the operation of our Board and our senior management, which comprises experienced and diverse individuals. Our Board currently comprises two executive Directors, four non-executive Directors and three independent non-executive Directors, and therefore has a strong independence element in its composition.

Save as disclosed above, our Company intends to comply with all code provisions under the Corporate Governance Code after the [REDACTED].

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into employment contracts, confidentiality agreements and non-competition agreements with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

DIRECTORS AND SENIOR MANAGEMENT

Non-competition

Within two years from the date of the employee's departure (the "**Non-compete Period**") and during the course of employment by our Group, he/she shall not, among others, be engaged by, hold equity or beneficiary interests in, any entity that competes with us. In addition, the employee shall not (i) solicit or attempt to induce any of our customers, suppliers or clients who are used to deal with our Group to become a customer or supplier of others or terminate its relationship with us; or (ii) solicit or attempt to induce any person who is employed by our Group to leave our Group.

We will pay compensation to the relevant employee during the Non-compete Period if any losses was incurred to the relevant employees due to the non-competition obligation.

Confidentiality

The employee shall keep in confidence and shall not disclose our trade secrets, including but not limited to our technical information and operational information in confidence during the term of their employment and thereafter.

Service Invention

The intellectual property rights in any invention, work or non-patent technical result that is (i) resulted from performing employee duties (ii) developed within one year after resignation or change of job and is relevant to performing employee duties before the resignation or change of job, or (iii) developed mainly using our material, technologies and information shall belong to us.

COMPLIANCE ADVISOR

We have appointed Fosun International Capital Limited as our compliance advisor (the "**Compliance Advisor**") pursuant to Rule 3A.19 of the Listing Rules. Our Compliance Advisor will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our 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 the business activities, development or results of our Group deviate from any forecast, estimate or other information in this document; and
- (d) where the Stock Exchange makes an inquiry to our Company regarding unusual movements in the price or trading volume of its [REDACTED] securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

The term of appointment of our Compliance Advisor shall commence on the [REDACTED] and is expected to end 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].

DIRECTORS AND SENIOR MANAGEMENT

REMUNERATION OF DIRECTORS AND SENIOR MANAGEMENT

For details on the service contracts and appointment letters signed between the Company and our Directors, please refer to the section “Statutory and General Information — C. Further Information about Our Directors — 1. Particulars of Directors’ service contracts and appointment letters” in Appendix IV to this document.

For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023 the total amount paid by us for payments of emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) to Directors were RMB8.8 million, RMB10.9 million and RMB12.6 million, respectively. For remuneration details of all Directors during the Track Record Period, please refer to Note 8 to the Accountants’ Report as set out in Appendix I to this document.

According to existing effective arrangements, the total amount of remuneration (excluding any possible payment of discretionary bonus) shall be paid by us to Directors for the financial year ending December 31, 2023 is expected to be approximately RMB3.9 million.

The remuneration of Directors has been determined with reference to the salaries of comparable companies and their experience, duties and performance.

For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, the five highest remunerated individuals of our Company included one Director, one Director and two Directors, respectively, whose remunerations were included in the total amount paid by us for the emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) of the relevant Directors. For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, the total amount of remuneration and benefits in kind (if applicable) paid by us to the five highest remunerated individuals were RMB14.9 million, RMB25.8 million and RMB22.7 million, respectively.

Save as disclosed in the section headed “Statutory and General Information — C. Further Information about Our Directors — 3. Disclosure of interests” in Appendix IV to this document, each of our Directors has no interests in the Shares within the meaning of Part XV of the SFO.

For the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, RMB0.3 million, RMB0.1 million and nil was paid to the five highest remunerated individuals of our Company, respectively, as incentives for joining or as rewards upon joining our Company. None of such payees is our Director. Other than the aforementioned payments, during the Track Record Period, no remuneration was paid by us nor receivable by Directors or the five highest remunerated individuals as incentives for joining or as rewards upon joining our Company. During the Track Record Period, no remuneration was paid by us nor receivable by Directors, past Directors or the five highest remunerated individuals as compensation for leaving positions relating to management affairs in any subsidiary of the Company.

During the Track Record Period, none of our Directors has waived any remuneration. Save as disclosed above, during the Track Record Period, no other amounts shall be paid or payable by us or any of our subsidiaries to the Directors or the five highest remunerated individuals.

DIRECTORS AND SENIOR MANAGEMENT

INCENTIVE PLANS

We have adopted the Incentive Plans, including the 2020 Share Incentive Plan and the 2023 Share Incentive Plan. For further details, please see “Statutory and General Information — D. Incentive Plans” in Appendix IV to this document.

Save as disclosed above, no Director is entitled to receive other special benefits from the Company.

SHARE CAPITAL

AUTHORIZED AND ISSUED SHARE CAPITAL

The following is a description of the authorized and issued share capital of our Company in issue and to be issued as fully paid or credited as fully paid immediately following the completion of the [REDACTED] and the [REDACTED].

Upon the [REDACTED], our authorized capital will be US\$[REDACTED] divided into [REDACTED] Shares of US\$0.0001 each. As at the Latest Practicable Date, our authorized share capital was US\$50,000.00 divided into 500,000,000 Shares of US\$0.0001 each, which include: (i) 460,186,516 ordinary Shares, (ii) 6,300,000 Series A Preferred Shares; (iii) 2,760,061 Series B-1 Preferred Shares, (iv) 1,910,811 Series B-2 Preferred Shares, (v) 12,678,554 Series B+ Preferred Shares, (vi) 12,190,291 Series C Preferred Shares, and (vii) 3,973,767 Series C+ Preferred Shares.

As at the date of this document, our issued share capital consisted of: (i) 44,349,294 ordinary Shares, (ii) 6,300,000 Series A Preferred Shares; (iii) 2,760,061 Series B-1 Preferred Shares, (iv) 1,910,811 Series B-2 Preferred Shares, (v) 12,678,554 Series B+ Preferred Shares, (vi) 12,190,291 Series C Preferred Shares, and (vii) 3,973,767 Series C+ Preferred Shares. Each Preferred Share in the Company held by the [REDACTED] Investors will be redesignated and reclassified into one ordinary Share upon the [REDACTED] becoming unconditional.

Assuming the [REDACTED] is not exercised, the share capital of our Company immediately after the [REDACTED] will be as follows:

Authorized Share Capital	Nominal Value
<i>As of the Latest Practicable Date⁽¹⁾:</i>	
500,000,000 of US\$0.0001 each	US\$50,000
<i>Upon the [REDACTED]</i>	
[REDACTED] of US\$0.0001 each	US\$[REDACTED]
Issued Share Capital	Nominal Value
<i>Ordinary Shares in issue upon completion of the repurchase of Shares from the 2023 ESOP Platform:</i>	
[REDACTED] of US\$0.0001 each	US\$[REDACTED]
<i>Preferred Shares to be converted to Shares on a one-for-one basis:</i>	
[REDACTED] of US\$0.0001 each	US\$[REDACTED]
<i>Shares to be issued pursuant to the [REDACTED]:</i>	
[REDACTED] of US\$0.0001 each	US\$[REDACTED]
<i>Shares to be issued pursuant to the [REDACTED]:</i>	
[REDACTED] of US\$0.0001 each	<u>US\$[REDACTED]</u>
<i>Total</i>	
[REDACTED] of US\$0.0001 each	<u><u>US\$[REDACTED]</u></u>

Note:

(1) The Preferred Shares will be converted into Shares on a one-to-one basis by way of re-designation to Shares on the [REDACTED].

SHARE CAPITAL

ASSUMPTIONS

The above table assumes that the [REDACTED] becomes unconditional, Shares are issued pursuant to the [REDACTED] and the [REDACTED] and the Shares held by the [REDACTED] Investors are re-designated into ordinary Shares on a one-to-one basis. It takes no account of any Shares which may be issued or repurchased by our Company pursuant to the general mandates granted to our Directors to issue or repurchase Shares as referred to below or any additional Shares which may be issued pursuant to the Incentive Plans.

RANKING

The [REDACTED] will rank *pari passu* in all respects with all Shares currently in issue or to be issued as mentioned in this document, and will qualify and rank in full for all dividends or other distributions declared, made or paid on the Shares in respect of a record date which falls after the date of this document.

CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Our Company will have only one class of Shares, namely ordinary Shares, and each ranks *pari passu* with other Shares upon completion of the [REDACTED] and the [REDACTED].

Pursuant to the Cayman Companies Act and the terms of the Memorandum of Association and Articles of Association, our Company may from time to time by ordinary resolution of Shareholders (i) increase its capital; (ii) consolidate and divide its capital into Shares of larger amount; (iii) divide its Shares into several classes; (iv) subdivide its Shares into Shares of smaller amount; and (v) cancel any Shares which have not been taken or agreed to be taken. In addition, our Company may subject to the provisions of the Cayman Companies Act reduce its share capital or capital redemption reserve by special resolution of Shareholders.

See the section headed "Appendix III — Summary of the Constitution of the Company and Cayman Islands Company Law" in this document for further details.

GENERAL MANDATE TO ISSUE SHARES

Subject to the [REDACTED] becoming unconditional, our Directors [have been] granted a general unconditional mandate to allot, issue and deal with Shares with a total number of not more than the sum of:

- 20% of the total number of the Shares in issue immediately following completion of the [REDACTED] and the [REDACTED] (excluding the Shares which may be allotted and issued pursuant to the exercise of the [REDACTED], if any); and
- the total number of Shares repurchased by us under the authority referred to in the paragraph headed "— General Mandate to Repurchase Shares" in this section.

This general mandate to issue Shares will expire at the earliest of:

- the conclusion of the next annual general meeting of our Company unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions;

SHARE CAPITAL

- the expiration of the period within which our Company’s next annual general meeting is required by the Memorandum of Association and Articles of Association or any other applicable laws to be held; or
- the date on which it is varied or revoked by an ordinary resolution of our Shareholders passed in a general meeting.

See the section headed “Statutory and General Information — A. Further Information about our Group — 4. Written Resolutions Passed by Our Shareholders on [●]” in Appendix IV to this document for further details of this general mandate to allot, issue and deal with Shares.

INCENTIVE PLANS

The Company has adopted the Incentive Plans, including the 2020 Share Incentive Plan and the 2023 Share Incentive Plan. For further details, please see “Statutory and General Information – D. Incentive Plans” in Appendix IV to this document.

GENERAL MANDATE TO REPURCHASE SHARES

Subject to the [REDACTED] becoming unconditional, our Directors have been granted a general unconditional mandate to exercise all the powers of our Company to repurchase our own securities with nominal value of up to 10% of the total number of our Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED] (excluding the Shares which may be allotted and issued pursuant to the exercise of the [REDACTED], if any).

The repurchase mandate only relates to repurchases made on the Stock Exchange, or on any other stock exchange on which our Shares are listed (and which are recognized by the SFC and the Stock Exchange for this purpose), and which are in accordance with the Listing Rules. A summary of the relevant Listing Rules is set out in the section headed “Statutory and General Information — A. Further Information about our Group — 5. Repurchase of our own securities” in Appendix IV to this document.

This general mandate to repurchase Shares will expire at the earliest of:

- the conclusion of the next annual general meeting of our Company unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions; or
- the expiration of the period within which our Company’s next annual general meeting is required by the Memorandum of Association and Articles of Association or any other applicable laws to be held; or
- the date on which it is varied or revoked by an ordinary resolution of our Shareholders passed in a general meeting.

See “Statutory and General Information — A. Further Information about our Group — 5. Repurchase of our own securities” in Appendix IV to this document for further details of the repurchase mandate.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] and assuming the [REDACTED] is not exercised, the following persons will have interests and/or short positions (as applicable) in the Shares or underlying Shares of our Company, which would be required to be disclosed to us and the Stock Exchange pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO or will, directly or indirectly, be interested in 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at the general meetings of the Company or any other members of the Group:

Long Positions in the Shares of our Company

Name of Substantial Shareholder	Nature of interest	Shares held as of the date of this document		Shares held with exercisable voting rights entitled immediately following the completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and [REDACTED] (assuming the [REDACTED] is not exercised) ⁽⁶⁾	
		Number of Shares	Approximate percentage	Number of Shares	Approximate percentage
Dr. Liu	Founder of a discretionary trust ⁽¹⁾	13,500,000	16.04%	[REDACTED]	[REDACTED]%
	Interest held through voting powers entrusted by other persons and/or vested Shares ⁽²⁾	8,849,294	10.51%	[REDACTED]	[REDACTED]%
Founder BVI	Beneficial owner ⁽¹⁾	13,500,000	16.04%	[REDACTED]	[REDACTED]%
The Bryn Mawr Trust Company of Delaware ⁽¹⁾	Trustee of a trust	13,500,000	16.04%	[REDACTED]	[REDACTED]%
The Core Trust Company Limited ⁽²⁾ ..	Trustee of a trust	8,849,294	10.51%	[REDACTED]	[REDACTED]
2020 ESOP Platform ⁽²⁾ ..	Beneficial owner	8,849,294	10.51%	[REDACTED]	[REDACTED]
Mr. LI Li ⁽³⁾	Interest in controlled corporation	20,252,535	24.06%	[REDACTED]	[REDACTED]%
Hepalink Biotechnology II Limited ⁽³⁾	Beneficial owner	18,000,000	21.39%	[REDACTED]	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Substantial Shareholder	Nature of interest	Shares held as of the date of this document		Shares held with exercisable voting rights entitled immediately following the completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and [REDACTED] (assuming the [REDACTED] is not exercised) ⁽⁶⁾	
		Number of Shares	Approximate percentage	Number of Shares	Approximate percentage
Hepalink ⁽³⁾	Beneficial owner	2,252,535	2.68%	[REDACTED]	[REDACTED]%
Hongtu Capital ⁽⁴⁾	Beneficial owner	7,618,932	9.05%	[REDACTED]	[REDACTED]%
Mr. MA Lixiong ⁽⁵⁾	Interest in controlled corporation Interest held through voting powers of vested Shares ⁽⁵⁾	5,032,359 nil	5.98% nil	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]%
Baiyi Capital ⁽⁵⁾	Beneficial owner	4,571,359	5.43%	[REDACTED]	[REDACTED]%
Pingtang Rongjing ⁽⁵⁾	Beneficial Owner	461,000	0.55%	[REDACTED]	[REDACTED]%

Notes:

- (1) As of the Latest Practicable Date, the Founder BVI held approximately 16.04% of the total issued Shares of the Company and Dr. Liu, being the investment advisor of the Family Trust, is entitled to exercise the voting rights attached to the 13,500,000 Shares held by the Founder BVI. The Founder BVI is wholly-owned by the Family Trust. The Bryn Mawr Trust Company of Delaware serves as the trustee of the Family Trust.
- (2) As of the Latest Practicable Date, the 2020 ESOP Platform held approximately 10.51% of the total issued Shares of our Company, and Dr. Liu was granted power of attorney to exercise the voting rights attached to the Shares held by the 2020 ESOP Platform pursuant to a deed executed by the trustee and the nominee of the Incentive Plans as well as our Company on November 28, 2019. The Core Trust Company Limited serves as the trustee of the 2020 ESOP Platform.
- (3) Hepalink Biotechnology II Limited is wholly-owned by Hepalink Healthcare Partners I L.P., which is a limited partnership established under the laws of the Cayman Islands. The general partner of Healthcare Partners I L.P. is Medi Prosperity Capital Inc.. The limited partner of Hepalink Healthcare Partners I L.P. is Hepalink (Hong Kong) Limited, which holds 100% of the interest in Hepalink Healthcare Partners I L.P. As of the Latest Practicable Date, Mr. LI Li was interested in approximately 62.90% of the shares in Hepalink, which in turn indirectly wholly-owned Hepalink Biotechnology II Limited. Therefore, Mr. LI Li was deemed to be interested in the Shares held by Hepalink Biotechnology II Limited and Hepalink. Immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), The Hepalink Entities will be entitled to exercise the voting rights attached to approximately [REDACTED]% of the total issued Shares. While the Hepalink Entities will become the single largest group of Shareholders of our Company upon [REDACTED] with approximately [REDACTED]% exercisable voting rights, the AIC Group will continue to have day-to-day control over the management and operation of our Group.
- (4) Hongtu Capital is owned as to 60% and 40% by LAI Hoi Man (賴海民) and CHAN See Ting (陳思廷), respectively, both of whom are Independent Third Parties.

SUBSTANTIAL SHAREHOLDERS

- (5) BAIYI Capital is wholly-owned investment holding company of AIH Capital L.P., which is controlled by Mr. MA Lixiong, our non-executive Director. Pingtan Rongjing is managed by its general partner, Yuthai Investment Management Co., Ltd., which is owned as to 80% by Mr. MA Lixiong, our non-executive Director. On the [REDACTED], Awards with up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares that were granted to Mr. MA Lixiong shall be [REDACTED] Vesting Shares.
- (6) The unvested Shares held in the 2020 ESOP Platform and the 2023 ESOP Platform and the Shares to be repurchased from the 2023 ESOP Platform have been excluded from both the denominator and the numerator when calculating the percentage of the exercisable voting rights immediately upon [REDACTED].

Save as otherwise disclosed herein, our Directors are not aware of any persons who will, immediately following completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised), have any interests and/or short positions in the Shares or underlying shares of our Company which would fall to be disclosed to the Company 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 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group.

CONNECTED TRANSACTION

OVERVIEW

Prior to the [REDACTED], we entered into certain transaction with party who will, upon the [REDACTED], become a connected person of the Company. Details of such continuing connected transaction of the Company following the [REDACTED] are set out below.

CONNECTED PERSON

We have entered into certain transaction with the following connected person, which will constitute our continuing connected transaction upon [REDACTED]:

<u>Connected Person</u>	<u>Connected Relationship</u>
Hepalink	As at the Latest Practicable Date, Hepalink was a substantial shareholder of the Company and a company in which Mr. LI Li, our non-executive Director, was interested in approximately 62.90% of its shares. Therefore, Hepalink is a connected person of the Company

SUMMARY OF OUR NON-EXEMPT CONTINUING CONNECTED TRANSACTION

<u>Nature of Transaction</u>	<u>Applicable Listing Rules</u>	<u>Connected Person</u>	<u>Waiver sought</u>
<i>HTD1801 Agreement</i>			
License and commercialization cooperation with Hepalink	Rule 14A.35, Rule 14A.36, Rule 14A.52, Rule 14A.53, and Rule 14A.105	Hepalink	Waiver from strict compliance with (i) reporting, announcement and independent Shareholders' approval requirements, (ii) the requirement of limiting the term of agreement to three years or less and (iii) the fixed monetary annual cap requirement

CONNECTED TRANSACTION

NON-EXEMPT CONTINUING CONNECTED TRANSACTION

HTD1801 Agreement

Principal Terms of the Transaction

The Company entered into the HTD1801 Agreement with Hepalink on August 29, 2020, pursuant to which the Company has granted Hepalink an exclusive, sublicensable (solely to Hepalink’s wholly-owned subsidiaries) and non-transferable license under certain intellectual property rights and know-how⁽¹⁾ in relation to HTD1801 for the commercialization of the therapeutic products containing HTD1801 (the “**Licensed Products**”) for the MASH indication and PSC indication in all European countries specified therein (the “**Licensed Territories**”). Hepalink also has the first right to acquire or obtain on the same terms as those offered by a third party the rights to any intellectual property rights and know-how in relation to the Licensed Products in Greater China in the event that the Company proposes to sell or transfer to a third party its title and interest in the intellectual properties and know-how in relation to HTD1801 for such Greater China territory. For further details, please see the section headed “Business — Collaboration Agreement — HTD1801 License-Out Agreement” in this document. In consideration of the rights granted to Hepalink, Hepalink is required to make various milestone and royalty payments to the Company as follows:

Milestone payment:

Hepalink is required to pay the Company milestone payment in cash in an amount of (i) RMB50.0 million no later than five business days from the date of the new drug application of HTD1801 for MASH indication obtaining the first marketing authorization in any one of the specified Licensed Territories; (ii) RMB50.0 million no later than one year after the approval of such marketing authorization; (iii) RMB30.0 million no later than five business days from the date of the new drug application of HTD1801 for PSC indication obtaining the first marketing authorization in any one of the specified Licensed Territories; and (iv) RMB30.0 million no later than one year after the approval of such marketing authorization.

As at the Latest Practicable Date, no milestone payment was made by Hepalink to the Company.

Royalty payment:

Hepalink is required to pay the Company royalty payments in cash for the sales of the Licensed Products based on annual net sales in the Licensed Territories.

As at the Latest Practicable Date, no royalty payment was made by Hepalink to the Company.

Note:

- (1) intellectual property and know-how of HTD1801, including (i) the PCT and Europe patent application of Berberine Salts, Ursodeoxycholic Salts and Combinations, Methods of Preparation and Application Thereof, EAPO patent application of Berberine Ursodeoxycholic Acid Salt and Application Thereof and the EAPO patent application of Berberine Salts, Ursodeoxycholic Salts and Their Combinations, Methods for Producing and Use; and (ii) new intellectual property rights generated from the development, registration and production of HTD1801 after the signing date of the HTD1801 Agreement.

CONNECTED TRANSACTION

Expected milestone payment

The expected milestone payment to be paid by Hepalink to the Company pursuant to the HTD1801 Agreement will be nil, nil and nil for 2023, 2024 and 2025, respectively, taking into account the uncertainties on the precise timing of the milestone event triggering the milestone payment (i.e. the first marketing authorization being obtained for HTD1801 for MASH indication or PSC indication).

Formula for royalty payment

The annual amount for royalty payment to be paid by Hepalink to the Company pursuant to the HTD1801 Agreement for 2023, 2024 and 2025 will be determined in accordance with the following formula:

Annual cap for royalty payment = 25% × annual net sales of the relevant products

The "annual net sales" means in one year, the total amount of the sale or other disposal or transfer of the Licensed Products by Hepalink in the Licensed Territory, less actual payments or allowances made in accordance with the applicable laws and regulations in the Licensed Territory and the Chinese Accounting Standards for Business Enterprises in relation to the sale of the Licensed Products which include (a) commercial discounts; (b) freight, transportation, insurance, postage and import taxes and duties; (c) credits, rebates, discounts, chargebacks, retroactive price reductions and adjustments, and amounts due to returns, recalls, or refunds; (d) commissions paid to third party purchasers in connection with the importation, distribution or advertising of Licensed Products; (e) sales tax, excise tax and value-added tax (other than general income tax) levied on the invoice amount; and (f) taxes, duties and other governmental charges levied or measured on the import, export, use, manufacture or sale of Licensed Products.

The HTD1801 Agreement was entered into on August 29, 2020 and will remain effective until the expiration of the latest applicable royalty term as further explained below. The expected expiration dates for existing intellectual properties in the European Union, United Kingdom or Switzerland will be 2035. The royalty term commences upon the first commercial sales of the Licensed Products in the Licensed Territories, and ends on the later of (i) the expiration of the last-to-expire valid claim within the existing intellectual properties and know-how and the new intellectual properties, including all of the data, results, information, documents, know-how, intellectual properties, clinical trial data, manufacturing technology and design, supply information, regulatory filings and packaging of development, registration and production relating to the Licensed Products in the European Union, United Kingdom or Switzerland within the Licensed Territories; or (ii) the expiration of all regulatory exclusivity, including market exclusivity (the period of exclusive right to market and sell the Licensed Product within the Licensed Territories, during which an application for a new drug based on published data or

CONNECTED TRANSACTION

containing an identical active ingredient is not acceptable) or data exclusivity (the period of protection to clinical data in relation to Licensed Products, during which the clinical data cannot be accessed by third parties), granted for the Licensed Products in the European Union, United Kingdom or Switzerland as within the Licensed Territories, with an exception that the royalty term would be earlier terminated immediately after the entry of a generic product of the Licensed Products into the European Union as part of the Licensed Territories. We have not yet applied for orphan designation from the EMA for the PSC indication of HTD1801. For more details of orphan designation by the EMA, please see "Regulatory Overview — Laws and Regulations in the United States and EU — Orphan Drugs". The HTD1801 Agreement may also be terminated earlier by mutual agreement in writing, or (a) by the Company if Hepalink materially breaches the payment terms of the HTD1801 Agreement and such breach cannot be cured within one month upon receiving notice from the Company; (b) by the Company for Hepalink's failure to initiate the commercialization of Licensed Products in a Licensed Territory within one year after the first marketing authorization has been obtained in such License Territory is obtained, (c) by the Company if Hepalink, directly or indirectly, commences, engages in or participates in any proceedings of challenging the Company's patents licensed to Hepalink under the HTD1801 Agreement, or intentionally or knowingly assists with or acquiesces in the commencement of such challenges; (d) by the Company if Hepalink fails to acquire and maintain the required insurance policy; or (e) by either party upon the dissolution or bankruptcy of the other party. CIC has confirmed that it is a market practice in the biotechnology pharmaceutical industry for similar cooperation agreement to be entered into for a long term or for an indefinite term, primarily due to the substantial amount of capital committed by the collaboration partners and the risks involved.

Reasons for and benefits of the transaction

The Company has a long-term strategic cooperative relationship with Hepalink, which is a major pharmaceutical company. Due to Hepalink's strong presence in Europe, the Company believes it would be more cost effective and efficient to license the commercialization of the Licensed Products in the Licensed Territories to Hepalink. By leveraging Hepalink's strong sales force established in Europe, its advantageous position in market share in the relevant jurisdictions and its established track record of sales of similar pharmaceutical products in the European pharmaceutical market, the Company believes Hepalink will be able to successfully promote the commercialization of the Licensed Products in the Licensed Territories, which is consistent with our long term operational strategies.

The royalty payment is a revenue sharing arrangement which was determined after arm's length negotiations between us and Hepalink. CIC has confirmed that the HTD1801 Agreement entered into by the Company and Hepalink is in line with the industry practice. Taking into consideration of the above, the Company believes that the HTD1801 Agreement is in the interest of the Company and its Shareholders as a whole.

Historical Amount

As HTD1801 has not been commercialized in the Licensed Territories and it is currently at clinical stage, there are no fees received under the HTD1801 Agreement. For the two years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, there were no fees paid by Hepalink to the Company under the HTD1801 Agreement.

CONNECTED TRANSACTION

Corporate Governance Measures

During the ordinary and usual course of business of our Company, we review potential product licensing opportunities, including product in-licensing and out-licensing, from time to time. When potential opportunity arises, we would normally assess the advantages and development prospect of the product, market forecasts for the demand of the product, competitive landscape and regulatory requirements of the product for that market as well as the regulatory and commercial capability of the potential business partner to commercialize the product. Furthermore, our business development team routinely evaluates licensing arrangement by third parties with similar mechanism of action for deal benchmarking and for term sheet evaluation purposes.

In addition, the commercial negotiations with potential licensing partners are led by our senior management, who are not interested in the licensing and will independently evaluate the terms taking into account all relevant factors as we consider necessary. A decision on whether to enter into licensing arrangements with another company will be made purely based on commercial considerations and only if we consider it is in the best interest of our Company and the Shareholders to enter into such licensing arrangement.

Listing Rule implications

Although the revenue ratio and the profit ratio are not applicable given that the Company is a pre-revenue biopharmaceutical company, the highest applicable percentage ratio in respect of each of the caps as the Company currently expects is, on an annual basis, more than 5%. As such, the transactions under the HTD1801 Agreement will be subject to the reporting, annual review, announcement and independent shareholders' approval requirements under Chapter 14A of the Listing Rules.

Waiver from strict compliance with contractual term requirements

Under Rule 14A.52 of the Listing Rules, a listed issuer is required to set a contractual term not exceeding three years. It is impracticable and extremely difficult for us to set a contractual term not exceeding three years in respect of the HTD1801 Agreement. Therefore, the Company applied to the Stock Exchange for, and the Stock Exchange [has granted] to the Company, a waiver under Rule 14A.52 of the Listing Rules from strict compliance with the contractual term requirements for the following reasons:

- (i) it is impractical and difficult for the Company to set a term of not exceeding three years in respect of the HTD1801 Agreement, as the Licensed Products have a product life cycle of more than three years from its development stage to commercialization;
- (ii) maintaining a long-term, exclusive cooperative relationship with Hepalink is critical to our businesses and development. Our continuous business relationship with Hepalink provides a strategic advantage for us to expand our drug portfolio covering different jurisdictions and to enhance our competitiveness. The indefinite term of the HTD1801 Agreement can secure a long-term, exclusive cooperative relationship with Hepalink, which provides strategic benefits for us to engage in commercialization of the Licensed Products in the Licensed Territories;

CONNECTED TRANSACTION

- (iii) a contractual arrangement of indefinite term is necessary and critical to the sustainability of our business and to ensure our smooth and continued operations, as well as stable revenue and cash flows from the future commercialization of the Licensed Products. If the HTD1801 Agreement is subject to renewal every three years and independent shareholders' approval, we may face the unnecessary and substantial risks of failing to renew such agreement upon expiry and bringing disruptions to the commercialization of the Licensed Products, and losing our competitive advantages. This may even prevent us from carrying on our business, bringing uncertainty to our continued operation; and
- (iv) our Directors consider that the terms of the HTD1801 Agreement are consistent with normal business practices for agreements of a similar nature in the biotechnology pharmaceutical industry and are in the best interest of our Group and our Shareholders as a whole, because (a) the indefinite term of the HTD1801 Agreement can secure a long-term exclusive cooperative relationship with Hepalink, thus avoiding unnecessary disruptions to our business and enable long-term development and continuity of our operations; and (b) as confirmed by CIC, it is common in the biotechnology pharmaceutical industry where similar long-term licensing arrangements or licensing arrangements with an indefinite-term are adopted.

Waiver from strict compliance with annual cap requirements

Under Rule 14A.53 of the Listing Rules, the listed issuer must set an annual cap for the continuing connected transactions. The Directors believe that strict compliance with the requirements of Rule 14A.53 of the Listing Rules for setting a fixed monetary annual cap in respect of the HTD1801 Agreement is impracticable and not in the best interests of the Shareholders. Therefore, the Company applied to the Stock Exchange for a waiver under Rule 14A.53 of the Listing Rules from strict compliance with the annual cap requirements for the following reasons:

- (i) it is impractical and difficult for the Company to set a monetary annual cap in respect of the milestone payment and/or the royalty payment under the HTD1801 Agreement. The Company cannot accurately estimate (a) the precise timing of the milestone event triggering the milestone payment (i.e. the first marketing authorization being obtained for HTD1801 for MASH indication or PSC indication); and (b) the amount of the royalty payment to be paid by Hepalink annually pursuant to the HTD1801 Agreement as the revenue to be derived from the sale of Licensed Products depends on the actual addressable market of the Licensed Products, which will in turn depend on various factors including the acceptance by the medical community and patient access, drug pricing, reimbursement and the number of affordable patients;

CONNECTED TRANSACTION

- (ii) as at the Latest Practicable Date, the Company has not commenced commercialization of HTD1801 and we have not generated revenue from sales of any of our drug products developed by us. Therefore, our historical financial results are not an appropriate basis for estimating our future transaction volume. The Company does not have sufficient reference to enable it to estimate the future transaction volume and amount. Accordingly, imposing an arbitrary monetary cap would be unduly burdensome and not in the interests of the Company's Shareholders after the [REDACTED];
- (iii) all of our products are in the research and development stage, and the revenue generated from the Licensed Products may account for a significant portion of the Company's revenue before the commercialization of the other products of the Company. Therefore, the disclosure of the annual caps in monetary terms would in effect provide Shareholders and investors as well as competitors of the Company with an indication of the Company's estimated revenue. The disclosure of such information is highly sensitive and would therefore put the Company in disadvantageous position in relation to its business operation and competition with other market players;
- (iv) imposing an arbitrary cap on the potential sales volume of the Licensed Products does not demonstrate commercial reasonableness and would be counter-productive as far as the interests of the Company and our Shareholders are concerned. It would also not be in the interest of the Company and the Shareholders to adopt a fixed monetary cap for such transactions as such a cap will impose an arbitrary ceiling on the profits that the Company could derive from the commercialization of the Licensed Products. In addition, a fixed annual cap is not helpful to incentivize our Group to generate more revenue and profit from commercializing the Licensed Products, and will restrict business growth of our Group, which would go against the commercial objective of the HTD1801 Agreement. If the actual sales volume of the Licensed Products exceeds the cap, Hepalink would be suspended from selling the Licensed Products to the market until relevant shareholder approval of the adjusted annual caps is obtained, which will affect not only our business but also the patients who need the Licensed Products for treatment. As far as the transactions are on normal commercial terms or better, and the profit margin of the Licensed Products and the revenue sharing percentage are commercially reasonable and in line with market standards, the interests of our Group and our Shareholders are protected, and there is no reason or benefit to impose such fixed cap; and
- (v) instead of setting a fixed annual cap in respect of the milestone payment and/or the royalty payment under the HTD1801 Agreement, if there is any material change to the milestone payment or the percentage of the royalty payment under the HTD1801 Agreement, we will re-comply with the applicable rules under Chapter 14A of the Listing Rules, including seeking independent shareholders' approval as the case may require, so as to further ensure the interest of our Group and our Shareholders.

CONNECTED TRANSACTION

The Stock Exchange [has granted] the waiver from strict compliance with the requirement under Rule 14A.52 and Rule 14A.53 of the Listing Rules in respect of the continuing connected transaction under the HTD1801 Agreement subject to the following conditions:

- (1) the Company will comply with the announcement, circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules if there is any material change to the terms of the HTD1801 Agreement;
- (2) the Company will designate a team to execute and ensure that the transactions in relation to the HTD1801 Agreement are undertaken in accordance with the terms therein;
- (3) the chief executive officer of the Company will use her best endeavours to supervise the compliance with the terms of the HTD1801 Agreement and applicable Listing Rules requirements to the extent not waived by the Stock Exchange on a regular basis;
- (4) the independent non-executive Directors and the auditors of the Company will review the transactions in relation to the HTD1801 Agreement on an annual basis and confirm in our annual reports the matters set out in Rules 14A.55 and 14A.56 of the Listing Rules, respectively;
- (5) the Company will disclose in the document the background for entering into the HTD1801 Agreement, the terms of the HTD1801 Agreement, the grounds for the waiver sought and the Directors' and Joint Sponsors' views on the fairness and reasonableness of the transactions under the HTD1801 Agreement; and
- (6) in the event of any future amendments to the Listing Rules imposing more stringent requirements than those as at the date of this document on the above continuing connected transaction, the Company will take immediate steps to ensure compliance with such new requirements.

[The waiver from strict compliance with the requirement under Rule 14A.53 of the Listing Rules is for a term of three years ending on December 31, 2025. When there is visibility with the timing and amounts payable under the HTD1801 Agreement, the Company will, after taking into account, among other things, the addressable market, the drug pricing and the historical transaction amount of the relevant products, re-assess whether a further waiver is required at the expiry of such initial term.]

CONNECTED TRANSACTION

DIRECTORS' CONFIRMATION

The Directors (including the independent non-executive Directors) are of the view that (i) the continuing connected transaction as set out above have been and will be entered into in the ordinary and usual course of business of the Company and on normal commercial terms, and are fair and reasonable and in the interest of the Company and the Shareholders as a whole, and the absence of annual caps for the years ending December 31, 2023, 2024 and 2025 is fair and reasonable and in the interests of the Company and the Shareholders as a whole; and (ii) the indefinite term of those transactions under the HTD1801 Agreement is in accordance with normal business practice, and the purpose of the agreements is to provide stability and certainty to the business of the Company and that therefore the indefinite term of those transactions is fair and reasonable, and in the interests of Shareholders as a whole.

JOINT SPONSORS' CONFIRMATION

Taken into account of the Directors' considerations as stated above and the relevant documents and information provided by the Company, the Joint Sponsors are of the view that: (i) the continuing connected transaction as set out above have been and will be entered into in the ordinary and usual course of business of the Company and on normal commercial terms, and are fair and reasonable and in the interest of the Company and the Shareholders as a whole, and the absence of annual caps for the years ending December 31, 2023, 2024 and 2025 is fair and reasonable and in the interests of the Company and the Shareholders as a whole; and (ii) the indefinite term of those transactions under the HTD1801 Agreement is in accordance with normal business practice, and the purpose of the agreements is to provide stability and certainty to the business of the Company and that therefore the indefinite term of those transactions is fair and reasonable, and in the interests of Shareholders as a whole.

In forming a view on the above matters, the Joint Sponsors have considered, among others, the nature of the transactions and coverage of the licenses, the rationale and basis for determining the pricing policies or mechanism, measures to review and adjust the pricing policies on a regular basis, the duration for similar arrangements for other companies, the business plan of the Company, information and data in the public domain, as well as the views and opinions of Industry Consultant, CIC, and the internal controls and measures to monitor the non-exempt continuing connected transaction.

FINANCIAL INFORMATION

You should read the following discussion and analysis in conjunction with our audited consolidated financial information, including the notes thereto, included in the Accountants’ Report set out in Appendix I to this document. Our audited consolidated financial information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance that involve risks and uncertainties. These statements are based on assumptions and analysis made by us in light of our experience and perception of historical events, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this document, including those set forth in “Risk Factors” and “Forward-Looking Statements” in this document.

For the purpose of this section, unless the context otherwise requires, references to 2021 and 2022 refer to our financial year ended December 31 of such years. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis.

OVERVIEW

We are a biopharmaceutical company specializing in the discovery, development and commercialization of multifunctional, multi-targeted therapies for the treatment of metabolic and digestive diseases. We have developed a product pipeline of five product candidates in-house, covering nine indications in metabolic and digestive diseases among which, five are at clinical-stage. Our Core Product, HTD1801 (berberine ursodeoxycholate), a new molecular entity, is a gut-liver anti-inflammatory metabolic modulator which targets multiple pathways pivotal to metabolic regulation, including those associated with metabolic and digestive diseases. It is created by forming a novel salt between two active moieties, berberine (“**BBR**”) and ursodeoxycholic acid (“**UDCA**”). HTD1801 has demonstrated good safety and efficacy across multiple clinical trials, including: a Phase IIa study in metabolic dysfunction-associated steatohepatitis (“**MASH**”) in the United States, a Phase II study in type 2 diabetes (“**T2DM**”) in China, a Phase Ib study in T2DM in China, a Phase II study in primary sclerosing cholangitis (“**PSC**”) in the United States and Canada, a Phase II study in primary biliary cholangitis (“**PBC**”) in the United States, and a Phase Ib/IIa study in hypercholesterolemia in Australia. We believe the good safety and efficacy profile strongly supports the “pipeline-in-a-product” potential of HTD1801 for selected metabolic and digestive diseases with suboptimal or no approved therapies.

BASIS OF PRESENTATION AND PREPARATION

Our consolidated financial information has been prepared in accordance with IFRSs, which comprise all standards and interpretations approved by the International Accounting Standards Board (“**IASB**”). All IFRSs effective for the accounting period commencing from January 1, 2022, together with the relevant transitional provisions, have been early adopted by our Group in the preparation of the consolidated financial information throughout the Track Record Period.

FINANCIAL INFORMATION

The historical financial information has been prepared under the historical cost convention except for certain financial instruments, which have been measured at fair value at the end of each of the reporting period.

KEY FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, affected by a number of factors, many of which may be beyond our control. The following are the principal factors that have affected, and we expect will continue to affect, our business, financial condition, results of operations and prospects.

Our Ability to Successfully Develop Our Drug Candidates

Our business and results of operations depend on our ability to successfully develop our drug candidates. As of the Latest Practicable Date, we have researched and developed in-house a pipeline with five proprietary drug candidates covering nine indications, including five indications that are at clinical stage. For more information on the development status of our various drug candidates, see “Business — Our Product Pipeline” in this document. Our business and results of operations depend on our drug candidates demonstrating favorable safety and efficacy clinical trial results, and our ability to obtain the requisite regulatory approvals for our drug candidates to initiate clinical trials, or to advance to the next stage of clinical development.

Our Ability to Successfully Commercialize Our Drug Candidates

As of the Latest Practicable Date, all of our drug candidates were in clinical development or preclinical development. We currently have no product approved for commercial sale and have not generated any revenue from product sales. However, we expect to commercialize one or more of our drug candidates over the coming years as they move towards the final stages of development. Our ability to generate revenue depends on our ability to obtain regulatory approvals for and to commercialize our drug candidates, establish manufacturing capabilities and sales channels, and undertake extensive sales and marketing activities. If our drug candidates fail to achieve the degree of market acceptance that we anticipate, we may not be able to generate revenue as expected.

Our Research and Development Costs

We believe our ability to successfully develop drug candidates is the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality drug candidates requires significant investments of financial resources over a prolonged period of time, and our core strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of preclinical and clinical-stage drug candidates has been steadily advancing and expanding. Our operations have consumed substantial amounts of cash since our inception. Our research and development costs were RMB84.0 million, RMB182.7 million and RMB120.1 million in 2021, 2022 and the six months ended June 30, 2023, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical assets and continue research and development of our preclinical assets and initiate additional clinical trials of, and seek regulatory approvals for, these and other future drug candidates.

FINANCIAL INFORMATION

Funding for Our Operations

In 2021 and 2022 and six months ended June 30, 2023, we funded our operations primarily through equity financing. Going forward, in the event of the successful commercialization of more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our drug products. However, with the continuing expansion of our business and the development of new drug candidates, we may require further funding through public or private equity offerings, debt financing and other sources. Any changes in our ability to fund our operations will affect our cash flow and results of operations.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles that conform with IFRSs issued by the IASB. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Our most critical accounting policies, judgments and estimates are summarized below. See Note 2.4 and Note 3 to the Accountants' Report set out in Appendix I to this document for a description of our significant accounting policies, judgments, and estimates.

Research and Development Costs

All research costs are charged to the statement of profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Fair Value Measurement

We measure certain financial instruments at fair value at each end of the Track Record Period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by us. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

FINANCIAL INFORMATION

We use valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 — based on quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly; and/or

Level 3 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

For assets and liabilities that are recognized in the financial statements on a recurring basis, we determine whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Track Record Period.

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 convertible redeemable preferred shares. Key valuation assumptions used to determine the fair value of convertible redeemable preferred shares are as follows:

	As at 31 December, 2021	As at 31 December, 2022	As of June 30, 2023
Risk-free interest rate	0.73%	4.70%	5.15%
Discount for lack of marketability (“ DLOM ”)	11%	14%	4%
Volatility	54%	61%	60%

We estimated the risk-free interest rate based on the yield of the U.S. Government Bond as of the valuation date. The DLOM was estimated based on the option-pricing method. Under the option-pricing method, the cost of a put option, which can hedge the price change before the privately held share can be sold, was considered as a basis to determine the discount for the lack of marketability. The volatility was estimated based on the annualised standard deviation of the daily stock price return of comparable companies for the period from the respective valuation date and with similar span as time to expiration.

FINANCIAL INFORMATION

Details of the fair value measurement of our level 3 financial instruments, particularly the fair value hierarchy, the valuation techniques and key inputs, are disclosed in Note 31 of the Accountants’ Report set out in Appendix I to this document. The Reporting Accountants performed its work in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 “Accountants’ Report on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants for the purpose of expressing an opinion on our historical financial information for the Track Record Period as a whole, and its opinion on the Group for the Track Record Period as a whole is set out in the Accountants’ Report in Appendix I to this document.

In relation to the valuation of the Level 3 Financial Liabilities, with reference to the “Guidance note on directors’ duties in the context of valuations in corporate transactions” issued by the SFC, our Directors have adopted the following procedures: (i) reviewing the terms of the relevant agreements and documents regarding the financial liabilities; (ii) engaging an independent valuer (the “**Valuer**”) to perform valuation procedures with necessary financial and non-financial information and discussing with the valuer on the relevant assumptions; (iii) obtaining sufficient understanding of the valuation model, methodologies and techniques on which the valuation is based; and (iv) reviewing the valuation works and results and the financial statements prepared in accordance with IFRS. Based on the above procedures, 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.

The Joint Sponsors have conducted relevant due diligence work in relation to the Level 3 Financial Liabilities, including: (i) reviewed the terms of the relevant agreements and documents in respect of the Level 3 Financial Liabilities, including the relevant investment agreements of the Company; (ii) reviewed the valuation report prepared by the Valuer; (iii) discussed with the Valuer to understand the basis for determining the valuation methodologies applied, including but not limited to the major assumptions and key parameters adopted in the valuation process; (iv) discussed with the management of the Company to understand the valuation methodology of the Level 3 Financial Liabilities, judgement of the management and the internal policies associated with the valuation of Level 3 Financial Liabilities; (v) reviewed the relevant notes in the Accountant’s Report as contained in Appendix I to this Document; and (vi) discussed with the Reporting Accountant to understand the audit standards relied by the Reporting Accountant in relation to the valuation of the Level 3 Financial Liabilities, the procedures they have conducted and their views on our Group’s historical financial information as a whole. Based upon the due diligence work conducted as stated above, nothing came to the Joint Sponsors’ attention that would cause them to question the valuation performed by us or the Valuer in relation to the Level 3 Financial Liabilities.

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.

FINANCIAL INFORMATION

Our Group as a lessee

We apply a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. We recognize lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

We recognize right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Property, office premises and plant	5 years
Equipment	3 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 recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by us and payments of penalties for terminating the lease, if the lease term reflects our exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognized as expenses in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, we use its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset.

FINANCIAL INFORMATION

(c) *Short-term leases and leases of low-value assets*

We apply the short-term lease recognition exemption to its short-term leases of machinery and equipment (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 are considered to be of low value.

Lease payments on short-term leases and leases of low-value assets are recognized as an expense on a straight-line basis over the lease term.

Investments and Other Financial Assets

Initial Recognition and Measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortized cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and 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.

In order for a financial asset to be classified and measured at amortized cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding. Financial assets with cash flows that are not solely payments of principal and interest are classified and measured at fair value through profit or loss, irrespective of the business model.

Our business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortized cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

All regular way purchases and sales of financial assets are recognized on the trade date, that is, the date that we commit to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

FINANCIAL INFORMATION

Subsequent Measurement

The subsequent measurement of financial assets depends on their classification:

Short-Term Time Deposits (Debt Instruments)

Short-term time deposits are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in profit or loss when the asset is derecognized, modified or impaired.

Financial Assets Measured at Fair Value through Profit or Loss ("FVTPL")

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognized in profit or loss.

Financial Liabilities at Amortized Cost

After initial recognition, interest-bearing loans and borrowings, trade payables, financial liabilities included in other payable and accruals and other borrowings are subsequently measured at amortized 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 recognized the consolidated statement of profit or loss when the liabilities are derecognized as well as through the effective interest rate amortization process.

Other Financial Instruments

If the conversion option of other financial instruments exhibits characteristics of an embedded derivative, it is separated from its liability component. On initial recognition, the derivative component of other financial instruments is measured at fair value and presented as part of financial instruments at FVTPL. Any excess of proceeds over the amount initially recognized as the derivative component is recognized as the liability component. Transaction costs are apportioned between the liability and derivative components of other financial instruments based on the allocation of proceeds to the liability and derivative components when the instruments are initially recognized. The portion of the transaction costs relating to the liability component is recognised initially as part of the liability. The portion relating to the derivative component is recognised immediately in the consolidated statement of profit or loss.

FINANCIAL INFORMATION

Financial Liabilities at FVTPL

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Government Grants

Government grants are recognized 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 recognized 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.

Share-based Payments

We have set up the employee long term incentive plan for our directors and employees. The fair value of the options is determined by the binomial model at the grant dates.

Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility, employee turnover rate, and dividend yield and making assumptions about them. The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in note 27 to the Accountants' Report set out in Appendix I to this document.

FINANCIAL INFORMATION

DESCRIPTION OF CERTAIN KEY ITEMS OF THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The following table sets forth a summary of our consolidated statements of profit or loss and other comprehensive income for the years indicated. Our historical results presented below are not necessarily indicative of the results that may be expected for any future period. During the Track Record Period and as of the Latest Practicable Date, we had not generated any revenue.

	For the year ended		For the six months ended	
	December 31,		June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Other income and gains	13,821	20,581	3,925	22,722
Fair value (losses)/gains on convertible redeemable preferred shares	(93,656)	23,242	31,247	(399,635)
Other expenses	(1)	(7,518)	(4,381)	(502)
Fair value losses on financial liabilities at FVTPL	(4,609)	–	–	–
Research and development costs	(84,012)	(182,651)	(76,322)	(120,088)
Administrative expenses	(48,064)	(43,433)	(28,357)	(52,014)
Finance costs	(4,528)	(426)	(217)	(201)
Loss before tax	(221,049)	(190,205)	(74,105)	(549,718)
Income tax expense	(96)	(32)	(72)	(26)
Loss for the year/period	<u>(221,145)</u>	<u>(190,237)</u>	<u>(74,177)</u>	<u>(549,744)</u>
Total comprehensive loss for the year/period ..	<u>(217,410)</u>	<u>(223,888)</u>	<u>(92,387)</u>	<u>(586,343)</u>
Attributable to:				
Owners of the parent	<u>(217,410)</u>	<u>(223,888)</u>	<u>(92,387)</u>	<u>(586,343)</u>

FINANCIAL INFORMATION

Other Income and Gains

Other income and gains primarily consist of (i) government grants, which primarily represent our subsidies received from the local governments for the purpose of our research and clinical trial activities, allowance for new drug development and funds for talents; (ii) bank interest income, representing interest income from our deposits in banks; (iii) investment income from short-term time deposits, which primarily represents the short-term time deposits which are deposited with creditworthy banks through a reputable financial institution; (iv) other investment income from financial assets at FVTPL, which primarily represents interest income from the wealth management products that we purchased from commercial banks; and (v) foreign exchange gains, which primarily represent the benefit of foreign currency translation.

The following table summarizes a breakdown of our other income and gains for the years indicated.

	For the year ended December 31,		For the six months ended June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Government grants	9,843	8,014	1,113	8,942
Bank interest income	964	3,545	2,290	696
Investment income from short-term time deposits	–	7,822	–	12,931
Other investment income from financial assets at FVTPL	2,366	1,012	521	120
Foreign exchange gains, net	603	–	–	–
Others	45	188	1	33
Total	13,821	20,581	3,925	22,722

Fair Value (Losses)/Gains on Convertible Redeemable Preferred Shares

Fair value (losses)/gains on convertible redeemable preferred shares are resulted from changes in valuation of the fair value of our convertible redeemable preferred shares issued to investors. We issued Series B+ Preferred Shares in September 2020 and August 2021, Series C Preferred Shares in November 2021 and Series C+ Preferred Shares in November 2022 and December 2022. For more details regarding Preferred Shares, see “History, Reorganization and Corporate Structure — [REDACTED] Investments”. The convertible redeemable preferred shares will be re-classified as equity as the convertible redeemable preferred shares will automatically convert into Shares upon [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares.

FINANCIAL INFORMATION

Other Expenses

Other expenses consist of (i) foreign exchange loss, net, which primarily represents the impact of foreign currency translation and (ii) loss on disposal of items of property, plant and equipment.

The following table sets forth the breakdown of our other expenses for the years indicated.

	For the year ended December 31,		For the six months ended June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Loss on disposal of items of property, plant and equipment	(1)	–	–	–
Foreign exchange losses, net	–	(7,518)	(4,381)	(502)
Total	(1)	(7,518)	(4,381)	(502)

Fair Value Losses on Financial Liabilities at FVTPL

Fair value losses on financial liabilities as FVTPL are resulted from our issuance of warrants to Series B+ investors in September 2020 (“**Series B+ Warrants**”), which were subsequently converted to Series B+ Preferred Shares in the first half of 2021.

Research and Development Costs

Our research and development costs primarily consist of (i) third-party contracting expenses primarily includes the early stage discovery expense, preclinical expenses, clinical development expenses for our drug candidates; (ii) staff costs, primarily consisting of salaries and benefits for our R&D team; (iii) ESOP expenses, representing expenses associated with share awards granted to our R&D team; and (iv) others, primarily including rental, depreciation and amortization in relation to fixed assets, intangible assets, right-of-use assets and raw materials.

FINANCIAL INFORMATION

The following table sets forth a breakdown of our research and development costs for the years indicated.

	For the year ended December 31,				For the six months ended June 30,			
	2021		2022		2022		2023	
	<i>(unaudited)</i>							
	<i>(RMB in thousands, except for percentages)</i>							
Third-party contracting								
expenses	53,058	63%	123,377	68%	52,215	69%	75,526	63%
Staff costs	19,827	24%	35,148	19%	14,812	19%	20,338	17%
ESOP expenses	5,455	6%	20,406	11%	7,936	10%	19,548	16%
Others	5,672	7%	3,720	2%	1,359	2%	4,676	4%
Total	84,012	100.0%	182,651	100.0%	76,322	100.0%	120,088	100.0%

The following table sets forth the clinical development expenses incurred for the Core Product HTD1801 during the Track Record Period by development stage.

	For the year ended December 31,				For the six months ended June 30,			
	2021		2022		2022		2023	
	<i>(unaudited)</i>							
	<i>(RMB in thousands, except for percentages)</i>							
Phase I	2,692	14%	36,690	44%	18,547	52%	2,240	4%
Phase II	16,399	86%	47,328	56%	16,917	48%	49,752	94%
Phase III	—	—	—	—	—	—	1,237	2%
Total	19,091	100.0%	84,018	100.0%	35,464	100.0%	53,229	100.0%

FINANCIAL INFORMATION

The following table sets forth the clinical development expenses incurred for the Core Product HTD1801 during the Track Record Period by clinical program. Other studies mainly include the Phase I clinical trials on healthy subjects for the Core Product.

	For the year ended December 31,				For the six months ended June 30,			
	2021		2022		2022		2023	
	<i>(unaudited)</i>							
	<i>(RMB in thousands, except for percentages)</i>							
T2DM	2,752	14%	38,180	45%	13,824	39%	4,514	8%
PSC	959	5%	154	0%	128	0%	–	–
PBC	13,917	73%	8,046	10%	7,039	20%	249	1%
MASH	1,463	8%	15,396	18%	636	2%	47,907	90%
Other studies ⁽ⁱ⁾	–	–	22,242	27%	13,837	39%	559	1%
Total	19,091	100.0%	84,018	100.0%	35,464	100.0%	53,229	100.0%

Note:

- (i) The clinical development expenses incurred for other studies are not dedicated to a single indication specifically and therefore such expenses cannot be attributed to a specific indication directly.

Administrative Expenses

Our administrative expenses primarily consist of compensation expenses for administrative and management personnel (including staff costs and ESOP expenses), professional services fees (mainly in relation to our financing transactions, business consulting and other professional service fees). The following table summarizes a breakdown of our administrative expenses for the years indicated.

	For the year ended December 31,				For the six months ended June 30,			
	2021		2022		2022		2023	
	<i>(unaudited)</i>							
	<i>(RMB in thousands, except for percentages)</i>							
Professional service fees*	39,146	81%	26,804	62%	19,538	69%	30,868	59%
Staff costs	5,338	11%	8,330	19%	5,225	18%	8,951	17%
ESOP expenses	1,849	4%	5,215	12%	2,330	8%	8,897	17%
Others	1,731	4%	3,084	7%	1,264	5%	3,298	7%
Total	48,064	100.0%	43,433	100.0%	28,357	100.0%	52,014	100.0%

Note: The [REDACTED] expenses included in the professional service fees amounted to RMB6.1 million, RMB4.1 million and RMB16.3 million in 2021, 2022 and the six months ended June 30, 2023, respectively.

FINANCIAL INFORMATION

Finance Costs

Our finance costs primarily consist of interest on interest-bearing bank borrowings, other borrowings and lease liabilities. The other borrowing represents a loan in the first half of 2021 which the accrual interests of such loan will be automatically waived upon the exercise of the Series B+ Warrants in the first half of 2021. The table below summarizes a breakdown of our finance costs for the years indicated.

	For the year ended December 31,		For the six months ended June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Interest on interest-bearing bank borrowings	309	303	164	137
Interest on other borrowings	4,152	–	–	–
Interest on lease liabilities	67	123	53	64
Total	4,528	426	217	201

Income Tax Expenses

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.

Cayman Islands

Under the current laws of the Cayman Islands, we are not subject to tax on income or capital gains. In addition, upon payments of dividends by us to our shareholders, no Cayman Islands withholding tax is imposed.

BVI

Under the current laws of the BVI, the subsidiary incorporated in the BVI is not subject to tax on income or capital gains. In addition, upon payments of dividends by these subsidiaries to their shareholders, no BVI withholding tax is imposed.

Hong Kong

Our subsidiary incorporated in Hong Kong is subject to income tax at the rate of 8.25% on the estimated assessable profits arising in Hong Kong during the Track Record Period.

The PRC

No provision for Mainland China income tax pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”) has been made as the Group’s subsidiaries, which operate in the PRC are in loss position and have no estimated taxable profits.

FINANCIAL INFORMATION

Shenzhen HighTide has been approved as a high technology enterprise under the relevant tax rules and regulations in December 2019, and accordingly, is entitled to a preferential CIT rate of 15% from 2019 to 2021. This qualification is subject to review by the relevant tax authority in the PRC for every three years. The renewed qualification was obtained in December 2022 and Shenzhen HighTide is entitled a preferential income tax rate of 15% from 2022 to 2024.

Australia

Our subsidiary incorporated in Australia is subject to income tax at the rate of 26% on the estimated assessable profits arising in Australia in 2021, 25% in 2022 and 2023.

United States

The subsidiary incorporated in Maryland is subject to a statutory federal corporate income tax at a rate of 21%. In addition, it is also subject to the state income tax in Maryland at a rate of 8.25% during the Track Record Period. Other states including California, Florida and New Jersey also impose state income tax on the subsidiary to the extent that a sufficient nexus, or taxable connection, exists between the subsidiary and the state. The subsidiary is subject to the state income tax in California at a rate of 8.84%, in Florida at a rate of 5.50% and in New Jersey at a rate of 7.50% during the Track Record Period.

PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Six Months Ended June 30, 2023 Compared with Six Months Ended June 30, 2022

Other Income and Gains

Our other income and gains significantly increased by 478.9% from RMB3.9 million in the six months ended June 30, 2022 to RMB22.7 million in the six months ended June 30, 2023. The increase was primarily attributable to an increase of RMB12.9 million in investment income from short-term time deposits and RMB7.8 million in government grants. The increase in the investment income from short-term time deposits in the six months ended June 30, 2023 was primarily due to an increase in time deposits and fluctuations in foreign currency interest rates.

Fair Value (Losses)/Gains on Convertible Redeemable Preferred Shares

We recorded fair value losses on convertible redeemable preferred shares of RMB399.6 million in the six months ended June 30, 2023 mainly due to the increase in fair value of our convertible redeemable preferred shares.

Other Expenses

Our other expenses decreased significantly from RMB4.4 million in the six months ended June 30, 2022 to RMB0.5 million in the six months ended June 30, 2023, primarily attributable to the decrease in foreign exchange losses, resulted from fluctuations in foreign currency exchange rates.

FINANCIAL INFORMATION

Research and Development Costs

Our research and development costs increased by 57.3% from RMB76.3 million in the six months ended June 30, 2022 to RMB120.1 million in the six months ended June 30, 2023. The increase was primarily attributable to an increase in expenditures for our clinical and preclinical development activities, including the increase in third-party contracting expenses, ESOP expenses and staff costs.

Administrative Expenses

Our administrative expenses increased by 83.4% from RMB28.4 million in the six months ended June 30, 2022 to RMB52.0 million in the six months ended June 30, 2023. The increase was primarily attributable to the increased professional service fees for the [REDACTED] and the increased ESOP expenses and staff costs.

Finance Costs

Our finance costs remained stable at RMB217 thousand in the six months ended June 30, 2022 and RMB201 thousand in the six months ended June 30, 2023.

Loss for the Period

As a result of the above, we recorded a loss of RMB74.2 million in the six months ended June 30, 2022, as compared to a loss of RMB549.7 million in the six months ended June 30, 2023.

Year Ended December 31, 2022 Compared with Year Ended December 31, 2021

Other Income and Gains

Our other income and gains increased by 48.9% from RMB13.8 million in 2021 to RMB20.6 million in 2022. The increase was primarily attributable to an increase of RMB2.6 million in bank interest income and RMB7.8 million in investment income from short-term time deposits, reflecting the significant increase in the balance of deposits in 2022 due to cash inflow from Series C Financing in 2021 and Series C+ Financing in 2022 respectively, which was partially offset by (i) decrease in government grants and (ii) decrease in other investment income from financial assets at FVTPL.

Fair Value (Losses)/Gains on Convertible Redeemable Preferred Shares

We recorded fair value losses on convertible redeemable preferred shares of RMB93.7 million in 2021 mainly because of the increase in fair value of Series B+ convertible redeemable preferred shares as of 31 December 2021 compared with 31 December 2020. We recorded fair value gains on convertible redeemable preferred shares of RMB23.2 million in 2022 mainly because of the decrease in fair value of Series B+ and C convertible redeemable preferred shares as of 31 December 2022 compared with 31 December 2021, resulting from the issuance of Series C+ convertible redeemable preferred shares in 2022, which retained with more preferential rights.

FINANCIAL INFORMATION

Other Expenses

Our other expenses increased significantly from RMB one thousand in 2021 to RMB7.5 million in 2022, primarily attributable to the foreign exchange losses, net of RMB7.5 million in 2022 due to fluctuations in foreign currency exchange rates and currency translation.

Fair Value Losses on Financial Liabilities at FVTPL

We incurred fair value losses on financial liabilities at FVTPL of RMB4.6 million in 2021, primarily due to fair value changes in our warrants to the Series B+ Warrants, which were subsequently converted to Series B+ Preferred Shares in the first half of 2021. We did not record any fair value losses on financial liabilities at FVTPL due to fair value changes in our warrants in 2022, as the Series B+ Warrants have been fully converted in 2021.

Research and Development Costs

Our research and development costs increased significantly by 117.4% from RMB84.0 million in 2021 to RMB182.7 million in 2022. The increase was primarily attributable to an increase in expenditures for our clinical and preclinical development activities, including increase in third-party contracting expenses, staff costs and ESOP expenses.

Administrative Expenses

Our administrative expenses decreased by 9.6% from RMB48.1 million in 2021 to RMB43.4 million in 2022. The decrease was primarily attributable to decreased professional services expenses as we incurred financial advisor expenses for our Series C financing in 2021 and partially offset by increase of ESOP expenses and staff costs as we recruited more employees in 2022 and raised salaries to the existing employees.

Finance Costs

Our finance costs decreased by 90.6% from RMB4.5 million in 2021 to RMB0.4 million in 2022. The decrease was primarily attributable to a decrease of RMB4.2 million in interests on other borrowings as all the Series B+ Warrants have been exercised as agreed and we have repaid the loans in first half of 2021.

Loss for the Year

As a result of the above, we recorded a loss of RMB190.2 million in 2022, as compared to a loss of RMB221.1 million in 2021.

DESCRIPTION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The following table sets forth a summary of our consolidated statements of financial position for the years indicated.

FINANCIAL INFORMATION

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		
Total non-current assets	3,450	4,806	5,263
Total current assets	775,182	851,018	753,319
Total assets	778,632	855,824	758,582
Total current liabilities	28,534	1,319,720	310,888
Total non-current liabilities	1,022,360	6,632	1,476,120
Total liabilities	1,050,894	1,326,352	1,787,008
Net liabilities	(272,262)	(470,528)	(1,028,426)
Net current assets/(liabilities)	746,648	(468,702)	442,431
Share Capital	33	36	39
Deficits	(272,262)	(470,528)	(1,028,456)

The following table sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of June 30,	As of October 31,
	2021	2022	2023	2023
	<i>(RMB in thousands)</i>			<i>(unaudited)</i>
CURRENT ASSETS				
Prepayments, other receivables and other assets	9,892	10,821	20,399	39,491
Short-term time deposits	–	427,857	–	–
Cash and bank balances	765,290	412,340	732,920	612,309
Total current assets	775,182	851,018	753,319	651,800
CURRENT LIABILITIES				
Trade payables	6,091	21,699	29,752	37,687
Other payables and accruals	15,192	28,747	22,356	25,157
Interest-bearing bank borrowings	7,000	8,150	8,000	6,600
Lease liabilities	251	1,111	1,646	707
Convertible redeemable preferred shares	–	1,260,013	249,134	–
Total current liabilities	28,534	1,319,720	310,888	70,151
NET CURRENT ASSETS/(LIABILITIES)	746,648	(468,702)	442,431	581,649

FINANCIAL INFORMATION

As of June 30, 2023, we maintained a net liabilities position, primarily due to the recognition of convertible redeemable preferred shares issued to investors as our non-current liabilities. We had net liabilities of RMB272.3 million, RMB470.5 million and RMB1,028.4 million as of December 31, 2021 and 2022, and June 30, 2023, respectively. The increase in our net liabilities was primarily due to the total comprehensive loss. Our total comprehensive loss increased from RMB217.4 million in 2021 to RMB223.9 million in 2022 and our total comprehensive loss increased from RMB92.4 million for the six months ended June 30, 2022 to RMB586.3 million for the six months ended June 30, 2023. The increase in total comprehensive loss was driven by the expanded research and development activities, fair value changes on convertible redeemable preferred shares issued to investors, as well as administrative expenses. The majority of our convertible redeemable preferred shares was reclassified from current liabilities as of December 31, 2022, to non-current liabilities as of June 30, 2023, as we entered into the supplementary deferred redemption agreement with majority of our investors of series B+, series C and series C+ convertible redeemable preferred shares. All preferred shares will be reclassified from financial liabilities to equity as a result of the automatic conversion into our Shares upon [REDACTED], which will reverse our net liability position to a net asset position. See the Accountants’ Report set out in Appendix I to this document for a detailed description of our statements of changes in equity.

Prepayments, Other Receivables and Other Assets

Our prepayments, other receivables and other assets primarily consist of (i) prepayments to suppliers of third-party services mainly used in our preclinical and clinical research and development; (ii) input value-added tax, representing input value-added taxes paid with respect to our procurement; (iii) rental deposit to our leased properties and (iv) other receivables and other current assets which represent rental deposits, social security paid for employees and capitalized [REDACTED].

The following table sets forth components of our prepayments, other receivables and other assets as of the dates indicated.

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		
Prepayments to suppliers	3,854	5,728	11,066
Input value-added tax	3,367	1,870	4,544
Deposits	497	404	716
Other receivables	275	469	565
Other current assets	1,899	2,350	3,508
Total	9,892	10,821	20,399

Our prepayments, other receivables and other assets increased significantly from RMB9.9 million as of December 31, 2021 to RMB10.8 million as of December 31, 2022 and further increased to RMB20.4 million as of June 30, 2023, which was primarily attributable to an increase of RMB5.3 million in our prepayments to suppliers of third-party services mainly used in our preclinical and clinical research and development.

As of October 31, 2023, approximately RMB9.9 million, or 48.3% of our prepayments, other receivables and other assets as of June 30, 2023 were settled.

FINANCIAL INFORMATION

Cash and Bank Balances

Our cash and bank balances primarily consist of cash in hand and at bank and short-term time deposits. Short term time deposits are made for varying periods of between one day and three months which depending on the immediate cash requirements of us and with the respective interest rates. The bank balances and restricted cash are deposited with banks.

Our cash and bank balances increased by 77.7% from RMB412.3 million as of December 31, 2022 to RMB732.9 million as of June 30, 2023, primarily attributable to cash inflow from our deposit transfers from a reputable financial institution.

Our cash and bank balances decreased by 46.1% from RMB765.3 million as of December 31, 2021 to RMB412.3 million as of December 31, 2022, primarily attributable to the withdrawal of deposits, which are deposited with creditworthy banks through a reputable financial institution of RMB427.8 million.

The following table sets forth a breakdown of our cash and bank balances as of the dates indicated.

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		
Cash and bank balances	765,290	412,340	732,920
Less:			
Bank deposits over three months	–	–	(170,498)
Restricted cash (<i>Note (i)</i>)	–	(139,293)	(144,524)
Cash and cash equivalents	765,290	273,047	417,898
Denominated in:			
Renminbi	72,700	83,832	158,986
US dollars	692,037	328,207	573,769
Australia dollars	553	283	56
HK dollars	–	18	109
Cash and bank balances	765,290	412,340	732,920

Note

- (i) represents the proceeds from the issuance of the convertible redeemable preferred shares, which have been placed in a restricted bank account to be used for core research and development activities and for the redemption of the convertible redeemable preferred shares. None of the amounts are impaired.

FINANCIAL INFORMATION

Trade Payables

Our trade payables mainly consist of payables for R&D services. Our trade payables increased significantly from RMB6.1 million as of December 31, 2021 to RMB21.7 million as of December 31, 2022 and further increased to RMB29.8 million as of June 30, 2023, primarily driven by the increase in third-party contracting expenses for clinical development of our Core Product HTD1801.

The following table sets forth an aging analysis of our trade payables as of the dates indicated.

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		
Within 12 months	6,091	21,699	29,752
Total	6,091	21,699	29,752

Our Directors confirm that we had no material defaults in payment of trade payables during the Track Record Period and up to the Latest Practicable Date.

As of October 31, 2023, RMB29.5 million or 99.2% of our trade payables as of June 30, 2023 were subsequently settled.

Other Payables and Accruals

Our other payables and accruals primarily consist of payables in relation to (i) professional service fees; (ii) payroll; and (iii) others.

The following table sets forth components of our other payables and accruals as of the dates indicated.

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		
Professional service fees	9,484	14,384	12,652
Payroll	5,263	9,166	7,393
Other	445	5,197	2,311
Total	15,192	28,747	22,356

FINANCIAL INFORMATION

Our other payables and accruals decreased from RMB28.7 million as of December 31, 2022 to RMB22.4 million as of June 30, 2023, primarily attributable to a decrease of RMB1.8 million in payroll and RMB1.7 million in professional service fees.

Our other payables and accruals increased significantly from RMB15.2 million as of December 31, 2021 to RMB28.7 million as of December 31, 2022, primarily attributable to an increase of RMB4.9 million in professional service fees in relation to our [REDACTED] payable to third parties, RMB3.9 million in payroll payable resulting from an increase in employee compensations and RMB4.8 million in other payable.

As of October 31, 2023, RMB11.6 million or 52.1% of our other payables and accruals as of June 30, 2023 were subsequently settled.

Interest-bearing Bank Borrowings

The following table sets forth our interest-bearing bank borrowings as of the dates indicated.

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Current			
Bank loans – secured	7,000	3,840	2,880
Bank loans – unsecured	–	4,310	5,120
Total	7,000	8,150	8,000

Lease Liabilities

The following table sets forth our lease liabilities as of the dates indicated.

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		
Current	251	1,111	1,646
Non current	902	1,513	1,549
Total	1,153	2,624	3,195

Our lease liabilities increased significantly from RMB1.2 million as of December 31, 2021 to RMB2.6 million as of December 31, 2022 and further increased to RMB3.2 million as of June 30, 2023, which were primarily in relation to the properties we leased for our office premises and R&D facilities.

FINANCIAL INFORMATION

Convertible Redeemable Preferred Shares

The following table sets for our convertible redeemable preferred shares as of the dates indicated.

	As of December 31,		As of June 30,
	2021	2022	2023
	<i>(RMB in thousands)</i>		
Current	–	1,260,013	249,134
Non current	1,005,903	–	1,472,519
Total	1,005,903	1,260,013	1,721,653

Our convertible redeemable preferred shares represent the carrying amount of Preferred Shares we issued pursuant to our Series B+ Investment, Series C Investment and Series C+ Investment. For more details regarding our Preferred Shares, see “History, Reorganization and Corporate Structure — [REDACTED] Investments”. Our convertible redeemable preferred shares increased from RMB1,005.9 million as of December 31, 2021 to RMB1,260.0 million as of December 31, 2022 and further increased to RMB1,721.7 million as of June 30, 2023 primarily due to (i) the currency translation differences; (ii) changes in the fair value of our Preferred Shares and (iii) the issuance of Series C+ Preferred Shares in 2022.

INDEBTEDNESS

As of December 31, 2021 and 2022, June 30, 2023 and October 31, 2023, except as disclosed in the table below, we did not have any outstanding mortgages, charges, debentures, other issued debt capital, bank overdrafts, borrowings, liabilities under acceptance or other similar indebtedness, any guarantees, litigations or claims of immaterial importance, pending or threatened against any member of our Company or other material contingent liabilities. Since October 31, 2023, the latest practicable date for the purpose of the indebtedness statement, and up to the date of this document, there had been no material adverse change to our indebtedness.

FINANCIAL INFORMATION

The following table sets forth the breakdown of our indebtedness as of the dates indicated.

	As of December 31,		As of June 30,	As of October 31,
	2021	2022	2023	2023
				<i>(unaudited)</i>
				<i>(RMB in thousands)</i>
Current				
Interest-bearing bank borrowings	7,000	8,150	8,000	6,600
Lease liabilities	251	1,111	1,646	708
Convertible redeemable preferred shares	–	1,260,013	249,134	–
Non current				
Lease liabilities	902	1,513	1,549	804
Convertible redeemable preferred shares	1,005,903	–	1,472,519	1,786,672
Total	1,014,056	1,270,787	1,732,848	1,794,784

As of October 31, 2023, we had no unutilized bank facilities.

KEY FINANCIAL RATIOS

	As of December 31,		As of the six months ended June 30,	
	2021	2022	2022	2023
				<i>(unaudited)</i>
Gearing Ratio ⁽¹⁾	(3%)	(2%)	(2%)	(1%)
Current Ratio ⁽²⁾	27.2	0.6	0.7	2.4

Notes:

- (1) Equals bank loans and other borrowings divided by total equity as of the same date.
- (2) Equals current assets divided by current liabilities as of the same date.

LIQUIDITY AND CAPITAL RESOURCES

Overview

Our primary uses of cash relate to the research and development of our drug candidates. We primarily funded our working capital requirement through equity financing during the Track Record Period. 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. As our business develops and expands, we expect to generate more cash from our operating activities through the launch of our drug candidates. We believe our future liquidity requirements will be mainly satisfied by using funds from a combination of our existing cash, net [REDACTED] from the [REDACTED] and bank borrowings if necessary.

FINANCIAL INFORMATION

Cash Flows

The following table sets forth a summary of our cash flows for the years indicated.

	For the year ended December 31,		For the six months ended June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Operating loss before changes in working capital	(103,864)	(197,141)	(92,936)	(136,606)
Changes in working capital	13,327	24,786	18,531	(7,197)
Income tax paid	(9)	(24)	(14)	(105)
Net cash flows used in operating activities	(90,546)	(172,379)	(74,419)	(143,908)
Net cash flows from/(used in) investing activities	1,588	(415,661)	2,749	271,034
Net cash flows from financing activities	493,982	46,034	845	(1,946)
Net increase/(decrease) in cash and cash equivalents	405,024	(542,006)	(70,825)	125,180
Cash and cash equivalents at beginning of year	367,252	765,290	765,290	273,047
Effects of foreign exchange rate changes, net	(6,986)	49,763	29,290	19,671
Cash and cash equivalents at end of year	765,290	273,047	723,755	417,898

Operating Activities

In the six months ended June 30, 2023, our net cash used in operating activities was RMB143.9 million. This net outflow from operating activities primarily reflected loss before tax of RMB549.7 million, positively adjusted primarily by (i) fair value gains on convertible redeemable preferred shares of RMB399.6 million, (ii) equity-settled share option arrangements of RMB28.4 million, and (iii) an increase in trade payables of RMB8.1 million, partially offset by (i) an increase in prepayments, other receivable and other assets of RMB8.4 million, and (ii) a decrease in other payables and accruals of RMB6.3 million.

In 2022, our net cash used in operating activities was RMB172.4 million. This net outflow from operating activities primarily reflected loss before tax of RMB190.2 million, positively adjusted primarily by (i) equity-settled share option arrangements of RMB25.6 million and (ii) foreign exchange differences, net of RMB7.5 million. The amount was further adjusted by changes in working capital, primarily including (i) an increase in trade payables of RMB15.6 million and (ii) an increase in other payables and accruals of RMB13.5 million, partially offset by a decrease in deferred income of RMB3.9 million.

FINANCIAL INFORMATION

In 2021, our net cash used in operating activities was RMB90.5 million. This net outflow from operating activities primarily reflected loss before tax of RMB221.0 million, positively adjusted primarily by (i) fair value losses on convertible redeemable preferred shares of RMB93.7 million and (ii) transaction costs for preferred shares of RMB16.2 million. This amount was further adjusted by changes in working capital, primarily including (i) an increase in other payables and accruals of RMB14.4 million and (ii) an increase in deferred income of RMB3.4 million, partially offset by an increase in prepayments, other receivables and other assets of RMB3.6 million.

We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. As our business develops and expands, we expect to generate net cash from our operating activities, through increasing sales revenue of our expected commercialized product. In view of our net operating cash outflows throughout the Track Record Period, we plan to improve such position by (i) rapidly advancing our pipeline products towards commercialization to generate revenue from product sales; (ii) adopting comprehensive measures to effectively control our cost and operating expenses, primarily including research and development costs and administrative expenses; (iii) enhancing working capital management efficiency; and (iv) successfully launching the [REDACTED] to obtain the [REDACTED].

Investing Activities

In the six months ended June 30, 2023, our net cash from investing activities was RMB271.0 million, which was primarily attributable to proceeds from disposal of short-term time deposits of RMB462.1 million, partially offset by purchase of bank deposits over three months of RMB166.6 million and purchase of short-term time deposits of RMB38.2 million.

In 2022, our net cash used in investing activities was RMB415.7 million, which was primarily attributable to purchase of financial assets at FVTPL of RMB717.8 million and purchase of short-term time deposits of RMB621.4 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB717.8 million, proceeds from disposal of short-term time deposits of RMB197.5 million, receipts of investment income from short-term time deposits of RMB3.9 million and bank interest received of RMB3.5 million.

In 2021, our net cash from investing activities was RMB1.6 million, which was primarily attributable to proceeds of financial assets at FVTPL of RMB1,545.7 million, partially offset by purchase of financial assets at FVTPL of RMB1,545.7 million.

In 2021, 2022 and the six months ended June 30, 2023, we purchased short-term wealth management products in order to generate reasonable low-risk returns. 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 Chief Financial Officer 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;

FINANCIAL INFORMATION

- Our Board is responsible for the approval of our material investments in wealth management products through a strict review and decision making process;
- Our finance department is responsible for implementation and management of our wealth management products; and
- All investments must be rated at least investment grade with a low risk of default at the beginning of the fixed interest term, except for wealth management product investments that are not rated, as long as such wealth management products are issued by a commercial bank or other financial institution that is regulated by its respective reputable regulatory authority.

Prior to making an investment, we ensure that there remains sufficient working capital for our business needs, operating activities, research and development and capital expenditures even after purchasing such wealth management products. We adopt a prudent approach in investing wealth management products. Our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, such as the duration of the investment and the expected returns. To control our risk exposure, we have in the past sought, and may continue in the future to seek, other low-risk wealth management products issued by a commercial bank or other financial institution that is regulated by its respective reputable regulatory authority. Our investments in wealth management products after the [REDACTED] will be subject to compliance with Chapter 14 of the Listing Rules.

Financing Activities

In the six months ended June 30, 2023, our net cash used in financing activities was RMB1.9 million, which was mainly attributable to the repayment of existing bank loans of RMB5.2 million and the settlement of [REDACTED] of RMB[REDACTED], partially offset by the addition of bank loans of RMB5.0 million.

In 2022, our net cash from financing activities was RMB46.0 million, which was primarily attributable to proceeds from Series C+ preferred shares of RMB47.1 million and new bank loans of RMB15.0 million, partially offset by repayment of bank loans of RMB13.9 million.

In 2021, our net cash from financing activities was RMB494.0 million, which was primarily attributable to (i) proceeds from issuance of series B+ convertible redeemable preferred shares of RMB179.9 million and (ii) proceeds from issuance of series C convertible redeemable preferred shares of RMB511.3 million, partially offset by repayments of other borrowings of RMB184.5 million.

FINANCIAL INFORMATION

CASH OPERATING COSTS

The following table sets forth information on our cash operating costs for the years indicated.

	For the year ended December 31,		For the six months ended June 30,
	2021	2022	2023
<i>(RMB in thousands)</i>			
Research and development costs			
<i>Research and development costs for Core Product</i>			
Third-party contracting expenses	53,437	103,808	73,838
Staff costs	13,612	28,097	19,412
Others	2,274	1,538	1,701
<i>Research and development costs for other product candidates</i>			
Third-party contracting expenses	2,486	2,577	1,240
Staff costs	2,348	3,896	2,157
Others	1,951	1,146	1,188
Workforce employment costs	4,297	7,582	9,492
Taxes	174	6,821	433
Total	80,579	155,465	109,461

WORKING CAPITAL CONFIRMATION

Our Directors are of the opinion that, taking into account the financial resources available to us, including cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED], and considering 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 our average monthly (i) net cash used in operating activities; (ii) capital expenditures and (iii) lease payments. Assuming an average cash burn rate going forward of 2.1 times the level in 2022, we estimate that our total cash balance as of June 30, 2023, will be able to maintain our financial viability for approximately 25 months or, if taking into account the estimated net [REDACTED] (based on the mid-point of the indicative [REDACTED] and assuming the [REDACTED] is not exercised) from the [REDACTED], for at least [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

CAPITAL EXPENDITURES

Our capital expenditures primarily consist of the purchase of items of (i) machinery and equipment, (ii) furniture, fittings and equipment and (iii) leasehold improvements. In 2021, 2022 and the six months ended June 30, 2023, our capital expenditure was RMB1.7 million, RMB0.2 million and RMB72 thousand, respectively.

The following table sets forth our capital expenditures for the years indicated.

	For the year ended of December 31,		For the six months ended June 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(RMB in thousands)</i>	
Machinery and equipment	1,104	–	–	8
Furniture, fittings and equipment	376	183	62	64
Leasehold improvements	265	–	–	–
Total	1,745	183	62	72

The decrease of our capital expenditure during the Track Record Period was primarily due to the one-off purchase of our machinery and equipment in 2021. We expect that our capital expenditures in 2023 will be approximately RMB120 thousand, which will primarily include purchases of furniture, fittings and equipment. We plan to fund our planned capital expenditures using our cash and cash equivalent and the net [REDACTED] received from the [REDACTED]. See “Future Plans and Use of [REDACTED]”. We may reallocate the fund to be utilized on capital expenditure based on our ongoing business needs.

CAPITAL COMMITMENTS

As of December 31, 2021 and 2022 and June 30, 2023, we did not have any capital commitments.

CONTINGENT LIABILITIES

As of December 31, 2021 and 2022 and June 30, 2023, we did not have any contingent liabilities. Our Directors confirm that there has been no material change in our contingent liabilities as of the Latest Practicable Date.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet arrangements.

FINANCIAL INFORMATION

QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to a variety of market risks, including foreign currency risk, credit risk and liquidity risk set out below. We manage and monitor these exposures to ensure appropriate measures are implemented in a timely and effective manner. See Note 32 to the Accountants' Report set out in Appendix I to this document for a detailed description of our financial risk management.

Foreign Currency Risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Certain bank balances, trade and other payables and convertible redeemable preferred shares of our Group are denominated in currencies other than the functional currency, which exposes us to foreign currency risk. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

For details and the sensitivity analysis of our profit before tax and our equity to a reasonably possible change in the U.S. dollar exchange rate for each year during the Track Record Period, with all other variables held constant, see note 32 to the Accountants' Report set out in Appendix I to this document.

Credit Risk

Credit risk refers to the risk that a counter party will default on contractual obligations resulting in financial loss to the Group. We are exposed to credit risk which arises from the amount of each class of financial assets. In order to minimize the credit risk, our management reviews the recoverable amount of each individual debt to ensure that adequate impairment losses are made for irrecoverable amounts. Other monitoring procedures are in place to ensure that follow-up action is taken to recover overdue debts. For further details, see note 32 to the Accountants' Report set out in Appendix I to this document.

Liquidity Risk

We monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance our operations and mitigate the effects of fluctuations in cash flows. For details and the maturity profile of our financial liabilities as of the end of each year during the Track Record Period, see note 32 in the Accountants' Report set out in Appendix I to this document.

MATERIAL RELATED PARTY TRANSACTIONS

During the Track Record Period, our only related party transaction is the key management personnel remuneration. Details of our transactions, with and the outstanding balances with related parties during the Track Record Period, are set out in Note 29 to the Accountants' Report set out in Appendix I to this document.

FINANCIAL INFORMATION

DIVIDENDS

We have never declared or paid regular cash dividends on our Shares. Any declaration and payment as well as the amount of dividends will be subject to our Memorandum and Articles and the Cayman Companies Act. Our Board of Directors has the discretion to pay interim dividends and to recommend to Shareholders to pay final dividends and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. In addition, our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman counsel, under the Cayman Companies Act, a Cayman Islands company may pay a dividend out of either profits and/or share premium account, provided that in no circumstances may a dividend be paid out of share premium if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

If we pay dividends in the future, in order for us to distribute dividends to our Shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries. Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, 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. See “Risk Factors — Risks Relating to Doing Business in the PRC” in this document.

DISTRIBUTABLE RESERVES

As of June 30, 2023, we did not have any distributable reserves.

[REDACTED]

Our [REDACTED] represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. Assuming an [REDACTED] of HK\$[REDACTED] per Share at the mid-point of the indicative [REDACTED] range stated in this document and no [REDACTED] is exercised, we estimated that the total [REDACTED] for the [REDACTED] are approximately HK\$[REDACTED], accounting for approximately [REDACTED]% of the gross [REDACTED] from the [REDACTED], including HK\$[REDACTED] that we have incurred for the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, of which HK\$[REDACTED] was charged to our consolidated statements of profit or loss, while the remaining amount of HK\$[REDACTED] was directly attributable to the issue of Shares as of June 30, 2023 and will be subsequently deducted from equity upon completion of the [REDACTED], and HK\$ [REDACTED] that we expect to further incur after June 30, 2023, of which HK\$[REDACTED] will be charged to our consolidated income statements, and 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]-related expenses, including [REDACTED] and other expenses, of HK\$[REDACTED]; and (ii)

FINANCIAL INFORMATION

non-[REDACTED]-related 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]. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

[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 June 30, 2023 (being the date on which the latest consolidated financial information of our Group was prepared) and there has been no event since June 30, 2023 which would materially and adversely affect the information shown in our historical financial information 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 have confirmed 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 more details of our future plans, see “Business — Strategies”.

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 exercise of the [REDACTED] and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] in this document.

We intend to use the net [REDACTED] from the [REDACTED] for the following purposes:

- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the continuing clinical research and development activities of our Core Product HTD1801:
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the continuing research and development of HTD1801 in Phase IIb clinical trial including R&D personnel costs and third party contracting expenses for MASH, covering the jurisdictions of the United States, Hong Kong, Mexico and Mainland China. The trial was initiated in the United States in December 2022 and in Hong Kong in October 2023, and we are actively enrolling patients in the United States and Hong Kong. We plan to initiate Phase IIb clinical trial sites in Mexico and Mainland China in December 2023:
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the continuing research and development of HTD1801 in Phase IIb clinical trial for MASH in United States;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the R&D personnel cost of HTD1801 in Phase IIb clinical trial for MASH in United States;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the third party contracting expenses of HTD1801 in Phase IIb clinical trial for MASH in United States;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the R&D personnel costs and third party contracting expenses of HTD1801 in Phase IIb clinical trial for MASH in Hong Kong;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the R&D personnel costs and third party contracting expenses of HTD1801 in Phase IIb clinical trial for MASH in Mexico; and

FUTURE PLANS AND USE OF [REDACTED]

- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the R&D personnel costs and third party contracting expenses of HTD1801 in Phase IIb clinical trial for MASH in Mainland China.
- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the research and development of HTD1801 in Phase III clinical trial including R&D personnel costs and third party contracting expenses for T2DM. The Phase II clinical trial for T2DM was initiated in Mainland China in March 2022 and completed in January 2023 with 113 patients enrolled. We initiated two Phase III registrational trials, one with HTD1801 as a standalone treatment for T2DM patients and one with HTD1801 as an add-on therapy with metformin treatment in November 2023 and plan to complete enrollment in 2024 in Mainland China:
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the research and development of HTD1801 in the Phase III clinical trial for T2DM as a standalone treatment;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the third party contracting expenses of HTD1801 in the Phase III clinical trial for T2DM as a standalone treatment;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund R&D personnel costs of HTD1801 in the Phase III clinical trial for T2DM as a standalone treatment;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the research and development of HTD1801 in the Phase III clinical trial for T2DM as an add-on therapy with metformin treatment;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the third party contracting expenses of HTD1801 in the Phase III clinical trial for T2DM as an add-on therapy with metformin treatment;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund R&D personnel costs of HTD1801 in the Phase III clinical trial for T2DM as an add-on therapy with metformin treatment;

FUTURE PLANS AND USE OF [REDACTED]

- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the research and development of HTD1801 in Phase II clinical trial including the R&D personnel costs and third party contracting expenses for SHTG. We plan to initiate a Phase II clinical trial of HTD1801 for the treatment of SHTG in the United States in the first half of 2024:
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the R&D personnel costs of HTD1801 in Phase II clinical trial for SHTG in the United States;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the third party contracting expenses of HTD1801 in Phase II clinical trial for SHTG in the United States.

Compared to the R&D expenses incurred for the clinical development of HTD1801 during the Track Record Period, the use of [REDACTED] to be allocated to the development of HTD1801 is higher because (i) the total number of patients planned to be enrolled in HTD1801's Phase III clinical trials are significantly higher than the patient enrolment size of the Phase I and Phase II clinical trials for the same indications during the Track Record Period; (ii) the expected duration of both the Phase II and III clinical trials will be around 24 to 48 months, whereas the completion time of the Phase I clinical trials was within 12 months; (iii) we plan to conduct MRCTs and the engagements of overseas CROs, SMOs and CDMOs and the communications and filings with relevant authorities in these jurisdictions would potentially incur additional expenses. Depending on the regulations in each territory, we may be required to conduct additional local clinical studies prior to commencing registrational trials; (iv) subject to the communication with the competent authorities, we may also submit NDAs for HTD1801's indication expansion, where additional clinical studies might be required. According to CIC, our R&D costs are in line with the industry's average. In addition, for PSC and PBC indications, we plan to collaborate with other companies for clinical development and commercialization. Therefore, no net [REDACTED] will be allocated to the clinical development of PSC and PBC indications of the Core Product.

- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the ongoing research and development including R&D personnel costs and third party contracting expenses for HTD1804 for obesity. We are currently conducting the preclinical study of HTD1804 in China.

FUTURE PLANS AND USE OF [REDACTED]

- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used for the early drug discovery and development of other drug candidates from continuously upgrading and enhancing our FUSIONTX™ development approach:
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], for the research and development of three innovative multifunctional drugs to advance from drug discovery to IND-enabling stage leveraging our FUSIONTX™ development approach in the next five years:
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the third party contracting expenses of drug discovery and preclinical studies to discover three innovative multifunctional drugs. Approximately HK\$[REDACTED] of the net [REDACTED] will be used to fund the third party contracting expenses for each innovative multifunctional drug;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the R&D personnel costs incurred for research and development of those three innovative multifunctional drugs and enhancing our FUSIONTX™ development approach;
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], for the ongoing research and development of our other drug candidates including but not limited to HTD4010, HTD1805 and HTD2802. We plan to leverage our R&D capabilities to advance our clinical-stage candidate HTD4010's development in treating AH and are currently conducting the preclinical studies for HTD1805 and HTD2802:
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the Phase II clinical trial of HTD4010. We expect to initiate Phase II clinical trial of HTD4010 for AH in the United States as early as the end of 2024.
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the preclinical studies of HTD1805.
 - Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used to fund the preclinical studies of HTD2802.
- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used for working capital and other general corporate purposes.

FUTURE PLANS AND USE OF [REDACTED]

The above allocation of the [REDACTED] will be adjusted on a pro rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the estimated [REDACTED] range. If the [REDACTED] is set at HK\$[REDACTED] per [REDACTED], being the high end of the indicative [REDACTED] range, the net [REDACTED] from the [REDACTED] will increase by approximately HK\$[REDACTED]. If the [REDACTED] is set at HK\$[REDACTED] per [REDACTED], being the low end of the indicative [REDACTED] range, the net [REDACTED] from the [REDACTED] will decrease by approximately HK\$[REDACTED].

If the [REDACTED] is exercised in full, and net [REDACTED] that we will receive will be approximately HK\$[REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the indicative [REDACTED] range). In the event that the [REDACTED] is exercised in full, we intend to apply the additional net [REDACTED] to the above purpose in the proportions stated above.

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 authorised financial institutions (as defined under the Securities and Futures Ordinance).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report, prepared for the purpose of incorporation in this document, received from the independent reporting accountants, Ernst & Young, Certified Public Accountants, Hong Kong.

[To insert the firm’s letterhead]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF HIGHTIDE THERAPEUTICS, INC., UBS SECURITIES HONG KONG LIMITED, AND HUATAI FINANCIAL HOLDINGS (HONG KONG) LIMITED

Introduction

We report on the historical financial information of HighTide Therapeutics, Inc. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-4 to I-59, which comprises the consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of years ended 31 December 2021 and 2022, and the six months ended 30 June 2023 (“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 2021 and 2022 and 30 June 2023 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-59 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [DATE] (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

APPENDIX I

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 presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively, 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 2021 and 2022 and 30 June 2023, and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively.

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, statement of comprehensive income, statement of changes in equity and statement of cash flows for the six months ended 30 June 2022 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 presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively. 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 presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively.

APPENDIX I

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-3 have been made.

Dividends

We refer to note 11 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

No historical financial statements for the Company

As at the date of this report, no statutory financial statements have been prepared for the Company since its date of incorporation.

Certified Public Accountants

Hong Kong

[Date]

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.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Notes	Year ended 31 December		Six months ended 30 June	
		2021	2022	2022	2023
		RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
Other income and gains	5	13,821	20,581	3,925	22,722
Fair value (losses)/gains on convertible redeemable preferred shares	6	(93,656)	23,242	31,247	(399,635)
Other expenses	5	(1)	(7,518)	(4,381)	(502)
Fair value losses on financial liabilities at fair value through profit or loss ("FVTPL")	6	(4,609)	–	–	–
Research and development costs		(84,012)	(182,651)	(76,322)	(120,088)
Administrative expenses		(48,064)	(43,433)	(28,357)	(52,014)
Finance costs	7	(4,528)	(426)	(217)	(201)
LOSS BEFORE TAX	6	(221,049)	(190,205)	(74,105)	(549,718)
Income tax expenses	10	(96)	(32)	(72)	(26)
LOSS FOR THE YEAR/PERIOD		(221,145)	(190,237)	(74,177)	(549,744)
Attributable to:					
Owners of the parent		(221,145)	(190,237)	(74,177)	(549,744)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT					
Basic and diluted					
For loss for the year/period (RMB per share)	12	(5.26)	(4.48)	(1.75)	(12.94)

APPENDIX I

ACCOUNTANTS' REPORT

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year ended 31 December		Six months ended 30 June	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
LOSS FOR THE YEAR/PERIOD	(221,145)	(190,237)	(74,177)	(549,744)
OTHER COMPREHENSIVE INCOME/(LOSS)				
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of the financial statements of subsidiaries	4,625	(20,342)	(11,442)	(8,896)
Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of the financial statements of the Company	(890)	(13,309)	(6,768)	(27,703)
OTHER COMPREHENSIVE INCOME/(LOSS)				
FOR THE YEAR/PERIOD, NET OF TAX	3,735	(33,651)	(18,210)	(36,599)
TOTAL COMPREHENSIVE LOSS				
FOR THE YEAR/PERIOD	(217,410)	(223,888)	(92,387)	(586,343)
Attributable to:				
Owners of the parent	(217,410)	(223,888)	(92,387)	(586,343)

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Notes	As at 31 December		As at 30 June
		2021	2022	2023
		RMB'000	RMB'000	RMB'000
NON-CURRENT ASSETS				
Property, plant and equipment	13	2,379	2,153	2,036
Right-of-use assets	14	1,071	2,653	3,035
Other non-current assets	15	–	–	192
Total non-current assets		3,450	4,806	5,263
CURRENT ASSETS				
Prepayments, other receivables and other assets	17	9,892	10,821	20,399
Short-term time deposits	18	–	427,857	–
Cash and bank balances	19	765,290	412,340	732,920
Total current assets		775,182	851,018	753,319
CURRENT LIABILITIES				
Trade payables	20	6,091	21,699	29,752
Other payables and accruals	21	15,192	28,747	22,356
Interest-bearing bank borrowings	22	7,000	8,150	8,000
Lease liabilities	14	251	1,111	1,646
Convertible redeemable preferred shares	26	–	1,260,013	249,134
Total current liabilities		28,534	1,319,720	310,888
NET CURRENT ASSETS/(LIABILITIES)		746,648	(468,702)	442,431
TOTAL ASSETS LESS CURRENT LIABILITIES				
		750,098	(463,896)	447,694
NON-CURRENT LIABILITIES				
Lease liabilities	14	902	1,513	1,549
Deferred income	25	15,555	5,119	2,052
Convertible redeemable preferred shares	26	1,005,903	–	1,472,519
Total non-current liabilities		1,022,360	6,632	1,476,120
Net liabilities		(272,262)	(470,528)	(1,028,426)
EQUITY				
Equity attributable to owners of the parent				
Share capital	28	33	36	39
Treasury shares		(3)	(6)	(9)
Deficits	29	(272,292)	(470,558)	(1,028,456)
Total deficit		(272,262)	(470,528)	(1,028,426)

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2021

	Attributable to owners of the parent								
	Share capital**	Treasury shares	Premium on ordinary shares*	Premium on convertible preferred shares*	Premium on Series B1 and B2 convertible preferred shares*	Share option reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total equity
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2021	32	(3)	30,612	96,401	156,319	107	(2)	(345,623)	(62,157)
Loss for the year	-	-	-	-	-	-	-	(221,145)	(221,145)
Other comprehensive income for the year	-	-	-	-	-	-	3,735	-	3,735
Total comprehensive loss for the year	-	-	-	-	-	-	3,735	(221,145)	(217,410)
Equity-settled share option arrangements	-	-	-	-	-	7,304	-	-	7,304
Issue of shares (note 28)	1	-	-	-	-	-	-	-	1
At 31 December 2021	<u>33</u>	<u>(3)</u>	<u>30,612</u>	<u>96,401</u>	<u>156,319</u>	<u>7,411</u>	<u>3,733</u>	<u>(566,768)</u>	<u>(272,262)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

Year ended 31 December 2022

	Attributable to owners of the parent								
	Share capital**	Treasury shares	Premium on ordinary shares*	Premium on Series A convertible preferred shares*	Premium on Series B1 and B2 convertible preferred shares*	Share option reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total equity
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2022	33	(3)	30,612	96,401	156,319	7,411	3,733	(566,768)	(272,262)
Loss for the year	-	-	-	-	-	-	-	(190,237)	(190,237)
Other comprehensive loss for the year	-	-	-	-	-	-	(33,651)	-	(33,651)
Total comprehensive loss for the year	-	-	-	-	-	-	(33,651)	(190,237)	(223,888)
Consolidation of special purpose vehicles for the share-based payment plan (note 28)	3	(3)	-	-	-	-	-	-	-
Equity-settled share option arrangements	-	-	-	-	-	25,622	-	-	25,622
At 31 December 2022	<u>36</u>	<u>(6)</u>	<u>30,612</u>	<u>96,401</u>	<u>156,319</u>	<u>33,033</u>	<u>(29,918)</u>	<u>(757,005)</u>	<u>(470,528)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

Six months ended 30 June 2022

	Attributable to owners of the parent								
	Share capital**	Treasury shares	Premium on ordinary shares*	Premium on Series A convertible preferred shares*	Premium on Series B1 and B2 convertible preferred shares*	Share option reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total equity
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2022	33	(3)	30,612	96,401	156,319	7,411	3,733	(566,768)	(272,262)
Loss for the period									
(unaudited)	-	-	-	-	-	-	-	(74,177)	(74,177)
Other comprehensive loss for the period									
(unaudited)	-	-	-	-	-	-	(18,210)	-	(18,210)
Total comprehensive loss for the period									
(unaudited)	-	-	-	-	-	-	(18,210)	(74,177)	(92,387)
Consolidation of special purpose vehicles for the share-based payment plan (note 28) (unaudited) . . .	3	(3)	-	-	-	-	-	-	-
Equity-settled share option arrangements									
(unaudited)	-	-	-	-	-	10,266	-	-	10,266
At 30 June 2022									
(unaudited)	36	(6)	30,612	96,401	156,319	17,677	(14,477)	(640,945)	(354,383)

APPENDIX I

ACCOUNTANTS’ REPORT

Six months ended 30 June 2023

Attributable to owners of the parent									
Share capital**	Treasury shares	Premium on ordinary shares*	Premium on Series A convertible preferred shares*	Premium on	Share option reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total equity	
				Series B1 and B2 convertible preferred shares*					
RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	
At 1 January 2023	36	(6)	30,612	96,401	156,319	33,033	(29,918)	(757,005)	(470,528)
Loss for the period	-	-	-	-	-	-	-	(549,744)	(549,744)
Other comprehensive loss for the period	-	-	-	-	-	-	(36,599)	-	(36,599)
Total comprehensive loss for the period	-	-	-	-	-	-	(36,599)	(549,744)	(586,343)
Consolidation of special purpose vehicles for the share-based payment plan (note 28)	3	(3)	-	-	-	-	-	-	-
Equity-settled share option arrangements	-	-	-	-	-	28,445	-	-	28,445
At 30 June 2023	<u>39</u>	<u>(9)</u>	<u>30,612</u>	<u>96,401</u>	<u>156,319</u>	<u>61,478</u>	<u>(66,517)</u>	<u>(1,306,749)</u>	<u>(1,028,426)</u>

* These reserve accounts comprise the consolidated deficits of RMB272,292,000, RMB470,558,000 and RMB1,028,456,000 in the consolidated statements of financial position as at 31 December 2021 and 2022 and 30 June 2023, respectively.

** Share capital includes share capital for both ordinary shares and preferred shares.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended 31 December		Six months ended 30 June	
		2021	2022	2022	2023
		RMB'000	RMB'000	RMB'000	RMB'000
					(unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		(221,049)	(190,205)	(74,105)	(549,718)
Adjustments for:					
Finance costs	7	4,528	426	217	201
Depreciation of property, plant and equipment	13	276	409	211	189
Depreciation of right-of-use assets	14	1,314	865	329	628
Equity-settled share option arrangements	30	7,304	25,622	10,266	28,445
Transaction costs for preferred shares	6	16,205	501	–	–
Bank interest income	5	(964)	(3,545)	(2,290)	(696)
Investment income from short-term time deposits	5	–	(7,822)	–	(12,931)
Fair value losses/(gains) on convertible redeemable preferred shares	26	93,656	(23,242)	(31,247)	399,635
Fair value losses on financial liabilities at FVTPL	24	4,609	–	–	–
Amortisation of government grants income	25	(6,775)	(6,544)	(102)	(2,741)
Covid-19-related rent concessions from lessors	14	–	(112)	(75)	–
Loss on disposal of items of property, plant and equipment	5	1	–	–	–
Other investment income from financial assets at FVTPL	5	(2,366)	(1,012)	(521)	(120)
Foreign exchange differences, net	5	(603)	7,518	4,381	502
Operating loss before changes in working capital		(103,864)	(197,141)	(92,936)	(136,606)
(Increase)/decrease in prepayments, other receivables and other assets		(3,637)	(477)	747	(8,420)
Increase in other non-current assets		–	–	–	(192)
Increase/(decrease) in other payables and accruals		14,360	13,547	9,945	(6,312)
(Decrease)/increase in trade payables		(811)	15,608	7,839	8,053
Increase/(decrease) in deferred income	25	3,415	(3,892)	–	(326)
Cash used in operations		(90,537)	(172,355)	(74,405)	(143,803)
Income tax paid		(9)	(24)	(14)	(105)
Net cash flows used in operating activities		(90,546)	(172,379)	(74,419)	(143,908)

APPENDIX I

ACCOUNTANTS’ REPORT

	Notes	Year ended 31 December		Six months ended 30 June	
		2021	2022	2022	2023
		RMB’000	RMB’000	RMB’000	RMB’000
(unaudited)					
CASH FLOWS FROM INVESTING ACTIVITIES					
Proceeds from disposal of items of					
property, plant and equipment		3	–	–	–
Purchases of items of property, plant and					
equipment	13	(1,745)	(183)	(62)	(72)
Purchase of short-term time deposits		–	(621,429)	–	(38,200)
Purchase of bank deposits over three months		–	–	–	(166,557)
Purchase of financial assets at FVTPL		(1,545,686)	(717,841)	(330,481)	(24,200)
Bank interest received		964	3,545	2,290	696
Receipts of investment income					
from short-term time deposits		–	3,881	–	12,931
Proceeds from disposal of					
short-term time deposits		–	197,513	–	462,116
Proceeds from disposal of financial assets at					
FVTPL		1,545,686	717,841	330,481	24,200
Receipts of investment income from					
financial assets at FVTPL	5	2,366	1,012	521	120
Net cash flows from/(used in) investing activities ..		1,588	(415,661)	2,749	271,034
CASH FLOWS FROM FINANCING ACTIVITIES					
Repayments of other borrowings	23	(184,515)	–	–	–
New bank loans		10,000	15,000	10,000	5,000
Repayment of bank loans		(3,000)	(13,850)	(8,500)	(5,150)
Principal portion of lease payments	14	(1,270)	(987)	(119)	(502)
Bank loan interest paid	7	(309)	(303)	(164)	(137)
[REDACTED] paid		(1,899)	(451)	(372)	(1,157)
Proceeds from issuance of Series B+ convertible					
redeemable preferred shares		179,873	–	–	–
Proceeds from issuance of Series C convertible					
redeemable preferred shares	26	511,307	–	–	–
Proceeds from Series C+ preferred shares		–	47,126	–	–
Financing fees from Series C preferred shares		(16,205)	–	–	–
Financing fees from Series C+ preferred shares ...		–	(501)	–	–
Net cash flows from/(used in)					
financing activities		493,982	46,034	845	(1,946)

APPENDIX I

ACCOUNTANTS’ REPORT

	<i>Notes</i>	<u>Year ended 31 December</u>		<u>Six months ended 30 June</u>	
		2021	2022	2022	2023
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
(unaudited)					
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS		405,024	(542,006)	(70,825)	125,180
Cash and cash equivalents at beginning of year/period		367,252	765,290	765,290	273,047
Effect of foreign exchange rate changes, net		(6,986)	49,763	29,290	19,671
CASH AND CASH EQUIVALENTS AT END OF YEAR/PERIOD	19	<u>765,290</u>	<u>273,047</u>	<u>723,755</u>	<u>417,898</u>
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS					
Cash and bank balances	19	765,290	412,340	723,755	732,920
Bank deposits over three months	19	–	–	–	(170,498)
Restricted cash	19	–	(139,293)	–	(144,524)
Cash and cash equivalents as stated in the consolidated statements of cash flows		<u>765,290</u>	<u>273,047</u>	<u>723,755</u>	<u>417,898</u>

APPENDIX I

ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	Notes	As at 31 December		As at
		2021	2022	30 June
		RMB’000	RMB’000	2023 RMB’000
NON-CURRENT ASSETS				
Interests in subsidiaries	16	242,971	420,613	604,433
Total non-current assets		242,971	420,613	604,433
CURRENT ASSETS				
Prepayments and other receivables	17	297,179	197,778	269,275
Short-term time deposits	18	–	427,857	–
Cash and bank balances	19	578,146	360,284	562,089
Total current assets		875,325	985,919	831,364
CURRENT LIABILITIES				
Other payables and accruals	21	8,785	24,824	10,771
Convertible redeemable preferred shares	26	–	1,260,013	249,134
Total current liabilities		8,785	1,284,837	259,905
NET CURRENT ASSETS/(LIABILITIES)		866,540	(298,918)	571,459
TOTAL ASSETS LESS CURRENT LIABILITIES				
		1,109,511	121,695	1,175,892
NON-CURRENT LIABILITIES				
Convertible redeemable preferred shares	26	1,005,903	–	1,472,519
Total non-current liabilities		1,005,903	–	1,472,519
Net assets/(liabilities)		103,608	121,695	(296,627)
EQUITY				
Share capital	28	33	36	39
Reserves/(deficits)	29	103,575	121,659	(296,666)
Total equity/(deficits)		103,608	121,695	(296,627)

APPENDIX I

ACCOUNTANTS’ REPORT

II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

HighTide Therapeutics, Inc. was established in the Cayman Islands on 28 February 2018 by Great Mantra Group Limited and its registered address is Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman KY1-1111, Cayman Islands.

The Company is an investment holding company. The Company and its subsidiaries now comprising the Group underwent the reorganisation as set out in the paragraph headed “Reorganisation” in the section headed “History, Reorganisation and Corporate Structure” in the Document (the “Reorganisation”). During the Relevant Periods, the Company and its subsidiaries were involved in the research and development of pharmaceutical products.

As at the date of this report, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies (or, if incorporated outside Hong Kong, have substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are set out below:

Name	Place and date of incorporation/ registration and place of operations	Issued ordinary/ registered share capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
HighTide Therapeutics Ltd (c)	British Virgin Islands 16 March 2018	1,000 shares of par value USD1 each	100%	–	Investment holding
HighTide Therapeutics USA, LLC (“HighTide USA”) (c).	United States of America (“USA”) 24 January 2018	USD0	100%	–	Assist in research and development
HighTide Therapeutics (Hong Kong) Limited (“HK HighTide”) (b).	Hong Kong 9 April 2018	1 share of par value HKD1	–	100%	Investment holding
Shenzhen HighTide Biopharmaceutical Ltd. (“Shenzhen HighTide”) (a)*	Mainland China 15 November 2011	RMB310,800,000	–	100%	Research and development
Shanghai HighTide Biopharmaceutical Ltd. (a)*	Mainland China 14 March 2014	RMB5,000,000	–	100%	Research and development
JSK Consumer Healthcare Ltd (a)*.	Mainland China 21 July 2015	RMB5,000,000	–	100%	Research and development
HighTide Biopharma Pty. Ltd. (c)	Australia 15 July 2015	10,000 shares of par value AUD0.1 each	–	100%	Research and development
Shanghai Fusion Therapeutics Ltd. (a)*	Mainland China 20 May 2021	RMB1,000,000	–	100%	Research and development
Nanchang Fusion Therapeutics Ltd. (a)*	Mainland China 29 November 2021	RMB56,000,000	–	100%	Research and development

Notes:

- (a) The statutory financial statements of these entities for the years ended 31 December 2021 and 2022 prepared in accordance with PRC Generally Accepted Accounting Principles (“PRC GAAP”) were audited by Shenzhen Lingnan Certified Public Accountants (深圳嶺南會計師事務所), certified public accountants registered in the People’s Republic of China (the “PRC”).
- (b) The statutory financial statements of this entity for the years ended 31 December 2021 and 2022 prepared in accordance with Hong Kong Financial Reporting Standards (“HKFRSs”) issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”) were audited by RICHFUL CPA LIMITED (瑞豐會計師事務所有限公司), certified public accountants registered in Hong Kong.
- (c) No financial statements have been prepared for these entities for the years ended 31 December 2021 and 2022 and the six months ended 30 June 2023, as the entities were not subject to such requirements under the relevant rules and regulations in their jurisdictions of incorporation.
- * The English names of these companies represent the best effort made by the directors of the Company (the “Directors”) to translate the Chinese names as these companies have not been registered with any official English names.

2.1 BASIS OF PRESENTATION

Pursuant to the Reorganisation, as more fully explained in the paragraph headed “Reorganisation” in the section headed “History, Reorganisation and Corporate Structure” in the Document, the Company became the holding company of the companies now comprising the Group after the Reorganisation.

As the Reorganisation mainly involved inserting new holding companies at the top of an existing company, Shenzhen HighTide, and has not resulted in any change of economic substance, for the purpose of this report, the Historical Financial Information for the Relevant Periods has been presented as a continuation of Shenzhen HighTide and its subsidiaries using the pooling of interest method as if the Company had been the holding company of Shenzhen HighTide and its subsidiaries at the beginning of the Relevant Periods.

The consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for the Relevant Periods and the six months ended 30 June 2022 include the results and cash flows of all companies now comprising the Group as if the current group structure had been in existence throughout the Relevant Periods and the six months ended 30 June 2022. The consolidated statements of financial position of the Group as at 31 December 2021 and 2022 and 30 June 2023 have been prepared to present the assets and liabilities of the subsidiaries or businesses using the existing book values. No adjustments are made to reflect fair values, or recognise any new assets or liabilities as a result of the Reorganisation.

All intra-group transactions and balances have been eliminated on consolidation.

The Historical Financial Information has been prepared on the assumption that the Group will continue as a going concern notwithstanding that the Group has recorded net liabilities of RMB1,028,426,000 as at 30 June 2023. The directors of the Company are of the opinion that the Group will be able to meet its financial liabilities and obligations as and when they fall due to sustain its operations for the next 12 months from at 30 June 2023 as the Group has entered into a supplemental agreement with the holders of Series B+, Series C and Series C+ convertible redeemable preferred shares in 2023 and such holders agree not to exercise their [REDACTED] redemption rights (as defined and detailed in note 26) before 31 December 2024, meanwhile such holders will not require the Company to redeem such preferred shares within the next 12 months from 30 June 2023. The directors of the Company are also of the opinion that the Group will have sufficient working capital to meet the expenditure for its research and developments activities for the next 12 months from 30 June 2023.

APPENDIX I

ACCOUNTANTS’ REPORT

2.2 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (“IASB”). All IFRSs effective for the accounting period commencing from 1 January 2023, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods and in the period covered by the Interim Comparative Financial Information.

The Historical Financial Information has been prepared under the historical cost convention except for certain financial instruments which have been measured at fair value at the end of each of the Relevant Periods.

2.3 ISSUED BUT NOT YET EFFECTIVE IFRSs

The Group has not applied the following revised IFRSs, that have been issued but are not yet effective, in the Historical Financial Information.

Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ²
Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i> ¹
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> ¹
Amendments to IAS 1	<i>Non-current Liabilities with Covenants</i> ¹
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i> ¹

¹ Effective for annual periods beginning on or after 1 January 2024

² No mandatory effective date yet determined but available for adoption

The Group is in the process of making an assessment of the impact of these revised IFRSs upon initial application. So far, the Group considers that these standards will not have any significant impact on the Group’s financial statements.

2.4 MATERIAL ACCOUNTING POLICY INFORMATION

Subsidiaries

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).

The financial statements of the subsidiaries are prepared for the same Relevant 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.

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. The results of subsidiaries are included in the Company’s profit or loss to the extent of dividends received and receivable. The Company’s investments in subsidiaries are stated at cost less any impairment losses.

APPENDIX I

ACCOUNTANTS' REPORT

Fair value measurement

The Group measures certain financial instruments at fair value at the end of Relevant Periods. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the Historical Financial Information 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 Historical Financial Information on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Relevant Periods.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than financial assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs. 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 the consolidated statements of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the Relevant Periods as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to the consolidated statements of profit or loss in the period in which it arises.

APPENDIX I

ACCOUNTANTS' REPORT

Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person's family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
 - (iii) the entity and the Group are joint ventures of the same third party;
 - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
 - (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
 - (vi) the entity is controlled or jointly controlled by a person identified in (a);
 - (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
 - (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment other than construction in progress are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to 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:

Machinery and equipment	9.5% to 19%
Furniture, fittings and equipment	9.5% to 19%
Leasehold improvements	The 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 each of the Relevant Periods.

APPENDIX I

ACCOUNTANTS' REPORT

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in the consolidated statements of profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents leasehold improvement under construction, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction and capitalised borrowing costs on related borrowed funds during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

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.

The 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*

The Group recognises right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities 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:

Property, office premises and plant	2 to 5 years
Equipment	3 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 terminating the lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as expenses in the period in which the event or condition that triggers the payment occurs.

APPENDIX I

ACCOUNTANTS' REPORT

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 the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset.

(c) *Short-term leases and leases of low-value assets*

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (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 are 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.

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.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets measured at amortised cost (debt instruments)

Financial assets measured at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised the consolidated statements of 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 statements of financial position at fair value with net changes in fair value recognised in the consolidated statements of profit or loss.

Dividends on equity investments classified as financial assets at fair value through profit or loss are also recognised as other income in the consolidated statements of profit or loss when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably

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 statements of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information. The Group considers that there has been a significant increase in credit risk when contractual payments are more than 30 days past due.

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.

APPENDIX I

ACCOUNTANTS' REPORT

A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets measured 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
- Stage 2 – Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs
- Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade payables, financial liabilities at fair value through profit or loss, financial liabilities included in other payables and accruals, interest-bearing bank and other borrowings and convertible redeemable preferred shares.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost

After initial recognition, interest-bearing loans and borrowings, trade payables, financial liabilities included in other payable and accruals and other 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 the consolidated statements of profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the consolidated statements of profit or loss.

Other financial instruments

If the conversion option of other financial instruments exhibits characteristics of an embedded derivative, it is separated from its liability component. On initial recognition, the derivative component of other financial instruments is measured at fair value and presented as part of financial instruments at FVTPL. Any excess of proceeds over the amount initially recognised as the derivative component is recognised as the liability component. Transaction costs are apportioned between the liability and derivative components of other financial instruments based on the allocation of proceeds to the liability and derivative components when the instruments are initially recognised. The portion of the transaction costs relating to the liability component is recognised initially as part of the liability. The portion relating to the derivative component is recognised immediately in the consolidated statements of profit or loss.

Financial liabilities at fair value through profit or loss

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities held for trading include derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments. Gains or losses on liabilities held for trading are recognised in the consolidated statements of profit or loss.

Financial liabilities such as the convertible redeemable preferred shares 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 fair value through profit or loss are recognised in the consolidated statements of 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 consolidated statements of profit or loss.

The convertible redeemable preferred shares with embedded derivatives whose economic risks and characteristics are not closely related to those of the host contract (the liability component) as a whole are designated as financial liabilities at fair value through profit or loss on initial recognition. Any directly attributable transaction costs are recognised as finance costs the consolidated statements of profit or loss. Subsequent to initial recognition, the convertible redeemable preferred shares are carried at fair value with changes in fair value recognised in the consolidated statements of profit or loss.

Derivative financial instruments

Initial recognition and subsequent measurement

The Group's derivative financial instruments are initially recognised at fair value on the date on which a derivative contract is entered into and are subsequently remeasured at fair value. Derivatives are carried as assets when the fair value is positive and as liabilities when the fair value is negative. Any gains or losses arising from changes in fair value of derivatives are taken directly to the consolidated statements of profit or loss.

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in the consolidated statements of profit or loss.

Treasury shares

Own equity instruments which are reacquired and held by the Company or the Group (treasury shares) are recognised directly in equity at cost. No gain or loss is recognised in the consolidated statements of profit or loss on the purchase, sale, issue or cancellation of the Group's own equity instruments.

APPENDIX I

ACCOUNTANTS' REPORT

Cash and cash equivalents

For the purpose of the consolidated statements of cash flows, cash and cash equivalents comprise cash on hand and demand deposits, and short term highly liquid investments that are readily convertible into known amounts of cash, are subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired, less bank overdrafts which are repayable on demand and form an integral part of the Group's cash management.

For the purpose of the consolidated statements of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

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 each of the Relevant 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 each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and joint ventures, 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 carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries, associates and joint ventures, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each of the Relevant 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 each of the Relevant 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 each of the Relevant Periods.

APPENDIX I

ACCOUNTANTS' REPORT

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 consolidated statements 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 consolidated statements of profit or loss by way of a reduced depreciation charge.

Revenue recognition

Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Share-based payments

The Group operates an employee long term incentive plan for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group's operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments ("equity-settled transactions").

The cost of equity-settled transactions with employees for grants is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 30 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in expenses, 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 of the Relevant Periods 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 profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

APPENDIX I

ACCOUNTANTS’ REPORT

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect of outstanding options is reflected as additional share dilution in the computation of earnings per share.

Other employee benefits

Pension schemes

The employees of the Group’s subsidiaries which operate in Mainland China are required to participate in a central pension scheme operated by the local municipal government. These subsidiaries 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 USA maintains multiple qualified contributory savings plans as allowed under Internal Revenue Code section 401(k) in the USA. These plans are defined contribution plans covering substantially all its qualifying employees 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 subsidiary in the USA with respect to the retirement benefits plans is to make the specified contributions under the plans.

The Group operates a defined contribution Mandatory Provident Fund retirement benefit scheme (the “MPF Scheme”) under the Mandatory Provident Fund Schemes Ordinance for the eligible employees from Hong Kong. Contributions are made based on a percentage of the employees’ basic salaries and are charged to the consolidated statements of profit or loss as they become payable in accordance with the rules of the MPF Scheme. The assets of the MPF Scheme are held separately from those of the Group in an independently administered fund. The Group’s employer contributions vest fully with the employees when contributed into the MPF Scheme.

Borrowing costs

All other borrowing costs are expensed in the period in which they are incurred. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

Foreign currencies

The Historical Financial Information is presented in RMB, which is different from the Company’s functional currency, the United States dollar (“USD”). As the major assets of the Group are derived from operations in Mainland China, RMB is chosen as the presentation currency to present the Historical Financial Information. 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 each of the Relevant Periods. Differences arising on settlement or translation of monetary items are recognised the consolidated statements of 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.

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. As at the end of each of the Relevant Periods, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of each of the Relevant Periods and the consolidated statements of profit or loss are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in the consolidated statements of profit or loss.

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 the consolidated statements of profit or loss as incurred. Expenses incurred on each pipeline to develop new products are capitalised and deferred in accordance with the accounting policy for research and development expenses in note 2.4 to the Historical Financial Information. Determining the amounts to be capitalised requires management to make judgements regarding the technical feasibility of the existing pipelines to be successfully commercialised and to generate economic benefits for the Company. The Group currently expenses all the milestone and upfront payments under the drug licensing agreements.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Relevant 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.

Fair value of financial liabilities at FVTPL

The convertible redeemable preferred shares and the warrants are not traded in an active market and the respective fair value is determined by using valuation techniques. The Group applies back-solve method and discounted cash flow method to determine the underlying equity value of the Company and adopts the equity allocation model to determine the fair value of the convertible redeemable preferred shares and the warrants. Such valuation is based on certain assumptions about discounts for lack of marketability and volatility, which are subject to uncertainty and might materially differ from the actual results. Further details are included in note 24, note 26 and note 34 to the Historical Financial Information.

Recognition of income taxes and deferred tax assets

Determining income tax provision involves judgement 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 judgement is required to assess the probability of future taxable profits. Management's assessment is revised as necessary and additional deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered. Further details are included in note 10 to the Historical Financial Information.

Share-based payments

The Group has set up the employee long term incentive plan for the Company’s directors and the Group’s employees. The fair value of the options is determined by the binomial model at the grant dates.

Estimating the fair value of share-based payment transactions requires the determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires the determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility, employee turnover rate, and dividend yield and making assumptions about them. The assumptions and models used to estimate the fair value of share-based payment transactions are disclosed in note 30.

Impairment of non-financial assets

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the Relevant Periods. Non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present values of those cash flows.

4. 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 senior management for purposes of resource allocation and performance assessment. Therefore, no further operating segment analysis thereof is presented.

Geographical information

Since all of the Group’s non-current assets were located in Mainland China, no geographical segment information in accordance with IFRS 8 *Operating Segments* is presented.

Information about major customers

No revenue was derived during the Relevant Periods and the six months ended 30 June 2022. Therefore, no information about major customer is presented.

APPENDIX I

ACCOUNTANTS’ REPORT

5. OTHER INCOME AND GAINS, AND OTHER EXPENSES

An analysis of other income and gains, and other expenses is as follows:

	Year ended 31 December		Six months ended 30 June	
	2021	2022	2022	2023
	RMB’000	RMB’000	RMB’000	RMB’000
			(unaudited)	
Other income and gains				
Government grants related to expense items*	9,631	7,828	1,011	8,875
Government grants related to assets**	212	186	102	67
Bank interest income	964	3,545	2,290	696
Investment income from short-term time deposits . .	–	7,822	–	12,931
Other investment income from financial assets at				
FVTPL	2,366	1,012	521	120
Foreign exchange gains, net	603	–	–	–
Others	45	188	1	33
	<u>13,821</u>	<u>20,581</u>	<u>3,925</u>	<u>22,722</u>
Other expenses				
Loss on disposal of items of property, plant and				
equipment	(1)	–	–	–
Foreign exchange losses, net	–	(7,518)	(4,381)	(502)
	<u>(1)</u>	<u>(7,518)</u>	<u>(4,381)</u>	<u>(502)</u>

* Government grants related to expense items mainly represent subsidies received from local governments for the purpose of compensation of expenses for research and clinical trial activities, allowance for new drug development and talent funds. The main grantor is the Shenzhen Science and Technology Innovation Committee. Government grants received for which related expenses have not yet been incurred are included in deferred income in the statements of financial position.

** Grants related to assets are credited to deferred income and released to the consolidated statements of profit or loss in equal annual instalments over the estimated useful lives of the related assets.

APPENDIX I

ACCOUNTANTS’ REPORT

6. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	Notes	Year ended 31 December		Six months ended 30 June	
		2021	2022	2022	2023
		RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Depreciation of property, plant and equipment	13	276	409	211	189
Depreciation of right-of-use assets	14	1,314	865	329	628
[REDACTED]		6,054	4,051	3,949	16,315
Transaction costs for preferred shares		16,205	501	–	–
Other professional service fees*		16,525	22,158	15,589	14,553
Lease payments not included in the measurement of lease liabilities		559	1,195	694	835
Foreign exchange differences, net	5	(603)	7,518	4,381	502
Loss on disposal of items of property, plant and equipment	5	1	–	–	–
Other investment income from financial assets at FVTPL	5	(2,366)	(1,012)	(521)	(120)
Fair value losses/(gains):					
Fair value losses/(gains) on convertible redeemable preferred shares	26	93,656	(23,242)	(31,247)	399,635
Fair value losses on financial liabilities at FVTPL	24	4,609	–	–	–
Employee benefit expense (excluding directors’ and chief executive’s remuneration):					
Wages and salaries		17,202	34,337	16,221	23,897
Pension scheme contributions (defined contribution scheme), social welfare and other welfare		2,136	2,850	1,700	2,793
Equity-settled share option expense		2,221	18,818	6,863	18,622
		<u>21,559</u>	<u>56,005</u>	<u>24,784</u>	<u>45,312</u>

* Other professional service fees mainly consisted of business consulting fees and other service fees paid to third-party professional service providers.

7. FINANCE COSTS

An analysis of finance costs is as follows:

	Notes	Year ended 31 December		Six months ended 30 June	
		2021	2022	2022	2023
		RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Interest on interest-bearing bank borrowings		309	303	164	137
Interest on other borrowings	23	4,152	–	–	–
Interest on lease liabilities	14	67	123	53	64
		<u>4,528</u>	<u>426</u>	<u>217</u>	<u>201</u>

APPENDIX I

ACCOUNTANTS’ REPORT

8. DIRECTORS’ REMUNERATION

Dr. Liu Liping was appointed as an executive director and the chief executive of the Company since 28 February 2018.

Ms. Yu Meng was appointed as an executive director of the Company on 11 May 2023.

Mr. Zhu Xun was appointed as a non-executive director of the Company on 30 November 2020.

Mr. Li Li was appointed as a non-executive director of the Company on 16 October 2018.

Mr. Yang Feng was appointed as a non-executive director of the Company on 4 September 2020 and resigned on 11 May 2023 for the reason that he would like to devote more time to his investment businesses.

Mr. Li Xiaoguang was appointed as a non-executive director of the Company on 4 September 2020 and resigned on 16 November 2021 for the reason that he would like to devote more time to his investment businesses.

Mr. Ma Lixiong was appointed as a non-executive director of the Company on 16 November 2021.

Mr. Jiang Feng was appointed as a non-executive director of the Company on 16 November 2022.

Certain of the directors received remuneration from the subsidiaries now comprising the Group for their appointment as the executive director, non-executive directors and chief executive of these subsidiaries. The remuneration of each director is set out below:

	Year ended 31 December		Six months ended 30 June	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Fees	-	-	-	-
Other emoluments:				
Salaries, bonuses, allowances and benefits in kind	3,723	4,051	1,986	2,699
Equity-settled share option expense	5,083	6,804	3,403	9,823
Pension scheme contributions	36	37	20	74
	<u>8,842</u>	<u>10,892</u>	<u>5,409</u>	<u>12,596</u>

During the Relevant Periods and the six months ended 30 June 2022, certain directors were granted share options in respect of their services to the Group under the share option scheme of the Company, further details of which are set out in note 30 to the Historical Financial Information. The fair values of such options, which have been recognised in the consolidated statements of profit or loss over the vesting periods, were determined as at the dates of grant and the amounts included in the Historical Financial Information for the Relevant Periods and the six months ended 30 June 2022 are included in the above directors’ and chief executive’s remuneration disclosures.

APPENDIX I

ACCOUNTANTS’ REPORT

Year ended 31 December 2021	Salaries, bonuses, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Equity-settled share option expense	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Executive director:					
Dr. Liu Liping	3,269	–	36	3,854	7,159
Non-executive directors:					
Dr. Zhu Xun	454	–	–	998	1,452
Mr. Li Li	–	–	–	–	–
Mr. Yang Feng	–	–	–	229	229
Mr. Li Xiaoguang ...	–	–	–	–	–
Mr. Ma Lixiong	–	–	–	2	2
	454	–	–	1,229	1,683
Year ended 31 December 2022					
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Executive director:					
Dr. Liu Liping	3,578	–	37	3,850	7,465
Non-executive directors:					
Dr. Zhu Xun	473	–	–	1,721	2,194
Mr. Li Li	–	–	–	–	–
Mr. Yang Feng	–	–	–	395	395
Mr. Ma Lixiong	–	–	–	838	838
Mr. Jiang Feng	–	–	–	–	–
	473	–	–	2,954	3,427

APPENDIX I

ACCOUNTANTS’ REPORT

Six months ended 30 June 2022	Salaries, bonuses, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Equity-settled share option expense	Total
(unaudited)	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Executive director:					
Dr. Liu Liping	1,758	–	20	1,930	3,708
Non-executive directors:					
Dr. Zhu Xun	228	–	–	858	1,086
Mr. Li Li	–	–	–	–	–
Mr. Yang Feng	–	–	–	197	197
Mr. Ma Lixiong	–	–	–	418	418
	228	–	–	1,473	1,701
Six months ended 30 June 2023					
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Executive directors:					
Dr. Liu Liping	1,822	–	19	3,994	5,835
Ms. Yu Meng	632	–	55	2,887	3,574
	2,454	–	74	6,881	9,409
Non-executive directors:					
Dr. Zhu Xun	245	–	–	574	819
Mr. Li Li	–	–	–	–	–
Mr. Yang Feng	–	–	–	87	87
Mr. Ma Lixiong	–	–	–	2,281	2,281
Mr. Jiang Feng	–	–	–	–	–
	245	–	–	2,942	3,187

There was no arrangement under which a director waived or agreed to waive any remuneration during the Relevant Periods and the six months ended 30 June 2022.

APPENDIX I

ACCOUNTANTS’ REPORT

9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees included one director during 2021, 2022 and the six months ended 30 June 2022, and two directors during the six months ended 30 June 2023, details of whose remuneration are set out in note 8 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		Six months ended 30 June	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Salaries, bonuses, allowances, and benefits in kind	6,231	8,067	4,812	3,241
Equity-settled share option expenses	1,239	9,796	3,637	9,884
Pension scheme contributions	299	427	153	166
	<u>7,769</u>	<u>18,290</u>	<u>8,602</u>	<u>13,291</u>

The numbers of non-director highest paid employees whose remuneration fell within the following bands are as follows:

	Year ended 31 December		Six months ended 30 June	
	2021	2022	2022	2023
			(unaudited)	
Nil to HKD1,000,000	–	–	–	–
HKD1,000,001 to HKD1,500,000	2	–	–	–
HKD1,500,001 to HKD2,000,000	–	–	1	–
HKD2,000,001 to HKD2,500,000	1	–	–	–
HKD2,500,001 to HKD3,000,000	–	–	2	–
HKD3,000,001 to HKD3,500,000	–	–	1	–
HKD3,500,001 to HKD4,000,000	–	1	–	1
HKD4,000,001 to HKD4,500,000	–	2	–	1
HKD4,500,001 to HKD5,000,000	1	–	–	–
HKD7,500,001 to HKD8,000,000	–	–	–	1
HKD8,000,001 to HKD8,500,000	–	1	–	–
	<u>4</u>	<u>4</u>	<u>4</u>	<u>3</u>

During the Relevant Periods and the six months ended 30 June 2022, share options were granted to four non-director highest paid employees in respect of their services to the Group, further details of which are included in the disclosures in note 30 to the Historical Financial Information. The fair value of such options, which has been recognised in the consolidated statements of 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 and the six months ended 30 June 2022 is included in the above non-director highest paid employees’ remuneration disclosures.

APPENDIX I

ACCOUNTANTS’ REPORT

10. 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.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

British Virgin Islands

Under the current laws of the British Virgin Islands (“BVI”), the subsidiary incorporated in the BVI is not subject to tax on income or capital gains. In addition, upon payments of dividends by the subsidiary to its shareholders, no BVI withholding tax is imposed.

Hong Kong

The subsidiary incorporated in Hong Kong was subject to income tax at the rate of 8.25% on the estimated assessable profits arising in Hong Kong during the Relevant Periods and the six months ended 30 June 2022.

Mainland China

No provision for Mainland China income tax pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”) has been made as the Group’s subsidiaries which operate in Mainland China are in loss position and have no estimated taxable profits.

Shenzhen HighTide was approved as a high technology enterprise under the relevant tax rules and regulations in December 2019, and accordingly, was entitled to a reduced preferential CIT rate of 15% from 2019 to 2021. This qualification is subject to review by the relevant tax authority in the PRC for every three years. The renewed qualification was obtained in December 2022 and Shenzhen HighTide is entitled a preferential income tax rate from 2022 to 2024.

JSK Consumer Healthcare Ltd, Shanghai HighTide Biopharmaceutical Ltd., Shanghai Fusion Therapeutics Inc. and Nanchang Fusion Therapeutics Inc. have met the requirement under the relevant tax rules and regulations for small and low-profit enterprises, and accordingly, were subject to a reduced preferential CIT rate of 20%, and the portion of the annual taxable income not more than RMB1,000,000 was entitled to be included in the actual taxable income at reduced rates of 12.50% in 2021, 2022 and 25% in the six months ended 30 June 2023, while the portion of the annual taxable income exceeding RMB1,000,000 but not exceeding RMB3,000,000 was entitled to be included in the actual taxable income at reduced rates of 50% in 2021 and, 25% in 2022 and the six months ended 30 June 2023.

Australia

The subsidiary incorporated in Australia was subject to income tax at the rate of 26% on the estimated assessable profits arising in Australia for the six months ended 30 June 2021 and it is subject to income tax at the rate of 25% afterwards.

USA

The subsidiary incorporated in Maryland, the USA is subject to statutory United States federal corporate income tax at a rate of 21%. In addition, it is also subject to the state income tax in Maryland at a rate of 8.25% during the Relevant Periods and the six months ended 30 June 2022. Other states including California, Florida and New Jersey also impose state income tax on the subsidiary to the extent that a sufficient nexus, or taxable connection, exists between the subsidiary and the respective states. The subsidiary was subject to the states income tax in California at a rate of 8.84%, in Florida at a rate of 5.50% and in New Jersey at a rate of 7.50% during the Relevant Periods and the six months ended 30 June 2022.

APPENDIX I

ACCOUNTANTS’ REPORT

The income tax expense of the Group during the Relevant Periods and the six months ended 30 June 2022 is analysed as follows:

	Year ended 31 December		Six months ended 30 June	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Current tax:				
Charge for the year/period	100	32	72	26
Deferred tax (<i>Note 27</i>)	(4)	–	–	–
Total tax expense for the year/period	<u>96</u>	<u>32</u>	<u>72</u>	<u>26</u>

A reconciliation of the tax expense applicable to loss before tax at the statutory rate for the jurisdictions in which the Company and the majority of its subsidiaries are domiciled to the tax expense at the effective tax rates, is as follows:

	Year ended 31 December		Six months ended 30 June	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Loss before tax	(221,049)	(190,205)	(74,105)	(549,718)
Tax at the applicable tax rate (25%)	(55,262)	(47,551)	(18,526)	(137,430)
Different tax rates enacted by local authorities	14,474	23,233	8,287	118,966
Additional deductible allowance for qualified research and development costs	(3,621)	(12,287)	(4,888)	(5,117)
Income not subject to tax	(60)	(12)	(11)	(2)
Expenses not deductible for tax	53	619	538	3,175
Tax losses not recognised	44,512	36,030	14,672	20,434
Tax charge at the Group’s effective rates	<u>96</u>	<u>32</u>	<u>72</u>	<u>26</u>

Deferred tax assets have not been recognised in respect of the following items:

	As at 31 December		As at
	2021	2022	30 June
	RMB'000	RMB'000	2023
			RMB'000
Unused tax losses	<u>136,302</u>	<u>408,706</u>	<u>555,955</u>

The Group has accumulated tax losses in Mainland China of RMB131,029,000, RMB406,439,000, and RMB551,964,000 as at 31 December 2021, 31 December 2022, and 30 June 2023, respectively, that will expire in one to ten years for offsetting against future taxable profits of the companies in which the losses arose.

The Group also has accumulated tax losses in Australia of RMB5,273,000, nil, and nil as at 31 December 2021, 31 December 2022, and 30 June 2023, respectively, that will be carried forward indefinitely for offsetting against future taxable profits of the company in which the losses arose.

The Group also has accumulated tax losses in Hong Kong of nil, RMB2,267,000, and RMB3,991,000 as at 31 December 2021, 31 December 2022, and 30 June 2023, respectively, that will be carried forward indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

APPENDIX I

ACCOUNTANTS’ REPORT

13. PROPERTY, PLANT AND EQUIPMENT

	Machinery and equipment	Furniture, fittings and equipment	Leasehold improvements	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2021				
At 1 January 2021:				
Cost	3,133	538	–	3,671
Accumulated depreciation	(2,356)	(401)	–	(2,757)
Net carrying amount	<u>777</u>	<u>137</u>	<u>–</u>	<u>914</u>
At 1 January 2021, net of accumulated depreciation				
depreciation	777	137	–	914
Additions	1,104	376	265	1,745
Disposals	–	(4)	–	(4)
Depreciation provided during the year	(181)	(67)	(28)	(276)
At 31 December 2021, net of accumulated depreciation	<u>1,700</u>	<u>442</u>	<u>237</u>	<u>2,379</u>
At 31 December 2021:				
Cost	4,237	872	265	5,374
Accumulated depreciation	(2,537)	(430)	(28)	(2,995)
Net carrying amount	<u>1,700</u>	<u>442</u>	<u>237</u>	<u>2,379</u>
31 December 2022				
At 1 January 2022:				
Cost	4,237	872	265	5,374
Accumulated depreciation	(2,537)	(430)	(28)	(2,995)
Net carrying amount	<u>1,700</u>	<u>442</u>	<u>237</u>	<u>2,379</u>
At 1 January 2022, net of accumulated depreciation				
depreciation	1,700	442	237	2,379
Additions	–	183	–	183
Depreciation provided during the year	(236)	(117)	(56)	(409)
At 31 December 2022, net of accumulated depreciation	<u>1,464</u>	<u>508</u>	<u>181</u>	<u>2,153</u>
At 31 December 2022:				
Cost	4,237	1,055	265	5,557
Accumulated depreciation	(2,773)	(547)	(84)	(3,404)
Net carrying amount	<u>1,464</u>	<u>508</u>	<u>181</u>	<u>2,153</u>

APPENDIX I

ACCOUNTANTS' REPORT

	Machinery and equipment	Furniture, fittings and equipment	Leasehold improvements	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
30 June 2023				
At 1 January 2023:				
Cost	4,237	1,055	265	5,557
Accumulated depreciation	(2,773)	(547)	(84)	(3,404)
Net carrying amount	<u>1,464</u>	<u>508</u>	<u>181</u>	<u>2,153</u>
At 1 January 2023, net of accumulated				
depreciation	1,464	508	181	2,153
Additions	8	64	–	72
Depreciation provided during the period ..	(96)	(65)	(28)	(189)
At 30 June 2023, net of accumulated				
depreciation	<u>1,376</u>	<u>507</u>	<u>153</u>	<u>2,036</u>
At 30 June 2023:				
Cost	4,245	1,119	265	5,629
Accumulated depreciation	(2,869)	(612)	(112)	(3,593)
Net carrying amount	<u>1,376</u>	<u>507</u>	<u>153</u>	<u>2,036</u>

As at 31 December 2021 and 2022 and 30 June 2023, there were no pledged property, plant and equipment.

APPENDIX I

ACCOUNTANTS’ REPORT

14. LEASES

The Group as a lessee

The Group has lease contracts for various items of properties and equipment used in its operations. Leases of properties generally have lease terms of two to five years and leases of equipment generally have lease terms of three 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:

	Property, office premises and plant	Equipment	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 31 December 2021			
As at 1 January 2021	1,125	–	1,125
Additions	1,260	–	1,260
Depreciation charge	(1,314)	–	(1,314)
	<u>1,071</u>	<u>–</u>	<u>1,071</u>
As at 31 December 2021	<u>1,071</u>	<u>–</u>	<u>1,071</u>
As at 31 December 2022			
As at 1 January 2022	1,071	–	1,071
Additions	–	2,447	2,447
Depreciation charge	(253)	(612)	(865)
	<u>818</u>	<u>1,835</u>	<u>2,653</u>
As at 31 December 2022	<u>818</u>	<u>1,835</u>	<u>2,653</u>
As at 30 June 2023			
As at 1 January 2023	818	1,835	2,653
Additions	1,051	–	1,051
Depreciation charge	(224)	(404)	(628)
Exchange realignment	(41)	–	(41)
	<u>1,604</u>	<u>1,431</u>	<u>3,035</u>
As at 30 June 2023	<u>1,604</u>	<u>1,431</u>	<u>3,035</u>

APPENDIX I

ACCOUNTANTS’ REPORT

(b) *Lease liabilities*

The carrying amounts of lease liabilities and the movements during the Relevant Periods are as follows:

	As at 31 December		As at
	2021	2022	30 June
	RMB'000	RMB'000	2023
			RMB'000
Carrying amount at 1 January	1,096	1,153	2,624
New leases	1,260	2,447	1,051
Accretion of interest recognised during the year/period	67	123	64
Covid-19-related rent concessions from lessors ..	–	(112)	–
Lease payment	(1,270)	(987)	(502)
Exchange realignment	–	–	(42)
	<u>1,153</u>	<u>2,624</u>	<u>3,195</u>
Carrying amount at 31 December/30 June			
Analysed into:			
Current portion	251	1,111	1,646
Non-current portion	902	1,513	1,549
	<u>1,153</u>	<u>2,624</u>	<u>3,195</u>

(c) The amounts recognised in the consolidated statements of profit or loss in relation to leases are as follows:

	Year ended 31 December		Six months ended 30 June	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Interest on lease liabilities	67	123	53	64
Depreciation charge of right-of-use assets	1,314	865	329	628
Expenses relating to short-term and low-value leases*	559	1,307	769	835
Covid-19-related rent concessions from lessors	–	(112)	(75)	–
	<u>1,940</u>	<u>2,183</u>	<u>1,076</u>	<u>1,527</u>
Total amount recognised in the consolidated statements of profit or loss				

* Included in “Administrative expenses” and “Research and development costs” in the consolidated statements of profit or loss.

(d) The total cash outflow for leases included in the consolidated statements of cash flows is disclosed in note 31(c) to the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

15. OTHER NON-CURRENT ASSETS

Group

	As at 31 December		As at
	2021	2022	30 June
	RMB’000	RMB’000	2023
Rental deposits	–	–	192

16. INTERESTS IN SUBSIDIARIES

Company

	As at 31 December		As at
	2021	2022	30 June
	RMB’000	RMB’000	2023
Cost of investments in subsidiaries	240,750	399,574	561,884
Equity-settled share-based payment*	2,221	21,039	42,549
	<u>242,971</u>	<u>420,613</u>	<u>604,433</u>

* The amount represents share-based payment expenses arising from the grant of restricted shares in the Company to employees of the subsidiaries (Note 30) in exchange for their services to these subsidiaries, which were deemed to be investments made by the Company in these subsidiaries.

17. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

Group

	As at 31 December		As at
	2021	2022	30 June
	RMB’000	RMB’000	2023
Prepayments	3,854	5,728	11,066
Input value-added tax	3,367	1,870	4,544
Deposits	497	404	716
Other receivables	275	469	565
Other current assets	1,899	2,350	3,508
	<u>9,892</u>	<u>10,821</u>	<u>20,399</u>

APPENDIX I

ACCOUNTANTS’ REPORT

Company

	As at 31 December		As at
	2021	2022	30 June
	RMB'000	RMB'000	2023
Amounts due from related parties	295,280	195,428	263,599
Other current assets	1,899	2,350	5,676
	<u>297,179</u>	<u>197,778</u>	<u>269,275</u>

Other receivables had no historical default. The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. In calculating the expected credit loss rate, the Group considers the historical loss rate and adjusts for forward-looking factors and information. As at 31 December 2021 and 2022 and 30 June 2023, the expected credit loss rates and the loss allowances were assessed to be minimal.

The Group seeks to maintain strict control over its outstanding receivables to minimise credit risk. Long ageing balances are reviewed regularly by senior management. In view of the fact that deposits and other receivables relate to diversified counterparties, there is no significant concentration of credit risk. The Group does not hold any other credit enhancements over its deposits and other receivable balances.

18. SHORT-TERM TIME DEPOSITS

Group

	As at 31 December		As at
	2021	2022	30 June
	RMB'000	RMB'000	2023
Short-term time deposits	–	427,857	–
	<u>–</u>	<u>427,857</u>	<u>–</u>

Company

	As at 31 December		As at
	2021	2022	30 June
	RMB'000	RMB'000	2023
Short-term time deposits	–	427,857	–
	<u>–</u>	<u>427,857</u>	<u>–</u>

As at 31 December 2022, short-term time deposits were made for varying periods of between one week and six months depending on the immediate cash requirements of the Company, and earned interest at the respective short term period rates of these financial assets. As at 31 December 2022, the deposits were deposited with creditworthy banks with no recent history of default through a reputable financial institution based on an investment agreement entered into between the Company and the financial institution.

In calculating the expected credit loss rate, the Group considers the historical loss rate and adjusts for forward-looking factors and information. As at 31 December 2022, the expected credit loss rate and the loss allowances for the short-term time deposits were assessed to be minimal.

APPENDIX I

ACCOUNTANTS’ REPORT

19. CASH AND BANK BALANCES

Group

	As at 31 December		As at
	2021	2022	30 June
	RMB’000	RMB’000	2023
			RMB’000
Cash and bank balances	765,290	412,340	732,920
Less:			
Bank deposits over three months	–	–	(170,498)
Restricted cash (i)	–	(139,293)	(144,524)
Cash and cash equivalents	<u>765,290</u>	<u>273,047</u>	<u>417,898</u>
Denominated in:			
RMB	72,700	83,832	158,986
USD	692,037	328,207	573,769
AUD	553	283	56
HKD	–	18	109
Cash and bank balances	<u>765,290</u>	<u>412,340</u>	<u>732,920</u>

Company

	As at 31 December		As at
	2021	2022	30 June
	RMB’000	RMB’000	2023
			RMB’000
Cash and bank balances	578,146	360,284	562,089
Less:			
Bank deposits over three months	–	–	(170,498)
Restricted cash (i)	–	(139,293)	(144,524)
Cash and cash equivalents	<u>578,146</u>	<u>220,991</u>	<u>247,067</u>
Denominated in:			
RMB	–	40,613	5,595
USD	578,146	319,671	556,494
Cash and bank balances	<u>578,146</u>	<u>360,284</u>	<u>562,089</u>

Note (i) This represents the proceeds from the issuance of the convertible redeemable preferred shares, which have been placed in a restricted bank account to be used for core research and development activities and for the redemption of the convertible redeemable preferred shares. None of the amounts are impaired.

The RMB is not freely convertible into other currencies, however, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, and Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

APPENDIX I

ACCOUNTANTS’ REPORT

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short term time deposits are made for varying periods of between one day and six months depending on the immediate cash requirements of the Group, and earn interest at the respective short term time deposits rates. The bank balances and restricted cash are deposited with creditworthy banks with no recent history of default.

20. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December		As at
	2021	2022	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within one year	6,091	21,699	29,752

The trade payables are non-interest-bearing and are normally settled within one month after the receipt of the invoice.

21. OTHER PAYABLES AND ACCRUALS

Group

	As at 31 December		As at
	2021	2022	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Deposits received from vendors	9	12	12
Payroll payables	5,263	9,166	7,393
Other tax payables	231	311	302
Professional service fees	9,484	14,384	12,652
Government grants repayable	–	4,642	1,400
Others	205	232	597
	<u>15,192</u>	<u>28,747</u>	<u>22,356</u>

Company

	As at 31 December		As at
	2021	2022	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Professional service fees	7,302	13,999	9,710
Amounts due to related parties	–	9,196	–
Payroll payable	1,292	1,561	1,049
Others	191	68	12
	<u>8,785</u>	<u>24,824</u>	<u>10,771</u>

APPENDIX I

ACCOUNTANTS’ REPORT

* Certain of the Group’s bank loans are guaranteed by third parties as follows:

- (i) Shenzhen Hi-tech Investment and Financing Guarantee Co., Ltd., a third party, has guaranteed a bank loan of RMB3,500,000 as at 31 December 2021, a bank loan of RMB3,840,000 as at 31 December 2022 and a bank loan of RMB2,880,000 as at 30 June 2023;
- (ii) Shenzhen SME Financing Guarantee Co., Ltd., a third party, has guaranteed a bank loan of RMB3,500,000 as at 31 December 2021.

All bank loans are denominated in RMB.

23. OTHER BORROWINGS

In September 2020, Shenzhen HighTide entered into loan agreements with certain independent investors (the “Investors”) to obtain loans with an aggregate principal amount of RMB184,515,000 (approximately USD26,616,000) at a simple interest rate of 6% per annum. The contractual maturity of the loans was six months. RMB184,515,000 of the principal amount was received between September 2020 and December 2020. Meanwhile, the Company issued certain warrants (the “Series B+ Warrants”) to the Investors for no consideration. The warrants allow the holders to purchase 5,650,954 Series B+ Preferred Shares at USD4.71 per share for USD26,616,000. Pursuant to the loan agreements, Shenzhen HighTide will repay the loans to the Investors to enable them to exercise the Series B+ Warrants to subscribe for 5,650,954 Series B+ Preferred Shares in the Company for USD26,616,000 upon the completion of the required outbound direct investment (“ODI”) filing with the relevant Chinese government authorities. The Investors have agreed that Shenzhen HighTide’s obligation to repay the accrued interest on these loans will be automatically waived upon exercise of the Series B+ Warrants.

In the first half year of 2021, the Investors exercised all the warrants as agreed and Shenzhen HighTide repaid the loans.

The loan component was measured at amortised cost over the period from the issuance date to the maturity date using the effective interest rate method. The derivative component was classified as financial liabilities at FVTPL and the movements are presented in note 24.

24. FINANCIAL LIABILITIES AT FVTPL

The movements of financial liabilities at FVTPL during the Relevant Periods are as follows:

	Financial liabilities at FVTPL
	<i>RMB’000</i>
As at 1 January 2021	5,435
Fair value changes	4,609
Exercise of warrants	(10,044)
	<hr/>
As at 31 December 2021	–
	<hr/> <hr/>

The Group has used the discounted cash flow method to determine the underlying share value of the Company and adopted the equity allocation model to determine the fair value of the financial instrument as of 1 January 2021.

APPENDIX I

ACCOUNTANTS’ REPORT

25. DEFERRED INCOME

	As at 31 December		As at 30 June
	2021	2022	2023
	RMB'000	RMB'000	RMB'000
As at 1 January	18,915	15,555	5,119
Grants received	3,415	750	–
Grants repayable	–	(4,642)	(326)
Amortisation	(6,775)	(6,544)	(2,741)
As at 31 December/30 June	<u>15,555</u>	<u>5,119</u>	<u>2,052</u>

The Group’s deferred government grants represented government grants received for projects and are credited to the consolidated statements of profit or loss on a straight-line basis over the expected lives of the related assets or recognised as income on a systematic basis over the periods that the costs, for which they are intended to compensate, are expensed.

26. CONVERTIBLE REDEEMABLE PREFERRED SHARES

	As at 31 December		As at 30 June
	2021	2022	2023
	RMB'000	RMB'000	RMB'000
Series B+ convertible redeemable preferred shares (note (iii)) ..	496,438	540,553	750,454
Series C convertible redeemable preferred shares (note (iv)) . . .	509,465	534,202	722,065
Series C+ convertible redeemable preferred shares (note (v)) . . .	–	185,258	249,134
As at 31 December/30 June	<u>1,005,903</u>	<u>1,260,013</u>	<u>1,721,653</u>
Analysed into:			
Current portion	–	1,260,013	249,134
Non-current portion	<u>1,005,903</u>	<u>–</u>	<u>1,472,519</u>

(i) Series A Convertible Preferred Shares

In June 2016 and December 2016, Shenzhen HighTide raised up to RMB100,000,000 from certain onshore investors and one existing shareholder (“Series A Investors”).

On 28 February 2018, the Company was incorporated in the Cayman Islands, and on 9 April 2018 HK HighTide was incorporated. Dr. Liu Liping, Shenzhen Hepalink Pharmaceutical Group Co., Ltd., and other Series A Investors then transferred their respective interests in Shenzhen HighTide to HK HighTide for a consideration of RMB130,640,000 (approximately USD19,339,000) and subscribed for 31,500,000 ordinary shares and 6,300,000 Series A convertible preferred shares (the “Series A Convertible Preferred Shares”) in the Company for the same amount of USD19,339,000.

(ii) Series B1 and B2 Convertible Preferred Shares

In October 2018 and February 2019, the Company issued 3,033,334 Series B1 Convertible Preferred Shares (the “Series B1 Convertible Preferred Shares”) to certain independent investors at USD4.2857 per share for a total consideration of USD13,000,000. The Company received proceeds of USD13,000,000 (approximately RMB89,876,000) from the issuance of the Series B1 Preferred Shares in 2018.

APPENDIX I

ACCOUNTANTS’ REPORT

In February 2019, the Company issued 2,100,000 Series B2 Convertible Preferred Shares (the “Series B2 Convertible Preferred Shares”, together with the Series B1 Convertible Preferred Shares, the “Series B Preferred Shares”) to certain independent investors at USD4.2857 per share for total consideration of USD9,000,000. The Company received proceeds of USD9,000,000 (approximately RMB60,443,000) from the issuance of the Series B2 Preferred Shares in 2019.

(iii) Series B+ Convertible Redeemable Preferred Shares

In September 2020 and April 2021, the Company issued 6,815,286 and 212,314 Series B+ Convertible Redeemable Preferred Shares (the “Series B+ Convertible Redeemable Preferred Shares”) to certain independent investors at USD4.71 per share for total consideration of USD32,100,000 and USD1,000,000, respectively. The Company received proceeds of USD32,100,000 and USD1,000,000 (approximately RMB217,995,000 and RMB6,545,000) from the issuance of Series B+ Convertible Redeemable Preferred Shares in 2020 and 2021, respectively. In April and May 2021, the holders of the Series B+ Warrants exercised the warrants and subscribed for 5,650,954 shares of Series B+ Convertible Redeemable Preferred Shares of the Company for USD26,616,000. The Company received proceeds of USD26,616,000 (approximately RMB173,328,000) from the issuance of the Series B+ Convertible Preferred Shares in April and May 2021 upon the exercise of the Series B+ Warrants.

(iv) Series C Convertible Redeemable Preferred Shares

In October 2021 and November 2021, the Company issued 7,618,932 and 4,571,359 Series C Convertible Redeemable Preferred Shares (the “Series C Convertible Redeemable Preferred Shares”) to certain independent investors at USD6.5626 per share for total considerations of USD50,000,000 and USD30,000,000, respectively. The Company received proceeds of USD50,000,000 and USD30,000,000 (approximately RMB319,535,000 and RMB191,772,000) from the issuance of the Series C Convertible Redeemable Preferred Shares in October 2021 and November 2021, respectively.

(v) Series C+ Convertible Redeemable Preferred Shares

In November 2022 and December 2022, the Company issued 985,972 and 2,987,795 Series C+ Convertible Redeemable Preferred Shares (the “Series C+ Convertible Redeemable Preferred Shares”) at USD6.6939 per share to certain independent investors for total consideration of USD6,600,000 and USD20,000,000, respectively. The Company received proceeds of RMB45,577,000 and USD20,000,000 (approximately RMB186,419,000 in total) from the issuance of the Series C+ Convertible Redeemable Preferred Shares in November 2022 and December 2022, respectively.

According to the original and amended Memorandum and Articles of Association (“MOA”) upon the issuance of each series of Convertible Preferred Shares, the Group classified the Series A, B1 and B2 Convertible Preferred Shares as equity and designated the Series B+, C and C+ Convertible Redeemable Preference Shares as financial liabilities measured at fair value through profit or loss. According to MOA of the Company in November 2022, the key terms of the Series A, B1, and B2 Convertible Preferred Shares, Series B+ Convertible Redeemable Preferred Shares, Series C Convertible Redeemable Preferred Shares and Series C+ Convertible Redeemable Preferred Shares (collectively, the “Preferred Shares”) are as follows:

(a) Liquidation preferences

The shareholders of the Series B1 and B2 Convertible Preferred Shares, Series B+ Convertible Redeemable Preferred Shares, Series C Convertible Redeemable Preferred Shares and Series C+ Convertible Redeemable Preferred Shares are entitled to require the Company to initiate the dissolution process and liquidate if any of the following occurs (the “Liquidation Event”): (i) liquidation, dissolution or winding up of the Company by any reason, (ii) any consolidation, amalgamation, scheme of arrangement or merger (including without limitation the statutory merger) of the Company or any subsidiaries (the “Group Company”) with or into any other person or any other corporate reorganisation in which the members of the Company or the Group Company immediately prior to such consolidation, amalgamation, merger, scheme of arrangement or reorganisation own less than a majority of the Company’s or the Group Company’s voting power immediately after such consolidation, merger, amalgamation, scheme of arrangement or reorganisation or any transaction or series of related transactions to which the Company or any

APPENDIX I

ACCOUNTANTS' REPORT

Group Company is a party and in which at least a majority of the Company's or such Group Company's voting power is transferred; (iii) a sale, transfer, lease, exclusive licence or other disposition, in a single transaction or series of related transactions, of all or substantially all of the assets or the intellectual property of the Company and the Group Companies, taken as a whole; or (iv) a sale of a majority of the outstanding voting securities of the Company.

In case of a Liquidation Event, the distributable assets shall be distributed in the following order: (a) Pay the liquidation fee, the salary of the employees, social insurance premiums and the statutory compensation according to the relevant laws and regulations and pay the due and outstanding taxes (the "Statutory Fee"); (b) After payment in full of the Statutory Fee by the Company, the holders of the Series C+ Preferred Share shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of the Ordinary Shares, Series A, B1 and B2 Convertible Preferred Shares and Series B+ Preferred Shares and Series C Preferred Shares or any other class or series of shares by reason of their ownership of such shares, with respect to each Series C+ Preferred Share (the "Series C+ Preference Amount"): an amount equal to $IP \times (1.08)^N$, where IP is the Original Issue Price of such Share and N is (i) the number of calendar days between the Original Issue Date of such Share and the date of payment in full of the Liquidation Preference Amount in respect of such Share, divided by (ii) three hundred and sixty five (365) days; and plus an amount equal to all accrued or declared but unpaid dividends on such Series C+ Preferred Share.

After distribution or payment in full of the Series C+ Preference Amount for all the Series C+ Preferred Shares, the holders of the Series C Preferred Share shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of the Ordinary Shares, Series A Preferred Shares and Series B1 Preferred Shares, Series B2 Preferred Shares and Series B+ Preferred Shares or any other class or series of shares by reason of their ownership of such shares, with respect to each Series C Convertible Redeemable Preferred Share (the "Series C Preference Amount"): an amount equal to $IP \times (1.08)^N$, where IP is the Original Issue Price of such Share and N is (i) the number of calendar days between the Original Issue Date of such Share and the date of payment in full of the Liquidation Preference Amount in respect of such Share, divided by (ii) three hundred and sixty five (365) days; and plus an amount equal to all accrued or declared but unpaid dividends on such Series C Preferred Share.

After distribution or payment in full of the Series C+ Preference Amount for all the Series C+ Preferred Shares and Series C Preference Amount for all the Series C Preferred Shares, the holders of the Series B+ Preferred Share shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of the Ordinary Shares, Series A Preferred Shares and Series B1 Preferred Shares, Series B2 Preferred Shares or any other class or series of shares by reason of their ownership of such shares, with respect to each Series B+ Convertible Redeemable Preferred Share (the "Series B+ Preference Amount"): an amount equal to $IP \times (1.08)^N$, where IP is the Original Issue Price of such Share and N is (i) the number of calendar days between the Original Issue Date of such Share and the date of payment in full of the Liquidation Preference Amount in respect of such Share, divided by (ii) three hundred and sixty five (365) days; and plus an amount equal to all accrued or declared but unpaid dividends on such Series B+ Preferred Share.

After distribution or payment in full of the Series C+ Preference Amount for all the Series C+ Preferred Shares, Series C Preference Amount for all the Series C Preferred Shares and the Series B+ Preference Amount for all the Series B+ Preferred Shares and before any distribution or payment shall be made to the holders of Ordinary Shares and Series A Preferred Shares, or any other class or series of shares by reason of their ownership of such shares, the holders of the Series B1 Preferred Shares and the holders of Series B2 Preferred Shares shall be entitled to receive, with respect to each Series B1 Preferred Share and/or Series B2 Preferred Share (the "Series B1/B2 Preference Amount"): an amount equal to $IP \times (1.06)^N$, but in no event higher than 130% of the Series B Issue Price, where IP is the Original Issue Price of such Share and N is (i) the number of calendar days between the Original Issue Date of such Share and the date of payment in full of the Liquidation Preference Amount in respect of such Share, divided by (ii) three hundred and sixty five (365) days.

APPENDIX I

ACCOUNTANTS' REPORT

After paying in full the Series C+ Preference Amount, Series C Preference Amount, Series B+ Preference Amount and the Series B1/B2 Preference Amount due, the remaining assets and funds of the Company available for distribution to Shareholders, if any, shall be distributed to the holders of the Ordinary Shares, the Series A Convertible Preferred Shares and Series B+ Convertible Redeemable Preferred Shares and Series C+ Preferred Shares on a pro rata basis, based on the number of Ordinary Shares then held by each holder (assuming all Series A Convertible Preferred Shares and Series B+ Convertible Redeemable Preferred Shares and Series C+ Preferred Shares held by such holders held by such holders have been converted into Ordinary Shares at the then effective Conversion Price).

(b) Conversion rights

Each Preferred Share shall automatically be converted into Ordinary Share, at the then applicable Conversion Price (i) immediately prior to the closing of a [REDACTED], or (ii) upon the prior written approval of the holders of at least two thirds of the Preferred Shares on an as-converted basis.

Unless converted automatically, each holder of the Preferred Shares shall have the right, at such holder's sole discretion, to convert all or any portion of the Preferred Shares into such number of fully paid and non-assessable Ordinary Shares at any time. The conversion rate for Preferred Shares shall be determined by dividing 100% of the Preferred Share Issue Price by the conversion price then in effect at the date of the conversion. The initial conversion price will be the Preferred Share Issue Price, which will be subject to adjustments to reflect share dividends, share splits and other events, as provided below (the "Conversion Price"):

In the event that after the Original Issue Date, the Company issues additional equity securities without consideration or for a consideration per share received by the Company less than the applicable Conversion Price in effect on the date of and immediately prior to such issue, then and in such event, the Conversion Price for the respective Series B1, B2, B+, C and C+ Preferred Shares shall each be reduced, concurrently with such issue, to a price (calculated to the nearest one hundredth of a cent) determined in accordance with the following formula: $CP2 = CP1 * (A + B) / (A + C)$. The following definitions shall apply for the foregoing formula: (a) CP2 shall mean the applicable Conversion Price in effect immediately after such issue of Additional Equity Securities; (b) CP1 shall mean the applicable Conversion Price in effect immediately prior to such issue of additional equity securities, which shall initially be equal to the applicable Original Issue Price; (c) "A" shall mean the number of Ordinary Shares outstanding immediately prior to such issue of additional equity securities, treating for this purpose as outstanding all Ordinary Shares issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities (including the Preferred Shares) outstanding immediately prior to such issue; (d) "B" shall mean the number of Ordinary Shares that would have been issued if such additional equity securities had been issued at a price per share equal to CP1 (determined by dividing the aggregate consideration received by the Company in respect of such issue by CP1); and (e) "C" shall mean the number of such additional equity securities issued in such transaction

All rights with respect to such shares shall immediately cease and terminate at the time of such conversion, except only the right of the holders thereof to receive Ordinary Shares in exchange therefor and to receive payment of any dividends declared but unpaid thereon.

(c) Series B+/C/C+ Preferred Shares redemption preferences

[REDACTED] ("[REDACTED]") means (i) a firm commitment [REDACTED] registered [REDACTED] by the Company of its Ordinary Shares (or depositary receipts or depositary shares therefore) on the NASDAQ or New York Stock Exchange in the United States, the Main Board of Hong Kong Stock Exchange, the Shanghai Stock Exchange, or the Shenzhen Stock Exchange or another internationally recognised stock exchange (or any combination of such exchanges and jurisdictions) reasonably acceptable to the Preferred Shareholders; or (ii) with the approval of the Board, a "back door [REDACTED]" or "special purpose acquisition company" transaction through a merger, acquisition, stock exchange, amalgamation or consolidation with or into, or a reverse takeover of, another enterprise already [REDACTED] on such stock exchange (including a special purpose acquisition company or its subsidiary), where the Shares are exchanged for cash or publicly [REDACTED] securities, in each case of (i) and (ii), with an [REDACTED] price or merger valuation that implies a market capitalisation of the Company immediately prior to such [REDACTED] or transaction of not less than the amount agreed among parties and being

APPENDIX I

ACCOUNTANTS’ REPORT

consummated without the Company completing any additional equity financing pursuant to which the Company sells and issues additional Equity Securities after the last closing of the purchase and sale of Series C+ Preferred Shares by all Series C+ Preferred Shareholders and the Company and prior to the submission of [REDACTED] (excluding for the avoidance of doubt the issuance of any Ordinary Shares or other Equity Securities convertible into Ordinary Shares pursuant to the ESOP Plan, as may be amended and restated).

Redemption Event means the earlier occurrence of any of the following events: (a) the Company fails to submit the [REDACTED] within twelve (12) months after the closing with the lead Series C+ investor under the subscription agreement; (b) the Company fails, for any reason, to consummate a [REDACTED] on or before 31 December 2023; (c) the ongoing phase II trial of T2DM in Mainland China does not conclude on or before 31 December 2023; and (d) prior to the submission of the Company’s [REDACTED], the Company, Dr Liping Liu (“the Founder”), and Great Mantra Group Limited (“the Founder Hold Company”), any of whom has committed a material breach of the terms of any transaction document that cannot be cured or remains uncured after sixty (60) days upon delivery of the written notice by any holder of Series B+ Preferred Shares, Series C Preferred Shares or Series C+ Preferred Shares.

The Company shall, at any time after the occurrence of the Redemption Event, upon the request from time to time of any holder of Series C+ Preferred Shares Series C and/or Series B+ Convertible Redeemable Preferred Shares, redeem the Series C+ Preferred Shares, the Series C or Series B+ Convertible Redeemable Preferred Shares held by such holder of Series C+ Preferred Shares Series C or Series B+ Convertible Redeemable Preferred Shares in accordance with the following terms: (i) the redemption price (the “Redemption Price”) for each Series C+ Preferred Share redeemed shall be equal to (i) 100% of the Series C+ Issue Price, proportionally adjusted for any share splits, share dividends, combinations, recapitalisations or similar transactions, plus (ii) any accrued or declared but unpaid dividend; plus (iii) an amount that would provide for a compound rate of return of 8% per annum commencing from the applicable Original Issue Date based on the applicable Original Issue Price of the Series C+, Series C and Series B+ Preferred Shares, minus (iv) the applicable Recovered Losses in respect to such Preferred Share.

In the event that the Company fails to redeem all the Series B+ Preferred Shares, Series C Preferred Shares and Series C+ Preferred Shares held by any holder of Series B+, C and C+ Preferred Shares requesting the Redemption, each of the holders of Series B+, C and C+ Convertible Redeemable Preferred Shares requesting the Redemption shall have the right to request the Founder to redeem its Series B+, C and C+ Convertible Redeemable Preferred Shares and the Founder shall redeem within thirty (30) days after receipt of such request from such holder of Series B+, C and C+ Convertible Redeemable Preferred Shares, provided that the Founder’s liability for such redemption shall be limited to any and all the equity securities the holder directly or indirectly holds in the Group.

The redemption rights have been automatically suspended immediately upon the Company’s submission of its application for a [REDACTED] and becomes exercisable if the [REDACTED] does not take place and will be in any event suspended upon [REDACTED]. The redemption rights shall be automatically restored and immediately resume to be exercisable if the [REDACTED] fails to consummate by the redemption restoration date agreed among parties (which is not earlier than 31 December 2023).

(d) Dividend Rights

If the Board shall declare any dividends to the shareholders, no dividends shall be made, whether in cash, in property, or in any other shares of the Company, with respect to any other class or series of shares of the Company, unless and until a dividend in like amount is first paid in full on Series C+ Preferred Shares. After the payment of such dividend on Series C+ Preferred Shares in full, a dividend in like amount shall be paid in full on Series B+ Preferred Shares if the Board declares any dividends to the Shareholders. After the payment of such dividend on Series B+ Preferred Shares in full, a dividend in like amount may be paid by the Company on the Shares on a pari passu and pro rata basis.

All the rights set forth above shall terminate upon the consummation of a [REDACTED] by the Company.

APPENDIX I

ACCOUNTANTS' REPORT

Presentation and classification

Series A, B1 and B2 Convertible Preferred Shares were entitled with Conversion Rights and Dividend Rights. The Group classified the Series A, B1 and B2 Convertible Preferred Shares as equity in accordance with the relevant IFRS mainly because the Company does not have any contractual obligation to deliver cash or another financial asset to the holders of the Series A, B1 and B2 Convertible Preferred Shares or to exchange financial assets or financial liabilities under conditions that are potentially unfavourable to the Company with the holders of the Series A, B1 and B2 Convertible Preferred Shares, nor does the Company have any contractual obligations to deliver a variable number of its own equity instruments for the settlement of the Series A, B1, and B2 Convertible Preferred Shares. Apart from Conversion Rights, Dividend Rights and Liquidation Preferences, Series B+, C and C+ Convertible Preferred Shares were further entitled with Redemption Rights. The Group designated the Series B+ Convertible Redeemable Preferred Shares, the Series C Convertible Redeemable Preferred Shares and the Series C+ Convertible Redeemable Preferred Shares as financial liabilities at fair value through profit or loss, presented as convertible redeemable preferred shares in the consolidated statements of financial position. The change in fair value of convertible redeemable preferred 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 fair value change in the Series B+ Convertible Redeemable Preferred Shares, Series C Convertible Redeemable Preferred Shares and Series C+ Convertible Redeemable Preferred Shares attributable to changes of its own credit risk is not significant.

The movements of the Series B+ Convertible Redeemable Preferred Shares, Series C Convertible Redeemable Preferred Shares and Series C+ Convertible Redeemable Preferred Shares during the Relevant Periods are as follows:

	As at 31 December		As at
	2021	2022	30 June
	RMB'000	RMB'000	2023
			RMB'000
Carrying amount at 1 January	217,009	1,005,903	1,260,013
Issuance of Series B+ Convertible Redeemable Preferred Shares	195,255	–	–
Issuance of Series C Convertible Redeemable Preferred Shares	511,307	–	–
Issuance of Series C+ Convertible Redeemable Preferred Shares	–	186,419	–
Fair value changes	93,656	(23,242)	399,635
Currency translation differences	(11,324)	90,933	62,005
	<u>1,005,903</u>	<u>1,260,013</u>	<u>1,721,653</u>
Carrying amount at 31 December/30 June			
Analysed into:			
Current portion	–	1,260,013	249,134
Non-current portion	1,005,903	–	1,472,519
	<u>1,005,903</u>	<u>1,260,013</u>	<u>1,472,519</u>

The Group applies back-solve method and discounted cash flow method to determine the underlying equity value of the Company and adopts the equity allocation model to determine the fair value of the Preferred Shares as at the end of each of the Relevant Periods.

APPENDIX I

ACCOUNTANTS’ REPORT

Key valuation assumptions used to determine the fair value of the Preferred Shares are as follows:

	As at 31 December		As at
	2021	2022	30 June
Risk-free interest rate	0.73%	4.70%	5.15%
Discount for lack of marketability (“DLOM”)	11%	14%	4%
Volatility	54%	61%	60%

The Group estimated the risk-free interest rate based on the yield of the US Government Bond as of the valuation date. The DLOM was estimated based on the option-pricing method. Under the option-pricing method, the cost of a put option, which can hedge the price change before the privately held share can be sold, was considered as a basis to determine the discount for the lack of marketability. The volatility was estimated based on the annualised standard deviation of the daily stock price return of comparable companies for the period from the respective valuation date and with similar span as time to expiration.

27. DEFERRED TAX LIABILITIES

Deferred tax liabilities

	As at 31 December		As at
	2021	2022	30 June
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount at 1 January	169	161	394
Deferred tax (credited)/charged to the consolidated statements of profit or loss occurred from right-of-use assets (<i>note 10</i>)	(8)	233	(14)
Carrying amount at 31 December/30 June	<u>161</u>	<u>394</u>	<u>380</u>

Deferred tax assets

	As at 31 December		As at
	2021	2022	30 June
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount at 1 January	165	161	394
Deferred tax (charged)/credited to the consolidated statements of profit or loss occurred from lease liabilities (<i>note 10</i>)	(4)	233	(14)
Carrying amount at 31 December/30 June	<u>161</u>	<u>394</u>	<u>380</u>
Net deferred tax liabilities at 31 December/30 June	<u>–</u>	<u>–</u>	<u>–</u>

APPENDIX I

ACCOUNTANTS' REPORT

28. SHARE CAPITAL

The Company was incorporated on 28 February 2018. As of 30 June 2023, the Company has an authorised share capital of US\$50,000 divided into 500,000,000 shares with a nominal value of US\$0.0001, of which (1) 44,349,294 are classified as ordinary shares of a par value of USD0.0001 each, all of which have been issued and outstanding; (2) 6,300,000 are classified as Series A Preferred Shares of a par value of USD0.0001 each, all of which have been issued and outstanding; (3) 2,760,061 are classified as Series B1 Preferred Shares of a par value of USD0.0001 each, all of which have been issued and outstanding; (4) 1,910,811 are classified as Series B2 Preferred Shares of a par value of USD0.0001 each, all of which have been issued and outstanding; (5) 12,678,554 are classified as Series B+ Preferred Shares of par value of USD0.0001 each, all of which have been issued and outstanding as aforementioned in note 26; (6) 12,190,291 are classified as Series C Preferred Shares of a par value of USD0.0001 each, all of which have been issued and outstanding as aforementioned in note 26; and (7) 3,973,767 are classified as Series C+ Preferred Shares of a par value of USD0.0001 each, all of which have been issued and outstanding as aforementioned in note 26.

Issued and fully paid as at 31 December 2021:

	Issued share capital		
	Number of shares in issue	Share capital	RMB equivalent
		<i>USD'000</i>	<i>RMB'000</i>
Issued and fully paid:			
Ordinary shares of USD0.0001 each	36,162,462	4	26
Series A Convertible Preferred Shares of USD0.0001 each	6,300,000	1	7
Series B1 Convertible Preferred Shares of USD0.0001 each	2,760,061	–	–
Series B2 Convertible Preferred Shares of USD0.0001 each	1,910,811	–	–
	<u>47,133,334</u>	<u>5</u>	<u>33</u>

Issued and fully paid as at 31 December 2022:

	Issued share capital		
	Number of shares in issue	Share capital	RMB equivalent
		<i>USD'000</i>	<i>RMB'000</i>
Issued and fully paid:			
Ordinary shares of USD0.0001 each	40,349,294	4	29
Series A Convertible Preferred Shares of USD0.0001 each	6,300,000	1	7
Series B1 Convertible Preferred Shares of USD0.0001 each	2,760,061	–	–
Series B2 Convertible Preferred Shares of USD0.0001 each	1,910,811	–	–
	<u>51,320,166</u>	<u>5</u>	<u>36</u>

APPENDIX I

ACCOUNTANTS’ REPORT

Issued and fully paid as at 30 June 2023:

	Issued share capital		
	Number of shares in issue	Share capital	RMB equivalent
		<i>USD’000</i>	<i>RMB’000</i>
Issued and fully paid:			
Ordinary shares of USD0.0001 each	44,349,294	4	32
Series A Convertible Preferred Shares of USD0.0001 each.....	6,300,000	1	7
Series B1 Convertible Preferred Shares of USD0.0001 each.....	2,760,061	–	–
Series B2 Convertible Preferred Shares of USD0.0001 each.....	1,910,811	–	–
	55,320,166	5	39

Movements in the issued share capital from 1 January 2021 to 30 June 2023 were as follows:

	Number of share in issue	Share capital
		<i>RMB’000</i>
At 1 January 2021	46,188,334	32
Issue of Series A Convertible Preferred Shares	945,000	1
At 31 December 2021 and 1 January 2022	47,133,334	33
Issue of ordinary shares	4,186,832	3
At 31 December 2022 and 1 January 2023	51,320,166	36
Issue of ordinary shares	4,000,000	3
At 30 June 2023.....	55,320,166	39

29. DEFICITS

Group

The amounts of the Group’s deficits and the movements therein for the Relevant Periods and the six months ended 30 June 2022 are presented in the consolidated statements of changes in equity.

Share premium

The share premium represents the difference between the par value of the shares issued and the consideration received for ordinary shares and Series A, B1 and B2 convertible preferred shares.

Share option reserve

The share option reserve of the Group represents the equity-settled share-based payments granted by the Group. Please refer to note 30 for details.

APPENDIX I

ACCOUNTANTS’ REPORT

Exchange fluctuation reserve

The exchange fluctuation reserve represents exchange differences arising from the translation of the financial statements of group companies whose functional currencies are different from the Group’s presentation currency.

Company

The amounts of the Company’s total deficits and the movements therein for the Relevant Periods are presented as follows:

	Share premium reserve*	Share option reserve	Exchange fluctuation reserve	Accumulated losses	Total deficits
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At 1 January 2021	257,664	107	(6,861)	(23,363)	227,547
Loss for the year	–	–	–	(156,054)	(156,054)
Other comprehensive loss for the year	–	–	(890)	–	(890)
Equity-settled share options ...	–	7,304	–	–	7,304
Issue of shares	25,668	–	–	–	25,668
At 31 December 2021 and 1 January 2022	283,332	7,411	(7,751)	(179,417)	103,575
Loss for the year	–	–	–	5,771	5,771
Other comprehensive loss for the year	–	–	(13,309)	–	(13,309)
Equity-settled share options ...	–	25,622	–	–	25,622
Issue of shares	–	–	–	–	–
At 31 December 2022 and 1 January 2023	283,332	33,033	(21,060)	(173,646)	121,659
Loss for the period	–	–	–	(419,067)	(419,067)
Other comprehensive loss for the period	–	–	(27,703)	–	(27,703)
Equity-settled share options ...	–	28,445	–	–	28,445
Issue of shares	–	–	–	–	–
At 30 June 2023	<u>283,332</u>	<u>61,478</u>	<u>(48,763)</u>	<u>(592,713)</u>	<u>(296,666)</u>

* Share premium reserve includes premiums for ordinary shares and preferred shares.

30. SHARE-BASED PAYMENTS

In January 2020, the Company adopted an employee long-term incentive plan (the “2020 Share Incentive Plan”) for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group. Eligible participants of the employee long-term incentive plan may include any officers, directors and employees of the Company who render or have rendered bona fide services to the Company. The maximum aggregate number of shares that may be issued is 4,662,462 shares (proportionally adjusted to reflect any share dividends, share splits, or similar transactions). In March 2022, the Company amended and restated the employee long-term incentive plan to attract and retain the best available personnel and to provide additional incentives to employees and directors to promote the success of the Company’s business. The maximum aggregate number of shares underlying all awards made under the 2020 Share Incentive Plan shall not exceed 8,849,294 shares (proportionally adjusted to reflect any share dividends, share splits, or similar transactions and excluding the awards that have lapsed or been cancelled or forfeited in accordance with this plan). In May 2023, the Company adopted a new employee long-term incentive plan to attract, retain and award the eligible adopted talents with 4,000,000 ordinary shares of the Company issuable under such plan.

APPENDIX I

ACCOUNTANTS’ REPORT

From 17 December 2020 to 30 June 2023, the Company had granted awards to 44 grantees to subscribe for an aggregate of 7,962,201 awards under the 2020 Share Incentive Plan. The awards shall be vested in four (4) years and the awards shall be vested in equal yearly instalments of 25% at each anniversary date commencing from the vesting commencement date. Additionally, subject to any restriction contained in the second plan, each award under the second plan shall not be vested if the [REDACTED] hasn’t occurred on or prior to the applicable vesting date of the individual Awards, and the vesting of such corresponding part of individual Awards shall be deferred to and effected on the date of [REDACTED] (or the immediately following trading day if such date is not a trading day).

The following share awards were outstanding under the equity share option plan during the years ended 31 December 2021 and 2022 and the six months ended 30 June 2023:

	Total awards	Exercise price per share	Fair value per share
		<i>US\$</i>	<i>US\$</i>
At 1 January 2021	653,846	0.81	1.35-1.37
Granted during the year	<u>1,177,369</u>	<u>1.06-1.72</u>	<u>3.24-3.77</u>
At 31 December 2021 and 1 January 2022	1,831,215	0.81-1.72	1.35-3.77
Granted during the year	<u>1,893,406</u>	<u>1.06-1.72</u>	<u>3.28-3.75</u>
At 31 December 2022 and 1 January 2023	3,724,621	0.81-1.72	1.35-3.77
Granted during the period	4,237,580	1.97-2.82	4.26-4.81
Forfeited during the period	<u>(243,628)</u>	<u>0.81-2.82</u>	<u>1.36-4.26</u>
At 30 June 2023	<u><u>7,718,573</u></u>	<u><u>0.81-2.82</u></u>	<u><u>1.35-4.81</u></u>

The fair values of the share awards granted during the years ended 31 December 2021 and 2022 and the six months ended 30 June 2023 were RMB21,006,000, RMB44,165,000 and RMB129,831,000, respectively, and the Group recognised share award expenses of RMB7,304,000, RMB25,622,000 and RMB28,445,000 during the years ended 31 December 2021 and 2022 and the six months ended 30 June 2023, respectively.

The fair value of the equity-settled share awards was estimated as at the date of grant using a binomial model, taking into account the terms and conditions upon which the awards were granted. The following table lists the inputs to the model used:

	Grant Day						
	On 1 December 2020	On 1 January 2021	On 1 February 2021	On 1 March 2021	On 30 December 2021	On 31 March 2022	On 1 April 2023
Expected volatility (%) . . .	46.1	46.1	47.5	47.9	48.7	52.0	53.1
Risk-free interest rate (%) .	0.9	0.9	1.1	1.4	1.5	2.3	3.6
Exercise multiple	2.5-2.8	2.5	2.8	2.8	2.2-2.8	2.2-2.8	2.2-2.8

The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome.

APPENDIX I

ACCOUNTANTS' REPORT

31. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the years ended 31 December 2021 and 2022 and the six months ended 30 June 2023, the Group had non-cash additions to right-of-use assets and lease liabilities of RMB1,260,000, RMB2,447,000 and RMB1,051,000, respectively, in respect of lease arrangements for plant and equipment.

(b) Changes in liabilities arising from financing activities

	Lease liabilities	Other borrowings	Convertible redeemable preferred shares	Bank and other loans	Financial liabilities at FVTPL	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2021	1,096	185,701	217,009	–	5,435	409,241
Changes from financing cash flows:						
Lease payment	(1,270)	–	–	–	–	(1,270)
Proceeds from issuance of convertible redeemable preferred shares	–	–	691,180	–	–	691,180
Proceeds from bank loans	–	–	–	10,000	–	10,000
Repayments of bank and other loans ..	–	(184,515)	–	(3,000)	–	(187,515)
Payments of bank loan interest	–	–	–	(309)	–	(309)
Total changes from financing cash flows	(1,270)	(184,515)	691,180	6,691	–	512,086
Other changes:						
New leases	1,260	–	–	–	–	1,260
Accretion of interest	67	4,152	–	309	–	4,528
Fair value changes	–	–	93,656	–	4,609	98,265
Exercise of warrants	–	(5,338)	15,382	–	(10,044)	–
Currency translation differences	–	–	(11,324)	–	–	(11,324)
Total other changes	1,327	(1,186)	97,714	309	(5,435)	92,729
At 31 December 2021	1,153	–	1,005,903	7,000	–	1,014,056

APPENDIX I

ACCOUNTANTS’ REPORT

	Lease liabilities	Other borrowings	Convertible redeemable preferred shares	Bank and other loans	Financial liabilities at FVTPL	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2022	1,153	–	1,005,903	7,000	–	1,014,056
Changes from financing cash flows:						
Lease payment	(987)	–	–	–	–	(987)
Proceeds from issuance of convertible redeemable preferred shares	–	–	186,419	–	–	186,419
Proceeds from bank loans	–	–	–	15,000	–	15,000
Repayments of bank and other loans .	–	–	–	(13,850)	–	(13,850)
Payments of bank loan interest	–	–	–	(303)	–	(303)
Total changes from financing cash flows	(987)	–	186,419	847	–	186,279
Other changes:						
New leases	2,447	–	–	–	–	2,447
Accretion of interest	123	–	–	303	–	426
Covid-19-related rent concessions from lessors	(112)	–	–	–	–	(112)
Fair value changes	–	–	(23,242)	–	–	(23,242)
Currency translation differences	–	–	90,933	–	–	90,933
Total other changes	2,458	–	67,691	303	–	70,452
At 31 December 2022	2,624	–	1,260,013	8,150	–	1,270,787

APPENDIX I

ACCOUNTANTS’ REPORT

	Lease liabilities	Other borrowings	Convertible redeemable preferred shares	Bank and other loans	Financial liabilities at FVTPL	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2023.....	2,624	–	1,260,013	8,150	–	1,270,787
Changes from financing cash flows:						
Lease payment.....	(502)	–	–	–	–	(502)
Proceeds from bank loans.....	–	–	–	5,000	–	5,000
Repayments of bank and other loans..	–	–	–	(5,150)	–	(5,150)
Payments of bank loan interest.....	–	–	–	(137)	–	(137)
Total changes from financing cash flows.....	(502)	–	–	(287)	–	(789)
Other changes:						
New leases.....	1,051	–	–	–	–	1,051
Accretion of interest.....	64	–	–	137	–	201
Fair value changes.....	–	–	399,635	–	–	399,635
Currency translation differences.....	(42)	–	62,005	–	–	61,963
Total other changes.....	1,073	–	461,640	137	–	462,850
At 30 June 2023.....	3,195	–	1,721,653	8,000	–	1,732,848
	<u>3,195</u>	<u>–</u>	<u>1,721,653</u>	<u>8,000</u>	<u>–</u>	<u>1,732,848</u>
	Lease liabilities	Other borrowings	Convertible redeemable preferred shares	Bank and other loans	Financial liabilities at FVTPL	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2022.....	1,153	–	1,005,903	7,000	–	1,014,056
Changes from financing cash flows:						
Lease payment.....	(119)	–	–	–	–	(119)
Proceeds from bank loans.....	–	–	–	10,000	–	10,000
Repayments of bank and other loans..	–	–	–	(8,500)	–	(8,500)
Payments of bank loan interest.....	–	–	–	(164)	–	(164)
Total changes from financing cash flows.....	(119)	–	–	1,336	–	1,217
Other changes:						
New leases.....	1,260	–	–	–	–	1,260
Accretion of interest.....	53	–	–	164	–	217
Fair value changes.....	–	–	(31,247)	–	–	(31,247)
Currency translation differences.....	–	–	51,884	–	–	51,884
Total other changes.....	1,313	–	20,637	164	–	22,114
At 30 June 2022 (unaudited).....	2,347	–	1,026,540	8,500	–	1,037,387
	<u>2,347</u>	<u>–</u>	<u>1,026,540</u>	<u>8,500</u>	<u>–</u>	<u>1,037,387</u>

APPENDIX I

ACCOUNTANTS’ REPORT

(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		Six months ended 30 June	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Within operating activities	559	1,307	769	835
Within financing activities	1,270	987	119	502
	<u>1,829</u>	<u>2,294</u>	<u>888</u>	<u>1,337</u>

32. **RELATED PARTY TRANSACTIONS**

The Group had the following transactions with related parties during the Relevant Periods and the six months ended 30 June 2022.

Compensation of key management personnel of the Group:

	Year ended 31 December		Six months ended 30 June	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Short term employee benefits	8,675	8,790	5,061	7,254
Equity-settled share option arrangements	4,791	15,207	5,830	19,324
Total compensation paid to key management personnel	<u>13,466</u>	<u>23,997</u>	<u>10,891</u>	<u>26,578</u>

Further details of directors’ emoluments are included in note 8 to the Historical Financial Information.

33. **FINANCIAL INSTRUMENTS BY CATEGORY**

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

As at 31 December 2021

Financial assets

	Financial assets measured at amortised cost
	RMB'000
Financial assets included in prepayments and other receivables	772
Cash and bank balances	<u>765,290</u>
	<u>766,062</u>

APPENDIX I

ACCOUNTANTS’ REPORT

Financial liabilities

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortised cost	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	–	6,091	6,091
Interest-bearing bank borrowings	–	7,000	7,000
Financial liabilities included in other payables and accruals	–	9,698	9,698
Convertible redeemable preferred shares	1,005,903	–	1,005,903
	<u>1,005,903</u>	<u>22,789</u>	<u>1,028,692</u>

As at 31 December 2022

Financial assets

	Financial assets measured at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayments, other receivables and other assets	873
Short-term time deposits	427,857
Cash and bank balances	412,340
	<u>841,070</u>

Financial liabilities

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortised cost	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	–	21,699	21,699
Interest-bearing bank borrowings	–	8,150	8,150
Financial liabilities included in other payables and accruals	–	19,270	19,270
Convertible redeemable preferred shares	1,260,013	–	1,260,013
	<u>1,260,013</u>	<u>49,119</u>	<u>1,309,132</u>

APPENDIX I

ACCOUNTANTS’ REPORT

As at 30 June 2023

Financial assets

	Financial assets measured at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayments, other receivables and other assets	1,281
Financial assets included in other non-current assets	192
Cash and bank balances	732,920
	<u>734,393</u>

Financial liabilities

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortised cost	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	–	29,752	29,752
Interest-bearing bank borrowings	–	8,000	8,000
Financial liabilities included in other payables and accruals	–	14,661	14,661
Convertible redeemable preferred shares	1,721,653	–	1,721,653
	<u>1,721,653</u>	<u>52,413</u>	<u>1,774,066</u>

APPENDIX I

ACCOUNTANTS’ REPORT

34. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

The carrying amounts and fair values of the Group’s financial instruments, other than those with carrying amounts that reasonably approximate to fair values, are as follows:

Carrying amounts			Fair value		
As at 31 December		As at 30 June	As at 31 December		As at 30 June
2021	2022	2023	2021	2022	2023
RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000

Financial liabilities

Convertible redeemable

preferred shares	1,005,903	1,260,013	1,721,653	1,005,903	1,260,013	1,721,653
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Management has assessed that the fair values of cash and bank balances, short-term time deposits, financial assets included in prepayments and other receivables, trade payables, interest-bearing bank borrowings, and financial liabilities included in other payables and accruals approximate to their carrying amounts largely due to the short term maturities of these instruments.

The Group’s finance department is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At the end of each of the Relevant Periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The Directors review the results of the fair value measurement of financial instruments periodically for financial reporting.

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.

The Group applies back-solve method and discounted cash flow method to determine the underlying equity value of the Company and adopts the equity allocation model to determine the fair value of the Preferred Shares as at the end of each of the Relevant Periods.

Fair value hierarchy

Unobservable inputs and sensitivity analysis of Level 3 assets and liabilities

Set out 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.

Significant unobservable inputs	Increase/(decrease) in the inputs	Increase/(decrease) in fair value of Convertible redeemable preferred shares		
		As at 31 December		As at 30 June
		2021	2022	2023
		RMB’000	RMB’000	RMB’000
	1%/	(3,936)/	(2,947)/	(2,863)/
Risk-free interest rate	(1%)	4,700	2,573	3,814
	1%/	(5,422)/	(6,019)/	(18,410)/
DLOM	(1%)	5,422	6,020	18,411
	1%/	5/	(302)/	(319)/
Volatility	(1%)	1,207	(332)	140

APPENDIX I

ACCOUNTANTS’ REPORT

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

As at 31 December 2021

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	
Financial liabilities				
Convertible redeemable preferred shares . .	–	–	1,005,903	1,005,903

As at 31 December 2022

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	
Financial liabilities				
Convertible redeemable preferred shares . .	–	–	1,260,013	1,260,013

As at 30 June 2023

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	
Financial liabilities				
Convertible redeemable preferred shares . .	–	–	1,721,653	1,721,653

APPENDIX I

ACCOUNTANTS’ REPORT

35. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments comprise interest-bearing bank borrowings, convertible redeemable preferred shares and cash and bank balances. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as trade payables, other receivables and other payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The Board of Directors reviews and agrees policies for managing each of these risks and they are summarised below.

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from financing by the Company or purchases by operating units in currencies other than their functional currencies.

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in foreign currency exchange rate, with all other variables held constant, of the Group’s loss before tax (due to changes in the fair values of monetary assets and liabilities) and the Group’s equity.

	Increase/ (decrease) in rate of foreign currency	Increase/ (decrease) in loss before tax	Increase/ (decrease) in equity
	%	RMB’000	RMB’000
31 December 2021			
If RMB weakens against USD	5	10	(177)
If RMB strengthens against USD	(5)	(10)	177
31 December 2022			
If RMB weakens against USD	5	2,563	4,246
If RMB strengthens against USD	(5)	(2,563)	(4,246)
30 June 2023			
If RMB weakens against USD	5	(31)	1,995
If RMB strengthens against USD.....	(5)	31	(1,995)

Credit risk

Credit risk is the risk that a counterparty will default on contractual obligations resulting in financial loss to the Group.

The credit risk of the Group’s financial assets, which primarily comprise cash and bank balances and financial assets included in prepayments and other receivables, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments.

As at the end of each of the Relevant Periods, cash and bank balances were deposited in reputable financial institutions without significant credit risk. For financial assets included in prepayments and other receivables, management makes periodic collective assessment as well as individual assessment on the recoverability of such assets based on historical settlement records and past experience.

None of the financial assets included in prepayments and other receivables at the end of each of the Relevant Periods were overdue, and all balances were categorised within Stage 1 for the measurement of expected credit losses. The Directors believe that there is no material credit risk inherent in the Group’s outstanding balances.

APPENDIX I

ACCOUNTANTS’ REPORT

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

As at 31 December 2021					
	Less than 1 year	1 to 2 years	2 to 3 years	More than 3 years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables	6,091	–	–	–	6,091
Lease liabilities	299	298	299	373	1,269
Financial liabilities included in other					
payables and accruals	9,698	–	–	–	9,698
Interest-bearing bank borrowings	7,021	–	–	–	7,021
Convertible redeemable preferred shares	–	947,462	–	–	947,462
	<u>23,109</u>	<u>947,760</u>	<u>299</u>	<u>373</u>	<u>971,541</u>

As at 31 December 2022					
	Less than 1 year	1 to 2 years	2 to 3 years	More than 3 years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables	21,699	–	–	–	21,699
Lease liabilities	1,210	1,029	472	74	2,785
Financial liabilities included in other					
payables and accruals	19,270	–	–	–	19,270
Interest-bearing bank borrowings	8,286	–	–	–	8,286
Convertible redeemable preferred shares	1,211,293	–	–	–	1,211,293
	<u>1,261,758</u>	<u>1,029</u>	<u>472</u>	<u>74</u>	<u>1,263,333</u>

As at 30 June 2023					
	Less than 1 year	1 to 2 years	2 to 3 years	More than 3 years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables	29,752	–	–	–	29,752
Lease liabilities	1,528	1,190	408	–	3,126
Financial liabilities included in other					
payables and accruals	14,661	–	–	–	14,661
Interest-bearing bank borrowings	8,147	–	–	–	8,147
Convertible redeemable preferred shares	195,348	1,063,066	–	–	1,258,414
	<u>249,436</u>	<u>1,064,256</u>	<u>408</u>	<u>–</u>	<u>1,314,100</u>

APPENDIX I

ACCOUNTANTS' REPORT

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 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 and the six months ended 30 June 2022.

36. EVENTS AFTER THE RELEVANT PERIODS

There were no significant events after the end of the Relevant Periods that require additional disclosure or adjustments.

37. 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 June 2023.

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

Set out below is a summary of certain provisions of the Memorandum and Articles of Association of the Company and of certain aspects of Cayman company law.

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on 28 February 2018 under the Companies Act (As Revised) of the Cayman Islands (the "**Companies Act**"). The Company's constitutional documents consist of its [Amended and Restated] Memorandum of Association (the "**Memorandum**") and its [Amended and Restated] Articles of Association (the "**Articles**").

1. MEMORANDUM OF ASSOCIATION

- (a) The Memorandum states, inter alia, that the liability of members of the Company is limited to the amount, if any, for the time being unpaid on the shares respectively held by them and that the objects for which the Company is established are unrestricted (including acting as an investment company), and that the Company shall have and be capable of exercising all the functions of a natural person of full capacity irrespective of any question of corporate benefit, as provided in section 27(2) of the Companies Act and in view of the fact that the Company is an exempted company that the Company will not trade in the Cayman Islands with any person, firm or corporation except in furtherance of the business of the Company carried on outside the Cayman Islands.
- (b) The Company may by special resolution alter its Memorandum with respect to any objects, powers or other matters specified therein.

2. ARTICLES OF ASSOCIATION

The Articles were [conditionally] adopted on [●] [with effect from the [REDACTED]]. The following is a summary of certain provisions of the Articles:

(a) Shares

(i) Classes of shares

The share capital of the Company consists of ordinary shares.

(ii) Variation of rights of existing shares or classes of shares

Subject to the Companies Act, if at any time the share capital of the Company is divided into different classes of shares, all or any of the special rights attached to the shares or any class of shares may (unless otherwise provided for by the terms of issue of that class) be varied, modified or abrogated either with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class or with the sanction of a special resolution passed at a separate general meeting of the holders of the shares of that class. To every such separate general meeting the provisions of the Articles relating to general meetings will *mutatis mutandis* apply, but so that the necessary quorum (including at an adjourned meeting)

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

shall be two persons holding or representing by proxy not less than one-third in nominal value of the issued shares of that class. Every holder of shares of the class shall be entitled to one vote for every such share held by him.

Any special rights conferred upon the holders of any shares or class of shares shall not, unless otherwise expressly provided in the rights attaching to the terms of issue of such shares, be deemed to be varied by the creation or issue of further shares ranking *pari passu* therewith.

(iii) Alteration of capital

The Company may by ordinary resolution of its members:

- (i) increase its share capital by the creation of new shares;
- (ii) consolidate all or any of its capital into shares of larger amount than its existing shares;
- (iii) divide its shares into several classes and attach to such shares any preferential, deferred, qualified or special rights, privileges, conditions or restrictions as the Company in general meeting or as the directors may determine;
- (iv) subdivide its shares or any of them into shares of smaller amount than is fixed by the Memorandum; or
- (v) cancel any shares which, at the date of passing of the resolution, have not been taken and diminish the amount of its capital by the amount of the shares so cancelled.

The Company may reduce its share capital or any capital redemption reserve or other undistributable reserve in any way by special resolution.

(iv) Transfer of shares

All transfers of shares may be effected by an instrument of transfer in the usual or common form or in a form prescribed by The Stock Exchange of Hong Kong Limited (the "Stock Exchange") or in such other form as the board may approve and which may be under hand or, if the transferor or transferee is a clearing house or its nominee(s), by hand or by machine imprinted signature or by such other manner of execution as the board may approve from time to time.

Notwithstanding the foregoing, for so long as any shares are [REDACTED] on the Stock Exchange, titles to such [REDACTED] shares may be evidenced and transferred in accordance with the laws applicable to and the rules and regulations of the Stock Exchange that are or shall be applicable to such [REDACTED] shares. The register of members in respect of its [REDACTED] shares (whether the principal

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

register or a branch register) may be kept by recording the particulars required by Section 40 of the Companies Act in a form otherwise than legible if such recording otherwise complies with the laws applicable to and the rules and regulations of the Stock Exchange that are or shall be applicable to such [REDACTED] shares.

The instrument of transfer shall be executed by or on behalf of the transferor and the transferee provided that the board may dispense with the execution of the instrument of transfer by the transferee. The transferor shall be deemed to remain the holder of the share until the name of the transferee is entered in the register of members in respect of that share.

The board may, in its absolute discretion, at any time transfer any share upon the principal register to any branch register or any share on any branch register to the principal register or any other branch register.

The board may decline to recognise any instrument of transfer unless a fee (not exceeding the maximum sum as the Stock Exchange may determine to be payable) determined by the Directors is paid to the Company, the instrument of transfer is properly stamped (if applicable), it is in respect of only one class of share and is lodged at the relevant registration office or registered office or such other place at which the principal register is kept accompanied by the relevant share certificate(s) and such other evidence as the board may reasonably require to show the right of the transferor to make the transfer (and if the instrument of transfer is executed by some other person on his behalf, the authority of that person so to do).

The registration of transfers may be suspended and the register closed on giving notice by advertisement in any newspaper or by any other means in accordance with the requirements of the Stock Exchange, at such times and for such periods as the board may determine. The register of members must not be closed for periods exceeding in the whole thirty (30) days in any year. The period of thirty (30) days may be extended for a further period or periods not exceeding thirty (30) days in respect of any year if approved by members by ordinary resolution.

Subject to the above, fully paid shares are free from any restriction on transfer and free of all liens in favour of the Company.

(v) Power of the Company to purchase its own shares

The Company is empowered by the Companies Act and the Articles to purchase its own shares subject to certain restrictions and the board may only exercise this power on behalf of the Company subject to any applicable requirements imposed from time to time by the Stock Exchange.

The board may accept the surrender for no consideration of any fully paid share.

(vi) Power of any subsidiary of the Company to own shares in the Company

There are no provisions in the Articles relating to ownership of shares in the Company by a subsidiary.

(vii) Calls on shares and forfeiture of shares

The board may from time to time make such calls upon the members in respect of any monies unpaid on the shares held by them respectively (whether on account of the nominal value of the shares or by way of premium). A call may be made payable either in one lump sum or by installments. If the sum payable in respect of any call or instalment is not paid on or before the day appointed for payment thereof, the person or persons from whom the sum is due shall pay interest on the same at such rate not exceeding twenty per cent. (20%) per annum as the board may agree to accept from the day appointed for the payment thereof to the time of actual payment, but the board may waive payment of such interest wholly or in part. The board may, if it thinks fit, receive from any member willing to advance the same, either in money or money's worth, all or any part of the monies uncalled and unpaid or installments payable upon any shares held by him, and upon all or any of the monies so advanced the Company may pay interest at such rate (if any) as the board may decide.

If a member fails to pay any call on the day appointed for payment thereof, the board may serve not less than fourteen (14) clear days' notice on him requiring payment of so much of the call as is unpaid, together with any interest which may have accrued and which may still accrue up to the date of actual payment and stating that, in the event of non-payment at or before the time appointed, the shares in respect of which the call was made will be liable to be forfeited.

If the requirements of any such notice are not complied with, any share in respect of which the notice has been given may at any time thereafter, before the payment required by the notice has been made, be forfeited by a resolution of the board to that effect. Such forfeiture will include all dividends and bonuses declared in respect of the forfeited share and not actually paid before the forfeiture.

A person whose shares have been forfeited shall cease to be a member in respect of the forfeited shares but shall, notwithstanding, remain liable to pay to the Company all monies which, at the date of forfeiture, were payable by him to the Company in respect of the shares, together with (if the board shall in its discretion so require) interest thereon from the date of forfeiture until the date of actual payment at such rate not exceeding twenty per cent. (20%) per annum as the board determines.

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

(b) **Directors**

(i) *Appointment, retirement and removal*

At each annual general meeting, one third of the Directors for the time being (or if their number is not a multiple of three, then the number nearest to but not less than one third) shall retire from office by rotation provided that every Director shall be subject to retirement at an annual general meeting at least once every three years. The Directors to retire by rotation shall include any Director who wishes to retire and not offer himself for re-election. Any further Directors so to retire shall be those who have been longest in office since their last re-election or appointment but as between persons who became or were last re-elected Directors on the same day those to retire will (unless they otherwise agree among themselves) be determined by lot.

Neither a Director nor an alternate Director is required to hold any shares in the Company by way of qualification. Further, there are no provisions in the Articles relating to retirement of Directors upon reaching any age limit.

The Directors have the power to appoint any person as a Director either to fill a casual vacancy on the board or as an addition to the existing board. Any Director so appointed shall hold office only until the first annual general meeting of the Company after his appointment and shall then be eligible for re-election.

A Director (including a managing or other executive Director) may be removed by an ordinary resolution of the Company before the expiration of his term of office (but without prejudice to any claim which such Director may have for damages for any breach of any contract between him and the Company) and members of the Company may by ordinary resolution appoint another in his place. Unless otherwise determined by the Company in general meeting, the number of Directors shall not be less than two. There is no maximum number of Directors.

The office of director shall be vacated if:

- (aa) he resigns by notice in writing delivered to the Company;
- (bb) he becomes of unsound mind or dies;
- (cc) without special leave, he is absent from meetings of the board for six (6) consecutive months, and the board resolves that his office is vacated;
- (dd) he becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors;
- (ee) he is prohibited from being a director by law; or

- (ff) he ceases to be a director by virtue of any provision of law or is removed from office pursuant to the Articles.

The board may appoint one or more of its body to be managing director, joint managing director, or deputy managing director or to hold any other employment or executive office with the Company for such period and upon such terms as the board may determine and the board may revoke or terminate any of such appointments. The board may delegate any of its powers, authorities and discretions to committees consisting of such Director or Directors and other persons as the board thinks fit, and it may from time to time revoke such delegation or revoke the appointment of and discharge any such committees either wholly or in part, and either as to persons or purposes, but every committee so formed must, in the exercise of the powers, authorities and discretions so delegated, conform to any regulations that may from time to time be imposed upon it by the board.

(ii) Power to allot and issue shares and warrants

Subject to the provisions of the Companies Act and the Memorandum and Articles and to any special rights conferred on the holders of any shares or class of shares, any share may be issued (a) with or have attached thereto such rights, or such restrictions, whether with regard to dividend, voting, return of capital, or otherwise, as the Directors may determine, or (b) on terms that, at the option of the Company or the holder thereof, it is liable to be redeemed.

The board may issue warrants or convertible securities or securities of similar nature conferring the right upon the holders thereof to subscribe for any class of shares or securities in the capital of the Company on such terms as it may determine.

Subject to the provisions of the Companies Act and the Articles and, where applicable, the rules of the Stock Exchange and without prejudice to any special rights or restrictions for the time being attached to any shares or any class of shares, all unissued shares in the Company are at the disposal of the board, which may offer, allot, grant options over or otherwise dispose of them to such persons, at such times, for such consideration and on such terms and conditions as it in its absolute discretion thinks fit, but so that no shares shall be issued at a discount to their nominal value.

Neither the Company nor the board is obliged, when making or granting any allotment of, offer of, option over or disposal of shares, to make, or make available, any such allotment, offer, option or shares to members or others with registered addresses in any particular territory or territories being a territory or territories where, in the absence of a registration statement or other special formalities, this would or might, in the opinion of the board, be unlawful or impracticable. Members affected as a result of the foregoing sentence shall not be, or be deemed to be, a separate class of members for any purpose whatsoever.

(iii) Power to dispose of the assets of the Company or any of its subsidiaries

There are no specific provisions in the Articles relating to the disposal of the assets of the Company or any of its subsidiaries. The Directors may, however, exercise all powers and do all acts and things which may be exercised or done or approved by the Company and which are not required by the Articles or the Companies Act to be exercised or done by the Company in general meeting.

(iv) Borrowing powers

The board may exercise all the powers of the Company to raise or borrow money, to mortgage or charge all or any part of the undertaking, property and assets and uncalled capital of the Company and, subject to the Companies Act, to issue debentures, bonds and other securities of the Company, whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party.

(v) Remuneration

The ordinary remuneration of the Directors is to be determined by the Company in general meeting, such sum (unless otherwise directed by the resolution by which it is voted) to be divided amongst the Directors in such proportions and in such manner as the board may agree or, failing agreement, equally, except that any Director holding office for part only of the period in respect of which the remuneration is payable shall only rank in such division in proportion to the time during such period for which he held office. The Directors are also entitled to be prepaid or repaid all travelling, hotel and incidental expenses reasonably expected to be incurred or incurred by them in attending any board meetings, committee meetings or general meetings or separate meetings of any class of shares or of debentures of the Company or otherwise in connection with the discharge of their duties as Directors.

Any Director who, by request, goes or resides abroad for any purpose of the Company or who performs services which in the opinion of the board go beyond the ordinary duties of a Director may be paid such extra remuneration as the board may determine and such extra remuneration shall be in addition to or in substitution for any ordinary remuneration as a Director. An executive Director appointed to be a managing director, joint managing director, deputy managing director or other executive officer shall receive such remuneration and such other benefits and allowances as the board may from time to time decide. Such remuneration may be either in addition to or in lieu of his remuneration as a Director.

The board may establish or concur or join with other companies (being subsidiary companies of the Company or companies with which it is associated in business) in establishing and making contributions out of the Company's monies to any schemes or funds for providing pensions, sickness or compassionate allowances, life assurance or other benefits for employees (which expression as used in this and

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

the following paragraph shall include any Director or past Director who may hold or have held any executive office or any office of profit with the Company or any of its subsidiaries) and ex-employees of the Company and their dependents or any class or classes of such persons.

The board may pay, enter into agreements to pay or make grants of revocable or irrevocable, and either subject or not subject to any terms or conditions, pensions or other benefits to employees and ex-employees and their dependents, or to any of such persons, including pensions or benefits additional to those, if any, to which such employees or ex-employees or their dependents are or may become entitled under any such scheme or fund as is mentioned in the previous paragraph. Any such pension or benefit may, as the board considers desirable, be granted to an employee either before and in anticipation of, or upon or at any time after, his actual retirement.

The board may resolve to capitalise all or any part of any amount for the time being standing to the credit of any reserve or fund (including a share premium account and the profit and loss account) whether or not the same is available for distribution by applying such sum in paying up unissued shares to be allotted to (i) employees (including directors) of the Company and/or its affiliates (meaning any individual, corporation, partnership, association, joint-stock company, trust, unincorporated association or other entity (other than the Company) that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, the Company) upon exercise or vesting of any options or awards granted under any share incentive scheme or employee benefit scheme or other arrangement which relates to such persons that has been adopted or approved by the members in general meeting, or (ii) any trustee of any trust to whom shares are to be allotted and issued by the Company in connection with the operation of any share incentive scheme or employee benefit scheme or other arrangement which relates to such persons that has been adopted or approved by the members in general meeting.

(vi) Compensation or payments for loss of office

Pursuant to the Articles, payments to any Director or past Director of any sum by way of compensation for loss of office or as consideration for or in connection with his retirement from office (not being a payment to which the Director is contractually entitled) must be approved by the Company in general meeting.

(vii) Loans and provision of security for loans to Directors

The Company must not make any loan, directly or indirectly, to a Director or his close associate(s) if and to the extent it would be prohibited by the Companies Ordinance (Chapter 622 of the laws of Hong Kong) as if the Company were a company incorporated in Hong Kong.

(viii) Disclosure of interests in contracts with the Company or any of its subsidiaries

A Director may hold any other office or place of profit with the Company (except that of the auditor of the Company) in conjunction with his office of Director for such period and upon such terms as the board may determine, and may be paid such extra remuneration therefor in addition to any remuneration provided for by or pursuant to the Articles. A Director may be or become a director or other officer of, or otherwise interested in, any company promoted by the Company or any other company in which the Company may be interested, and shall not be liable to account to the Company or the members for any remuneration, profits or other benefits received by him as a director, officer or member of, or from his interest in, such other company. The board may also cause the voting power conferred by the shares in any other company held or owned by the Company to be exercised in such manner in all respects as it thinks fit, including the exercise thereof in favour of any resolution appointing the Directors or any of them to be directors or officers of such other company, or voting or providing for the payment of remuneration to the directors or officers of such other company.

No Director or proposed or intended Director shall be disqualified by his office from contracting with the Company, either with regard to his tenure of any office or place of profit or as vendor, purchaser or in any other manner whatsoever, nor shall any such contract or any other contract or arrangement in which any Director is in any way interested be liable to be avoided, nor shall any Director so contracting or being so interested be liable to account to the Company or the members for any remuneration, profit or other benefits realised by any such contract or arrangement by reason of such Director holding that office or the fiduciary relationship thereby established. A Director who to his knowledge is in any way, whether directly or indirectly, interested in a contract or arrangement or proposed contract or arrangement with the Company must declare the nature of his interest at the meeting of the board at which the question of entering into the contract or arrangement is first taken into consideration, if he knows his interest then exists, or in any other case, at the first meeting of the board after he knows that he is or has become so interested.

A Director shall not vote (nor be counted in the quorum) on any resolution of the board approving any contract or arrangement or other proposal in which he or any of his close associates is materially interested, but this prohibition does not apply to any of the following matters, namely:

(aa) the giving of any security or indemnity either:-

(aaa) to the Director or his close associate(s) in respect of money lent or obligations incurred or undertaken by him or any of them at the request of or for the benefit of the Company or any of its subsidiaries; or

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

- (bbb) to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or his close associate(s) has himself/ themselves assumed responsibility in whole or in part and whether alone or jointly under a guarantee or indemnity or by the giving of security;
 - (bb) any proposal concerning an offer of shares or debentures or other securities of or by the Company or any other company which the Company may promote or be interested in for subscription or purchase where the Director or his close associate(s) is/are or is/are to be interested as a participant in the [REDACTED] or sub-[REDACTED] of the offer;
 - (cc) any proposal or arrangement concerning the benefit of employees of the Company or its subsidiaries including:-
 - (aaa) the adoption, modification or operation of any employees' share scheme or any share incentive or share option scheme under which the Director or his close associate(s) may benefit; or
 - (bbb) the adoption, modification or operation of a pension fund or retirement, death or disability benefits scheme which relates to the Directors, his close associate(s) and employee(s) of the Company or any of its subsidiaries and does not provide in respect of any Director, or his close associate(s), as such any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates;
 - (dd) any contract or arrangement in which the Director or his close associate(s) is/are interested in the same manner as other holders of shares or debentures or other securities of the Company by virtue only of his/their interest in shares or debentures or other securities of the Company.
- (c) **Proceedings of the Board**

The board may meet for the despatch of business, adjourn and otherwise regulate its meetings as it considers appropriate. Questions arising at any meeting shall be determined by a majority of votes. In the case of an equality of votes, the chairman of the meeting shall have an additional or casting vote.

(d) Alterations to constitutional documents and the Company's name

The Articles may be rescinded, altered or amended by the Company in general meeting by special resolution. The Articles state that a special resolution shall be required to alter the provisions of the Memorandum, to amend the Articles or to change the name of the Company.

(e) Meetings of members

(i) *Special and ordinary resolutions*

A special resolution of the Company must be passed by a majority of not less than three-fourths of the votes cast by such members as, being entitled so to do, vote in person or, in the case of such members as are corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of which notice has been duly given in accordance with the Articles.

Under the Companies Act, a copy of any special resolution must be forwarded to the Registrar of Companies in the Cayman Islands within fifteen (15) days of being passed.

An ordinary resolution is defined in the Articles to mean a resolution passed by a simple majority of the votes of such members of the Company as, being entitled to do so, vote in person or, in the case of corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of which notice has been duly given in accordance with the Articles.

(ii) *Voting rights and right to demand a poll*

Subject to any special rights or restrictions as to voting for the time being attached to any shares, at any general meeting on a poll every member present in person or by proxy or, in the case of a member being a corporation, by its duly authorised representative shall have one vote for every fully paid share of which he is the holder but so that no amount paid up or credited as paid up on a share in advance of calls or installments is treated for the foregoing purposes as paid up on the share. A member entitled to more than one vote need not use all his votes or cast all the votes he uses in the same way.

At any general meeting a resolution put to the vote of the meeting is to be decided by way of a poll save that the chairman of the meeting may in good faith, allow a resolution which relates purely to a procedural or administrative matter to be voted on by a show of hands in which case every member present in person (or being a corporation, is present by a duly authorized representative), or by proxy(ies) shall have one vote provided that where more than one proxy is appointed by a member which is a clearing house (or its nominee(s)), each such proxy shall have one vote on

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

a show of hands. Votes (whether on a show of hands or by way of poll) may be cast by such means, electronic or otherwise, as the Directors or the chairman of the meeting may determine.

Any corporation which is a member may by resolution of its directors or other governing body authorise such person as it thinks fit to act as its representative at any general meeting of the Company or at any meeting of any class of members.

The person so authorised shall be entitled to exercise the same powers on behalf of such corporation as the corporation could exercise if it were an individual member and such corporation shall for the purposes of the Articles be deemed to be present in person at any such meeting if a person so authorised is present thereat.

If a recognised clearing house (or its nominee(s)) is a member of the Company it may authorise such person or persons as it thinks fit to act as its representative(s) at any meeting of the Company or at any meeting of any class of members of the Company provided that, if more than one person is so authorised, the authorisation shall specify the number and class of shares in respect of which each such person is so authorised. A person authorised pursuant to this provision shall be deemed to have been duly authorised without further evidence of the facts and be entitled to exercise the same powers on behalf of the recognised clearing house (or its nominee(s)) as if such person was the registered holder of the shares of the Company held by that clearing house (or its nominee(s)) including, the right to speak and to vote, and where a show of hands is allowed, the right to vote individually on a show of hands.

All members have the right to speak and vote at a general meeting except where a member is required, by the rules of the Stock Exchange, to abstain from voting to approve the matter under consideration.

Where the Company has any knowledge that any member is, under the rules of the Stock Exchange, required to abstain from voting on any particular resolution of the Company or restricted to voting only for or only against any particular resolution of the Company, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

(iii) Annual general meetings and extraordinary general meetings

The Company must hold an annual general meeting of the Company for each financial year and such general meeting must be held within six (6) months after the end of the Company's financial year unless a longer period would not infringe the rules of the Stock Exchange.

Extraordinary general meetings may be convened on the requisition of one or more members holding, at the date of deposit of the requisition, not less than one-tenth of the paid up capital of the Company having the right of voting at general meetings, on a one vote per share basis. Such requisition shall be made in writing to the board or the secretary for the purpose of requiring an extraordinary general

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

meeting to be called by the board for the transaction of any business or resolution specified in such requisition. Such meeting shall be held within 2 months after the deposit of such requisition. If within 21 days of such deposit, the board fails to proceed to convene such meeting, the requisitionist(s) himself/herself (themselves) may do so in the same manner, and all reasonable expenses incurred by the requisitionist(s) as a result of the failure of the board shall be reimbursed to the requisitionist(s) by the Company.

Notwithstanding any provisions in the Articles, any general meeting or any class meeting may be held by means of such telephone, electronic or other communication facilities as to permit all persons participating in the meeting to communicate with each other, and participation in such a meeting shall constitute presence at such meeting.

(iv) Notices of meetings and business to be conducted

An annual general meeting must be called by notice of not less than twenty-one (21) clear days. All other general meetings must be called by notice of at least fourteen (14) clear days. The notice is exclusive of the day on which it is served or deemed to be served and of the day for which it is given, and must specify the time and place of the meeting and particulars of resolutions to be considered at the meeting and, in the case of special business, the general nature of that business.

In addition, notice of every general meeting must be given to all members of the Company other than to such members as, under the provisions of the Articles or the terms of issue of the shares they hold, are not entitled to receive such notices from the Company, and also to, among others, the auditors for the time being of the Company.

Any notice to be given to or by any person pursuant to the Articles may be served on or delivered to any member of the Company personally, by post to such member's registered address or by advertisement in newspapers in accordance with the requirements of the Stock Exchange. Subject to compliance with Cayman Islands law and the rules of the Stock Exchange, notice may also be served or delivered by the Company to any member by electronic means.

All business that is transacted at an extraordinary general meeting and at an annual general meeting is deemed special, save that in the case of an annual general meeting, each of the following business is deemed an ordinary business:

- (aa) the declaration and sanctioning of dividends;
- (bb) the consideration and adoption of the accounts and balance sheet and the reports of the directors and the auditors;
- (cc) the election of directors in place of those retiring;
- (dd) the appointment of auditors and other officers; and

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

(ee) the fixing of the remuneration of the directors and of the auditors.

(v) *Quorum for meetings and separate class meetings*

No business shall be transacted at any general meeting unless a quorum is present when the meeting proceeds to business, but the absence of a quorum shall not preclude the appointment of a chairman.

The quorum for a general meeting shall be two members present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy or, for quorum purposes only, two persons appointed by the clearing house as authorized representative or proxy, and entitled to vote. In respect of a separate class meeting (including an adjourned meeting) convened to sanction the modification of class rights the necessary quorum shall be two persons holding or representing by proxy not less than one-third in nominal value of the issued shares of that class.

(vi) *Proxies*

Any member of the Company entitled to attend and vote at a meeting of the Company is entitled to appoint another person as his proxy to attend and vote instead of him. A member who is the holder of two or more shares may appoint more than one proxy to represent him and vote on his behalf at a general meeting of the Company or at a class meeting. A proxy need not be a member of the Company and is entitled to exercise the same powers on behalf of a member who is an individual and for whom he acts as proxy as such member could exercise. In addition, a proxy is entitled to exercise the same powers on behalf of a member which is a corporation and for which he acts as proxy as such member could exercise as if it were an individual member. Votes may be given either personally (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy.

(f) **Accounts and audit**

The board shall cause true accounts to be kept of the sums of money received and expended by the Company, and the matters in respect of which such receipt and expenditure take place, and of the property, assets, credits and liabilities of the Company and of all other matters required by the Companies Act or necessary to give a true and fair view of the Company's affairs and to explain its transactions.

The accounting records must be kept at the registered office or at such other place or places as the board decides and shall always be open to inspection by any Director. No member (other than a Director) shall have any right to inspect any accounting record or book or document of the Company except as conferred by law or authorised by the board or the Company in general meeting. However, an exempted company must make available at its registered office in electronic form or any other medium, copies of its books of account or

parts thereof as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act of the Cayman Islands.

A copy of every balance sheet and profit and loss account (including every document required by law to be annexed thereto) which is to be laid before the Company at its general meeting, together with a printed copy of the Directors' report and a copy of the auditors' report, shall not less than twenty-one (21) days before the date of the meeting and at the same time as the notice of annual general meeting be sent to every person entitled to receive notices of general meetings of the Company under the provisions of the Articles; however, subject to compliance with all applicable laws, including the rules of the Stock Exchange, the Company may send to such persons summarised financial statements derived from the Company's annual accounts and the directors' report instead provided that any such person may by notice in writing served on the Company, demand that the Company sends to him, in addition to summarised financial statements, a complete printed copy of the Company's annual financial statement and the directors' report thereon.

At the annual general meeting or at a subsequent extraordinary general meeting in each year, the members shall by ordinary resolution appoint an auditor to audit the accounts of the Company and such auditor shall hold office until the next annual general meeting. Moreover, the members may, at any general meeting, by ordinary resolution remove the auditor at any time before the expiration of his terms of office and shall by ordinary resolution at that meeting appoint another auditor for the remainder of his term. The remuneration of the auditors shall be fixed and approved by the Company by an ordinary resolution passed at a general meeting or in such manner as the members may by ordinary resolution determine.

The financial statements of the Company shall be audited by the auditor in accordance with generally accepted auditing standards which may be those of a country or jurisdiction other than the Cayman Islands. The auditor shall make a written report thereon in accordance with generally accepted auditing standards and the report of the auditor must be submitted to the members in general meeting.

(g) Dividends and other methods of distribution

The Company in general meeting may declare dividends in any currency to be paid to the members but no dividend shall be declared in excess of the amount recommended by the board.

The Articles provide dividends may be declared and paid out of the profits of the Company, realised or unrealised, or from any reserve set aside from profits which the directors determine is no longer needed. With the sanction of an ordinary resolution dividends may also be declared and paid out of share premium account or any other fund or account which can be authorised for this purpose in accordance with the Companies Act.

Except in so far as the rights attaching to, or the terms of issue of, any share may otherwise provide, (i) all dividends shall be declared and paid according to the amounts paid up on the shares in respect whereof the dividend is paid but no amount paid up on a share in

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

advance of calls shall for this purpose be treated as paid up on the share and (ii) all dividends shall be apportioned and paid pro rata according to the amount paid up on the shares during any portion or portions of the period in respect of which the dividend is paid. The Directors may deduct from any dividend or other monies payable to any member or in respect of any shares all sums of money (if any) presently payable by him to the Company on account of calls or otherwise.

Whenever the board or the Company in general meeting has resolved that a dividend be paid or declared on the share capital of the Company, the board may further resolve either (a) that such dividend be satisfied wholly or in part in the form of an allotment of shares credited as fully paid up, provided that the members entitled thereto will be entitled to elect to receive such dividend (or part thereof) in cash in lieu of such allotment, or (b) that members entitled to such dividend will be entitled to elect to receive an allotment of shares credited as fully paid up in lieu of the whole or such part of the dividend as the board may think fit.

The Company may also upon the recommendation of the board by an ordinary resolution resolve in respect of any one particular dividend of the Company that it may be satisfied wholly in the form of an allotment of shares credited as fully paid up without offering any right to members to elect to receive such dividend in cash in lieu of such allotment.

Any dividend, interest or other sum payable in cash to the holder of shares may be paid by cheque or warrant sent through the post addressed to the holder at his registered address, or in the case of joint holders, addressed to the holder whose name stands first in the register of the Company in respect of the shares at his address as appearing in the register or addressed to such person and at such addresses as the holder or joint holders may in writing direct. Every such cheque or warrant shall, unless the holder or joint holders otherwise direct, be made payable to the order of the holder or, in the case of joint holders, to the order of the holder whose name stands first on the register in respect of such shares, and shall be sent at his or their risk and payment of the cheque or warrant by the bank on which it is drawn shall constitute a good discharge to the Company. Any one of two or more joint holders may give effectual receipts for any dividends or other moneys payable or property distributable in respect of the shares held by such joint holders.

Whenever the board or the Company in general meeting has resolved that a dividend be paid or declared the board may further resolve that such dividend be satisfied wholly or in part by the distribution of specific assets of any kind.

All dividends or bonuses unclaimed for one year after having been declared may be invested or otherwise made use of by the board for the benefit of the Company until claimed and the Company shall not be constituted a trustee in respect thereof. All dividends or bonuses unclaimed for six years after having been declared may be forfeited by the board and shall revert to the Company.

No dividend or other monies payable by the Company on or in respect of any share shall bear interest against the Company.

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

(h) Inspection of corporate records

Pursuant to the Articles, the register and branch register of members maintained in Hong Kong shall be open to inspection for at least two (2) hours during business hours by members without charge, or by any other person upon a maximum payment of HK\$2.50 or such lesser sum specified by the board, at the registered office or such other place at which the register is kept in accordance with the Companies Act or, upon a maximum payment of HK\$1.00 or such lesser sum specified by the board, at the office where the branch register of members is kept, unless the register is closed in accordance with the Articles.

(i) Rights of minorities in relation to fraud or oppression

There are no provisions in the Articles relating to rights of minority shareholders in relation to fraud or oppression. However, certain remedies are available to members of the Company under Cayman Islands law, as summarised in paragraph 3(f) of this Appendix.

(j) Procedures on liquidation

Unless otherwise provided by the Companies Act, a resolution that the Company be wound up by the court or be wound up voluntarily shall be a special resolution.

Subject to any special rights, privileges or restrictions as to the distribution of available surplus assets on liquidation for the time being attached to any class or classes of shares:

- (i) if the Company is wound up and the assets available for distribution amongst the members of the Company shall be more than sufficient to repay the whole of the capital paid up at the commencement of the winding up, the excess shall be distributed *pari passu* amongst such members in proportion to the amount paid up on the shares held by them respectively; and
- (ii) if the Company is wound up and the assets available for distribution amongst the members as such shall be insufficient to repay the whole of the paid-up capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members in proportion to the capital paid up, or which ought to have been paid up, at the commencement of the winding up on the shares held by them respectively.

If the Company is wound up (whether the liquidation is voluntary or by the court) the liquidator may, with the authority of a special resolution and any other sanction required by the Companies Act divide among the members in specie or kind the whole or any part of the assets of the Company whether the assets shall consist of property of one kind or shall consist of properties of different kinds and the liquidator may, for such purpose, set such value as he deems fair upon any one or more class or classes of property to be divided as aforesaid and may determine how such division shall be carried out as between the members or different classes of members. The liquidator may, with the like authority, vest any part of

APPENDIX III

**SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW**

the assets in trustees upon such trusts for the benefit of members as the liquidator, with the like authority, shall think fit, but so that no contributory shall be compelled to accept any shares or other property in respect of which there is a liability.

(k) Subscription rights reserve

The Articles provide that to the extent that it is not prohibited by and is in compliance with the Companies Act, if warrants to subscribe for shares have been issued by the Company and the Company does any act or engages in any transaction which would result in the subscription price of such warrants being reduced below the par value of a share, a subscription rights reserve shall be established and applied in paying up the difference between the subscription price and the par value of a share on any exercise of the warrants.

3. CAYMAN ISLANDS COMPANY LAW

The Company is incorporated in the Cayman Islands subject to the Companies Act and, therefore, operates subject to Cayman Islands law. Set out below is a summary of certain provisions of Cayman company law, although this does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of Cayman company law and taxation, which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar:

(a) Company operations

As an exempted company, the Company's operations must be conducted mainly outside the Cayman Islands. The Company is required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the amount of its authorised share capital.

(b) Share capital

The Companies Act provides that where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount of the value of the premiums on those shares shall be transferred to an account, to be called the "share premium account". At the option of a company, these provisions may not apply to premiums on shares of that company allotted pursuant to any arrangement in consideration of the acquisition or cancellation of shares in any other company and issued at a premium.

The Companies Act provides that the share premium account may be applied by the company subject to the provisions, if any, of its memorandum and articles of association in (a) paying distributions or dividends to members; (b) paying up unissued shares of the company to be issued to members as fully paid bonus shares; (c) the redemption and repurchase of shares (subject to the provisions of section 37 of the Companies Act); (d) writing-off the preliminary expenses of the company; and (e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company.

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

No distribution or dividend may be paid to members out of the share premium account unless immediately following the date on which the distribution or dividend is proposed to be paid, the company will be able to pay its debts as they fall due in the ordinary course of business.

The Companies Act provides that, subject to confirmation by the Grand Court of the Cayman Islands (the "**Court**"), a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, by special resolution reduce its share capital in any way.

(c) Financial assistance to purchase shares of a company or its holding company

There is no statutory restriction in the Cayman Islands on the provision of financial assistance by a company to another person for the purchase of, or subscription for, its own or its holding company's shares. Accordingly, a company may provide financial assistance if the directors of the company consider, in discharging their duties of care and acting in good faith, for a proper purpose and in the interests of the company, that such assistance can properly be given. Such assistance should be on an arm's-length basis.

(d) Purchase of shares and warrants by a company and its subsidiaries

A company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, issue shares which are to be redeemed or are liable to be redeemed at the option of the company or a shareholder and the Companies Act expressly provides that it shall be lawful for the rights attaching to any shares to be varied, subject to the provisions of the company's articles of association, so as to provide that such shares are to be or are liable to be so redeemed. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares. However, if the articles of association do not authorise the manner and terms of purchase, a company cannot purchase any of its own shares unless the manner and terms of purchase have first been authorised by an ordinary resolution of the company. At no time may a company redeem or purchase its shares unless they are fully paid. A company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any issued shares of the company other than shares held as treasury shares. A payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

Shares purchased by a company is to be treated as cancelled unless, subject to the memorandum and articles of association of the company, the directors of the company resolve to hold such shares in the name of the company as treasury shares prior to the purchase. Where shares of a company are held as treasury shares, the company shall be entered in the register of members as holding those shares, however, notwithstanding the foregoing, the company is not to be treated as a member for any purpose and must not exercise any right in respect of the treasury shares, and any purported exercise of such a right shall be void, and a treasury share must not be voted, directly or indirectly, at any

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

meeting of the company and must not be counted in determining the total number of issued shares at any given time, whether for the purposes of the company's articles of association or the Companies Act.

A company is not prohibited from purchasing and may purchase its own warrants subject to and in accordance with the terms and conditions of the relevant warrant instrument or certificate. There is no requirement under Cayman Islands law that a company's memorandum or articles of association contain a specific provision enabling such purchases and the directors of a company may rely upon the general power contained in its memorandum of association to buy and sell and deal in personal property of all kinds.

Under Cayman Islands law, a subsidiary may hold shares in its holding company and, in certain circumstances, may acquire such shares.

(e) Dividends and distributions

The Companies Act permits, subject to a solvency test and the provisions, if any, of the company's memorandum and articles of association, the payment of dividends and distributions out of the share premium account. With the exception of the foregoing, there are no statutory provisions relating to the payment of dividends. Based upon English case law, which is regarded as persuasive in the Cayman Islands, dividends may be paid only out of profits.

No dividend may be declared or paid, and no other distribution (whether in cash or otherwise) of the company's assets (including any distribution of assets to members on a winding up) may be made to the company, in respect of a treasury share.

(f) Protection of minorities and shareholders' suits

The Courts ordinarily would be expected to follow English case law precedents which permit a minority shareholder to commence a representative action against or derivative actions in the name of the company to challenge (a) an act which is ultra vires the company or illegal, (b) an act which constitutes a fraud against the minority and the wrongdoers are themselves in control of the company, and (c) an irregularity in the passing of a resolution which requires a qualified (or special) majority.

In the case of a company (not being a bank) having a share capital divided into shares, the Court may, on the application of members holding not less than one fifth of the shares of the company in issue, appoint an inspector to examine into the affairs of the company and to report thereon in such manner as the Court shall direct.

Any shareholder of a company may petition the Court which may make a winding up order if the Court is of the opinion that it is just and equitable that the company should be wound up or, as an alternative to a winding up order, (a) an order regulating the conduct of the company's affairs in the future, (b) an order requiring the company to refrain from doing or continuing an act complained of by the shareholder petitioner or to do an act which the shareholder petitioner has complained it has omitted to do, (c) an order authorising civil

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

proceedings to be brought in the name and on behalf of the company by the shareholder petitioner on such terms as the Court may direct, or (d) an order providing for the purchase of the shares of any shareholders of the company by other shareholders or by the company itself and, in the case of a purchase by the company itself, a reduction of the company's capital accordingly.

Generally claims against a company by its shareholders must be based on the general laws of contract or tort applicable in the Cayman Islands or their individual rights as shareholders as established by the company's memorandum and articles of association.

(g) Disposal of assets

The Companies Act contains no specific restrictions on the power of directors to dispose of assets of a company. However, as a matter of general law, every officer of a company, which includes a director, managing director and secretary, in exercising his powers and discharging his duties must do so honestly and in good faith with a view to the best interests of the company and exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

(h) Accounting and auditing requirements

A company must cause proper books of account to be kept with respect to (i) all sums of money received and expended by the company and the matters in respect of which the receipt and expenditure takes place; (ii) all sales and purchases of goods by the company; and (iii) the assets and liabilities of the company.

Proper books of account shall not be deemed to be kept if there are not kept such books as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions.

An exempted company must make available at its registered office in electronic form or any other medium, copies of its books of account or parts thereof as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act of the Cayman Islands.

(i) Exchange control

There are no exchange control regulations or currency restrictions in the Cayman Islands.

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

(j) Taxation

Pursuant to the Tax Concessions Act of the Cayman Islands, the Company has obtained an undertaking:

- (1) that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciation shall apply to the Company or its operations; and
- (2) that the aforesaid tax or any tax in the nature of estate duty or inheritance tax shall not be payable on or in respect of the shares, debentures or other obligations of the Company.

The undertaking for the Company is for a period of twenty years from 20 September 2021.

The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to the Company levied by the Government of the Cayman Islands save for certain stamp duties which may be applicable, from time to time, on certain instruments executed in or brought within the jurisdiction of the Cayman Islands. The Cayman Islands are a party to a double tax treaty entered into with the United Kingdom in 2010 but otherwise is not party to any double tax treaties.

(k) Stamp duty on transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands.

(l) Loans to directors

There is no express provision in the Companies Act prohibiting the making of loans by a company to any of its directors.

(m) Inspection of corporate records

The notice of registered office is a matter of public record. A list of the names of the current directors and alternate directors (if applicable) is made available by the Registrar of Companies for inspection by any person on payment of a fee. The register of mortgages is open to inspection by creditors and members.

Members of the Company have no general right under the Companies Act to inspect or obtain copies of the register of members or corporate records of the Company. They will, however, have such rights as may be set out in the Company's Articles.

(n) Register of members

An exempted company may maintain its principal register of members and any branch registers at such locations, whether within or without the Cayman Islands, as the directors may, from time to time, think fit. The register of members shall contain such particulars as required by Section 40 of the Companies Act. A branch register must be kept in the same manner in which a principal register is by the Companies Act required or permitted to be kept. The company shall cause to be kept at the place where the company's principal register is kept a duplicate of any branch register duly entered up from time to time.

There is no requirement under the Companies Act for an exempted company to make any returns of members to the Registrar of Companies of the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection. However, an exempted company shall make available at its registered office, in electronic form or any other medium, such register of members, including any branch register of members, as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act of the Cayman Islands.

(o) Register of Directors and Officers

The Company is required to maintain at its registered office a register of directors and officers which is not available for inspection by the public. A copy of such register must be filed with the Registrar of Companies in the Cayman Islands and any change must be notified to the Registrar within thirty (30) days of any change in such directors or officers.

(p) Beneficial Ownership Register

An exempted company is required to maintain a beneficial ownership register at its registered office that records details of the persons who ultimately own or control, directly or indirectly, 25% or more of the equity interests or voting rights of the company or have rights to appoint or remove a majority of the directors of the company. The beneficial ownership register is not a public document and is only accessible by a designated competent authority of the Cayman Islands. Such requirement does not, however, apply to an exempted company with its shares listed on an approved stock exchange, which includes the Stock Exchange. Accordingly, for so long as the shares of the Company are [REDACTED] on the Stock Exchange, the Company is not required to maintain a beneficial ownership register.

(q) Winding up

A company may be wound up (a) compulsorily by order of the Court, (b) voluntarily, or (c) under the supervision of the Court.

The Court has authority to order winding up in a number of specified circumstances including where the members of the company have passed a special resolution requiring the company to be wound up by the Court, or where the company is unable to pay its debts, or where it is, in the opinion of the Court, just and equitable to do so. Where a petition is presented by members of the company as contributories on the ground that it is just and equitable that the company should be wound up, the Court has the jurisdiction to make certain other orders as an alternative to a winding-up order, such as making an order regulating the conduct of the company's affairs in the future, making an order authorising civil proceedings to be brought in the name and on behalf of the company by the petitioner on such terms as the Court may direct, or making an order providing for the purchase of the shares of any of the members of the company by other members or by the company itself.

A company (save with respect to a limited duration company) may be wound up voluntarily when the company so resolves by special resolution or when the company in general meeting resolves by ordinary resolution that it be wound up voluntarily because it is unable to pay its debts. In the case of a voluntary winding up, such company is obliged to cease to carry on its business (except so far as it may be beneficial for its winding up) from the time of passing the resolution for voluntary winding up or upon the expiry of the period or the occurrence of the event referred to above.

For the purpose of conducting the proceedings in winding up a company and assisting the Court therein, there may be appointed an official liquidator or official liquidators; and the court may appoint to such office such person, either provisionally or otherwise, as it thinks fit, and if more persons than one are appointed to such office, the Court must declare whether any act required or authorised to be done by the official liquidator is to be done by all or any one or more of such persons. The Court may also determine whether any and what security is to be given by an official liquidator on his appointment; if no official liquidator is appointed, or during any vacancy in such office, all the property of the company shall be in the custody of the Court.

As soon as the affairs of the company are fully wound up, the liquidator must make a report and an account of the winding up, showing how the winding up has been conducted and how the property of the company has been disposed of, and thereupon call a general meeting of the company for the purposes of laying before it the account and giving an explanation thereof. This final general meeting must be called by at least 21 days' notice to each contributory in any manner authorised by the company's articles of association and published in the Gazette.

(r) Reconstructions

There are statutory provisions which facilitate reconstructions and amalgamations approved by (i) a majority in number representing seventy-five per cent. (75%) in value of creditors, or (ii) seventy-five per cent. (75%) in value of shareholders or class of shareholders, as the case may be, as are present at a meeting called for such purpose and thereafter sanctioned by the Court. Whilst a dissenting shareholder would have the right to express to the Court his view that the transaction for which approval is sought would not provide the shareholders with a fair value for their shares, the Court is unlikely to disapprove the transaction on that ground alone in the absence of evidence of fraud or bad faith on behalf of management.

The Companies Act also contains statutory provisions which provide that a company may present a petition to the Court for the appointment of a restructuring officer on the grounds that the company (a) is or is likely to become unable to pay its debts within the meaning of section 93 of the Companies Act; and (b) intends to present a compromise or arrangement to its creditors (or classes thereof) either, pursuant to the Companies Act, the law of a foreign country or by way of a consensual restructuring. The petition may be presented by a company acting by its directors, without a resolution of its shareholders or an express power in its articles of association. On hearing such a petition, the Court may, among other things, make an order appointing a restructuring officer or make any other order as the Court thinks fit.

(s) Take-overs

Where an offer is made by a company for the shares of another company and, within four (4) months of the offer, the holders of not less than ninety per cent. (90%) of the shares which are the subject of the offer accept, the offeror may at any time within two (2) months after the expiration of the said four (4) months, by notice in the prescribed manner require the dissenting shareholders to transfer their shares on the terms of the offer. A dissenting shareholder may apply to the Court within one (1) month of the notice objecting to the transfer. The burden is on the dissenting shareholder to show that the Court should exercise its discretion, which it will be unlikely to do unless there is evidence of fraud or bad faith or collusion as between the offeror and the holders of the shares who have accepted the offer as a means of unfairly forcing out minority shareholders.

(t) Indemnification

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Court to be contrary to public policy (e.g. for purporting to provide indemnification against the consequences of committing a crime).

APPENDIX III

SUMMARY OF THE CONSTITUTION OF THE COMPANY
AND CAYMAN ISLANDS COMPANY LAW

(u) **Economic Substance Requirements**

Pursuant to the International Tax Cooperation (Economic Substance) Act of the Cayman Islands ("**ES Act**") that came into force on 1 January 2019, a "relevant entity" is required to satisfy the economic substance test set out in the ES Act. A "relevant entity" includes an exempted company incorporated in the Cayman Islands as is the Company; however, it does not include an entity that is tax resident outside the Cayman Islands. Accordingly, for so long as the Company is a tax resident outside the Cayman Islands, including in Hong Kong, it is not required to satisfy the economic substance test set out in the ES Act.

4. GENERAL

Conyers Dill & Pearman, the Company's special legal counsel on Cayman Islands law, have sent to the Company a letter of advice summarising certain aspects of Cayman Islands company law. This letter, together with a copy of the Companies Act, is available for inspection as referred to in the paragraph headed "Documents on display" in Appendix III to this document. Any person wishing to have a detailed summary of Cayman Islands company law or advice on the differences between it and the laws of any jurisdiction with which he is more familiar is recommended to seek independent legal advice.

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation

Our Company is an exempted company with limited liability incorporated in the Cayman Islands on February 28, 2018. Our registered office address is at Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman KY1-1111, Cayman Islands. Accordingly, our Company’s corporate structure and Memorandum and Articles are subject to the relevant laws of the Cayman Islands, a summary of which is set out in “Summary of the Constitution of the Company and Cayman Islands Company Law” in Appendix III to this document.

Our registered place of business in Hong Kong is at 40/F, Dah Sing Financial Centre, No. 248 Queen’s Road East, Wanchai, Hong Kong. We were registered as a non-Hong Kong company under Part 16 of the Companies Ordinance on February 10, 2022. Ms. CHU Pik Man (朱璧敏) has been appointed as the authorized representative of our Company for the acceptance of service of process in Hong Kong. The address for service of process in Hong Kong is at 40/F, Dah Sing Financial Centre, No. 248 Queen’s Road East, Wanchai, Hong Kong.

2. Changes in the share capital of our Company

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on February 28, 2018. As of the date of our Company’s incorporation, the authorized share capital of our Company was US\$50,000 divided into 50,000 Shares with a par value of US\$1 each.

For the share capital of our Company as at the Latest Practicable Date, see the section headed “Share Capital” in this document for details.

Save as disclosed in the section headed “History, Reorganization and Corporate Structure” in this document, there is no alteration in our share capital within two years immediately preceding the date of this document.

3. Changes in the share capital of our subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in Note 1 to the Accountants’ Report as set out in Appendix I to this document.

The following sets out the alterations in the registered capital of our subsidiaries that took place within two years preceding the date of this document:

Shenzhen HighTide

On January 30, 2023, the registered capital of Shenzhen HighTide was increased from RMB66,450,000 to RMB70,000,000. And on April 26, 2023, the registered capital of Shenzhen HighTide was increased from RMB70,000,000 to RMB310,800,000.

Nanchang Fusion

On April 27, 2023, the registered capital of Nanchang Fusion was increased from RMB12,000,000 to RMB56,000,000.

Hebei Puhui

On September 27, 2023, Hebei Puhui was established with registered capital of RMB100,000,000.

Save as disclosed above, there is no alteration in the share capital of any of the subsidiaries of our Company within the two years immediately preceding the date of this document.

4. Written Resolutions Passed by Our Shareholders on [●], 2023

Written resolutions of the Shareholders of our Company were passed on [●], 2023, pursuant to which, among others:

- (a) our Company approved and conditionally adopted the Memorandum and Articles of Association with effect from the [REDACTED];
- (b) our authorized share capital was increased from US\$50,000 to US\$[REDACTED] by the creation of an additional [REDACTED] Shares, and following such increase, the authorized share capital of our Company was US\$[REDACTED] divided into [REDACTED] ordinary Shares comprising of (i) [REDACTED] Shares, (ii) 6,300,000 Series A Preferred Shares; (iii) 2,760,061 Series B-1 Preferred Shares, (iv) 1,910,811 Series B-2 Preferred Shares, (v) 12,678,554 Series B+ Preferred Shares, (vi) 12,190,291 Series C Preferred Shares, and (vii) 3,973,767 Series C+ Preferred Shares;
- (c) conditional on (1) the Listing Committee granting [REDACTED] of, and permission to deal in, the Shares in issue and to be issued as stated in this document and such [REDACTED] and permission not subsequently having been revoked prior to the commencement of dealing in the Shares on the Stock Exchange; (2) the [REDACTED] having been determined and (3) the obligations of the [REDACTED] under the [REDACTED] Agreements becoming unconditional and the [REDACTED] Agreements not being terminated in accordance with their terms or otherwise, in each case on or before such dates as may be specified in the [REDACTED] Agreements:
 - (i) all the issued [Preferred Shares], of a par value of US\$0.0001, be redesignated and reclassified into Shares, on a one-to-one basis, following which:
 - (A) our authorized share capital will be US\$[50,000] divided into [500,000,000] Shares, with par value of [US\$0.0001] each; and
 - (B) all the ordinary Shares of a par value of [US\$0.0001] in issue to remain as Shares.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- (ii) the [REDACTED] and the [REDACTED] was approved, and the proposed allotment and issue of the [REDACTED] under the [REDACTED] and the [REDACTED] were approved, and the Board was authorized to determine the [REDACTED] for, and to allot and issue the [REDACTED];
- (iii) the [REDACTED] was approved and the Directors were authorized to effect the same and to allot and issue up to an aggregate of [REDACTED] Shares upon the exercise of the [REDACTED];
- (iv) a general mandate was given to our Directors to exercise all powers of our Company to allot, issue and deal with Shares or securities convertible into Shares and to make or grant offers, agreements or options (including any warrants, bonds, notes and debentures conferring any rights to subscribe for or otherwise receive Shares) which might require Shares to be allotted and issued or dealt with subject to the requirement that the aggregate number of our Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, otherwise than by way of the [REDACTED], rights issue or pursuant to the exercise of any subscription rights attaching to any warrants which may be allotted and issued by the Company from time to time or allotment and issue of Shares in lieu of the whole or part of a dividend on Shares in accordance with the Articles of Association on a specific authority granted by our Shareholders in a general meeting, shall not exceed the sum of (i) 20% of the aggregate number of our Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED] (but excluding any Shares which may be issued pursuant to the exercise of the [REDACTED]); and (ii) the aggregate number of shares of the Company purchased by the Company pursuant to the authority granted to the Directors as referred to in (b)(v) below;
- (v) a general mandate was given to our Directors to exercise all powers of our Company to repurchase its own Shares (the "**Repurchase Mandate**") on the Stock Exchange or on any other stock exchange on which the securities of our Company may be [REDACTED] and which is recognized by the SFC and the Stock Exchange for this purpose, in accordance with all applicable laws and the requirement of the Listing Rules such number of Shares as will represent up to 10% of the aggregate number of our Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED]; and

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- (vi) the general mandate as mentioned in paragraph (iv) above was extended by the addition to the aggregate number of our Shares which may be allotted and issued or agreed to be allotted and issued by our Directors pursuant to such general mandate of an amount representing the aggregate number of our Shares purchased by our Company pursuant to the Repurchase Mandate referred to in paragraph (v) above (up to 10% of the aggregate number of our Shares in issue immediately following the completion of the [REDACTED]).

Each of the general mandates referred to in paragraphs (c)(iv), (c)(v), and (c)(vi) above will remain in effect until whichever is the earliest of:

- the conclusion of the next annual general meeting of our Company;
- the expiration of the period within which the next annual general meeting of our Company is required to be held by any applicable law or the Articles; or
- the time when such mandate is revoked or varied by an ordinary resolution of the Shareholders in a general meeting.

5. Repurchase of our own securities

The following paragraphs include, among others, certain information required by the Stock Exchange to be included in this document concerning the repurchase of our own securities.

(a) Provision of the Listing Rules

The Listing Rules permit companies with a primary listing on the Stock Exchange to repurchase their own securities on the Stock Exchange subject to certain restrictions, the most important of which are summarized below:

(i) Shareholder's approval

All proposed repurchases of securities (which must be fully paid up in the case of shares) by a company with a primary listing on the Stock Exchange must be approved in advance by an ordinary resolution of the shareholders in a general meeting, either by way of general mandate or by specific approval of a particular transaction.

Pursuant to a resolution passed by our Shareholders on [●], 2023, the Repurchase Mandate was given to our Directors authorizing them to exercise all powers of our Company to repurchase Shares on the Stock Exchange, or on any other stock exchange on which the securities of our Company may be listed and which is recognized by the SFC and the Stock Exchange for this purpose, with a total nominal value up to 10% of the aggregate number of our Shares in issue immediately following the completion of the [REDACTED] and the

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

[REDACTED] with such mandate to expire at the earliest of (i) the conclusion of the next annual general meeting of our Company (unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions), (ii) the expiration of the period within which our Company's next annual general meeting is required by the Articles of Association or any other applicable laws to be held, and (iii) the date on which it is varied or revoked by an ordinary resolution of our Shareholders in a general meeting.

(ii) *Source of funds*

Purchases must be funded out of funds legally available for the purpose in accordance with the Memorandum and Articles and the applicable laws and regulations of Hong Kong and the Cayman Islands. A listed company may not purchase its own securities on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange from time to time. As a matter of Cayman law, any purchases by our Company may be made out of profits or out of the proceeds of a new issue of shares made for the purpose of the purchase or from sums standing to the credit of our share premium account and, in the case of any premium payable on the purchase over the par value of the shares to be purchased must have been provided for out of profits or from sums standing to the credit of our share premium account. Subject to the Cayman Companies Act, a repurchase of Shares may also be paid out of capital.

(iii) *Trading restrictions*

The total number of shares which a listed company may repurchase on the Stock Exchange is the number of shares representing up to a maximum of 10% of the aggregate number of shares in issue.

A company may not issue or announce a proposed issue of new securities for a period of 30 days immediately following a repurchase (other than an issue of securities pursuant to an exercise of warrants, share options or similar instruments requiring the company to issue securities which were outstanding prior to such repurchase) without the prior approval of the Stock Exchange. In addition, a listed company is prohibited from repurchasing its shares on the Stock Exchange if the purchase price is 5% or more than the average closing market price for the five preceding trading days on which its shares were traded on the Stock Exchange. The Listing Rules also prohibit a listed company from repurchasing its securities if the repurchase would result in the number of listed securities which are in the hands of the public falling below the relevant prescribed minimum percentage as required by the Stock Exchange. A listed company is required to procure that the broker appointed by it to effect a repurchase of securities discloses to the Stock Exchange such information with respect to the repurchase as the Stock Exchange may require.

(iv) Status of repurchased Shares

The listing of all purchased securities (whether on the Stock Exchange or otherwise) is automatically canceled and the relative certificates must be canceled and destroyed. Under the laws of the Cayman Islands, unless, prior to the purchase the Directors of our Company resolve to hold the shares purchased by our Company as treasury shares, shares purchased by our Company shall be treated as canceled and the amount of our Company's issued share capital shall be diminished by the nominal value of those shares. However, the purchase of shares will not be taken as reducing the amount of the authorized share capital under Cayman Islands laws.

(v) Suspension of repurchase

A listed company may not make any repurchase of securities after a price sensitive development has occurred or has been the subject of a decision until such time as the price sensitive information has been made publicly available. In particular, during the period of one month immediately preceding the earlier of (a) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of a listed company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules) and (b) the deadline for publication of an announcement of a listed company's results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), the listed company may not repurchase its shares on the Stock Exchange other than in exceptional circumstances. In addition, the Stock Exchange may prohibit a repurchase of securities on the Stock Exchange if a listed company has breached the Listing Rules.

(vi) Reporting requirements

Certain information relating to repurchases of securities on the Stock Exchange or otherwise must be reported to the Stock Exchange not later than 30 minutes before the earlier of the commencement of the morning trading session or any pre-opening session on the following Business Day. In addition, a listed company's annual report is required to disclose details regarding repurchases of securities made during the year, including a monthly analysis of the number of securities repurchased, the purchase price per share or the highest and lowest price paid for all such repurchases, where relevant, and the aggregate prices paid.

(vii) *Core connected persons*

The Listing Rules prohibit a company from knowingly purchasing securities on the Stock Exchange from a "core connected person", that is, a director, chief executive or substantial shareholder of the company or any of its subsidiaries or a close associate of any of them (as defined in the Listing Rules) and a core connected person shall not knowingly sell his securities to the company.

(b) *Reasons for repurchases*

Our Directors believe that it is in the best interests of our Company and Shareholders for our Directors to have a general authority from the Shareholders to enable our Company to repurchase Shares in the market. Such repurchases may, depending on market conditions and funding arrangements at the time, lead to an enhancement of the net asset value per Share or earnings per Share and will only be made where our Directors believe that such repurchases will benefit our Company and Shareholders.

(c) *Funding of repurchases*

Repurchase of the Shares must be funded out of funds legally available for such purpose in accordance with the Articles of Association and the applicable laws of the Cayman Islands.

Our Directors may not repurchase the Shares on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange. Subject to the foregoing, our Directors may make repurchases out of profits of the Company, out of the share premium account of the Company or out of the proceeds of a new issuance of shares made for the purpose of the repurchase and, in the case of any premium payable on the repurchase, out of profits of our Company or from sums standing to the credit of the share premium account of our Company. Subject to the Cayman Companies Act, a repurchase may also be made out of capital.

However, our Directors do not propose to exercise the general mandate to such an extent as would, in the circumstances, have a material adverse effect on the working capital requirements of our Company or its gearing levels which, in the opinion of our Directors, are from time to time appropriate for our Company.

(d) General

The exercise in full of the Repurchase Mandate, on the basis of [REDACTED] Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED], excluding any Shares which may be issued pursuant to the exercise of the [REDACTED], could accordingly result in up to approximately [REDACTED] Shares being repurchased by our Company during the period prior to the earliest of:

- the conclusion of the next annual general meeting of our Company unless renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions;
- the expiration of the period within which our Company's next annual general meeting is required by the Articles of Association or any other applicable laws to be held; or
- the date on which it is varied or revoked by an ordinary resolution of our Shareholders in a general meeting.

None of our Directors nor, to the best of their knowledge having made all reasonable enquiries, any of their associates currently intends to sell any Shares to our Company.

Our Directors have undertaken to the Stock Exchange that, so far as the same may be applicable, they will exercise the Repurchase Mandate in accordance with the Listing Rules and the applicable laws in the Cayman Islands.

If, as a result of any repurchase of Shares, a Shareholder's proportionate interest in the voting rights of our Company increases, such increase will be treated as an acquisition for the purposes of the Takeovers Code. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of our Company and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Code. Save as aforesaid, our Directors are not aware of any consequences which would arise under the Takeovers Code as a consequence of any repurchases pursuant to the Repurchase Mandate.

Any repurchase of Shares that results in the number of Shares held by the public being reduced to less than 25% of the Shares then in issue could only be implemented if the Stock Exchange agreed to waive the Listing Rules requirements regarding the public shareholding referred to above. It is believed that a waiver of this provision would not normally be granted other than in exceptional circumstances.

No core connected person of our Company has notified our Company that he or she has a present intention to sell Shares to our Company, or has undertaken not to do so, if the Repurchase Mandate is exercised.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of material contracts

The following contract (not being contracts entered into in the ordinary course of business) has been entered into by members of our Group within the two years preceding the date of this document and are or may be material:

- (a) the sixth amended and restated shareholders agreement dated September 5, 2022 entered into among our Company, HighTide Therapeutics USA, LLC, HighTide Therapeutics, Ltd., HighTide Therapeutics (Hong Kong) limited, HighTide Biopharma Pty. Ltd., Shenzhen HighTide Biopharmaceutical, Ltd. (深圳君聖泰生物技術有限公司), Shanghai HighTide Biopharmaceutical, Ltd. (上海君聖泰生物技術有限公司), JSK Consumer Healthcare Ltd. (深圳君聖康生物技術有限公司), Shanghai Fusion Therapeutics, Ltd. (上海福藥生物技術有限公司), Nanchang Fusion Therapeutics, Ltd. (南昌福藥生物技術有限公司), LIU Liping, Great Mantra Group Limited, Wisdom Spring Group Limited, Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司), Hepalink Biotechnology II Limited, Shenzhen Qianhai Haichuang Fund Partnership (Limited Partnership) (深圳市前海海創基金合夥企業(有限合夥)), Able Holdings International Limited, Goldlink Capital Fund SPC - Goldlink Greater China Fund SP V, Green Pine Growth Fund I LP, Greaty Investment Limited, ZT Global Energy Investment Fund I LP, Blue Ocean Healthcare Project I, Ltd, Orient Champion Investment Limited, Poly Platinum Enterprises Limited, Hongkong Tigermed Co., Limited, Pluto Connection Limited, Shenzhen Taixun Enterprise Management Consulting Partnership (Limited Partnership) (深圳泰洵企業管理諮詢合夥企業(有限合夥)), Shenzhen BioResearch Investment Fund, L.P. (深圳市柏奧瑞思投資合夥企業(有限合夥)), Shenzhen Winzac Jingfeng Venture Capital Enterprise (Limited Partnership) (深圳市穩正景豐創業投資企業(有限合夥)), Sichuan Rongxin Zhiyuan Industrial Co., Ltd (四川榮信致遠實業有限公司), Xinyu Cowin Guosheng Sci-Tech Innovation Investment Partnership (Limited Partnership) (新余市同創國盛科創產業投資合夥企業(有限合夥)), Ningbo Borui Allen Equity Investment Partnership (LLP) (寧波博睿艾倫股權投資合夥企業(有限合夥)), BAIYI Capital Limited, Hongtu Capital Limited, Guangzhou Yuexiu Jinchuan Phase IV Investment Fund Partnership (Limited Partnership) (廣州越秀金蟬四期投資合夥企業(有限合夥)) and Guangdong Chinese Medicine Comprehensive Health Equity Investment Fund Partnership (Limited Partnership) (廣東中醫藥大健康股權投資基金合夥企業(有限合夥)), together with (i) the deed of adherence dated November 2, 2022 entered into between our Company and Pingtan Rongjing Investment Partnership (Limited Partnership) (平潭榮景投資合夥企業(有限合夥)), and (ii) the deed of adherence dated November 2, 2022 entered into between our Company and MPCAPITAL INTERNATIONAL COMPANY LIMITED, in the form of the exhibit A to the sixth amended and restated shareholders agreement, pursuant to which the parties agreed on the terms and conditions to regulate the affairs of the Company and the rights of the shareholders; and
- (b) [REDACTED].

APPENDIX IV STATUTORY AND GENERAL INFORMATION

2. Intellectual property rights

(a) Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be or may be material to our business:

<u>No.</u>	<u>Marks</u>	<u>Category</u>	<u>Owner</u>	<u>Place of Registration</u>	<u>Registration Number</u>	<u>Registration date</u>	<u>Expiry Date</u>
1.		Class 5	Shenzhen HighTide	PRC	12220709	August 14, 2014	August 13, 2024
2.		Class 5	Shenzhen HighTide	PRC	12220741	January 14, 2015	January 13, 2025
3.	HIGHTIDE	Class 5	Shenzhen HighTide	PRC	12220722	August 14, 2014	August 13, 2024
4.	HIGHTIDE	Class 5 Class 10 Class 42 Class 44	Shenzhen HighTide	Hong Kong	305577607	August 10, 2021	March 28, 2031
5.	FUSIONTX	Class 5 Class 10	Shenzhen HighTide	PRC	58399584 58383642	February 7, 2022 February 14, 2022	February 6, 2032 February 13, 2032
6.		Class 5 Class 10 Class 42 Class 44	Shenzhen HighTide	Hong Kong	305739355	January 31, 2022	September 6, 2031
7.		Class 5 Class 10 Class 42 Class 44	Shenzhen HighTide	Hong Kong	305577599	August 10, 2021	March 28, 2031
8.		Class 10 Class 35 Class 44	Shenzhen HighTide	PRC	70397866 70415719 70410955	September 7, 2023	September 6, 2033

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

As of the Latest Practicable Date, we had applied for the registration of the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Place of Application	Application Number	Applicant	Application Date
1.	 HIGHTIDE	PRC	71496879	Shenzhen HighTide	May 11, 2023
2.	 HighTide	US	88047574	Shenzhen HighTide	July 22, 2018
3.	HIGHTIDE	US	88047279	Shenzhen HighTide	July 21, 2018
4.	FUSIONTX	US	97313672	U.S. HighTide	March 15, 2022
5.	   	Hong Kong	306242409	Shenzhen HighTide	May 12, 2023
6.	 君圣泰 HIGHTIDE	PRC	72529296	Shenzhen HighTide	June 29, 2023

APPENDIX IV STATUTORY AND GENERAL INFORMATION

(b) Patents

As of the Latest Practicable Date, we owned the following registered patent which we consider to be or may be material to our business:

No.	Type	Patent	Place of Registration	Patent Number	Owner	Authorization Announcement Date
1.	Invention	Berberine salts, ursodeoxycholic salts and combinations, methods of preparation and application thereof	Australia	2015296098	Shenzhen	June 17, 2019
			Canada	3174874		HighTide
			EPO	6917144		August 11, 2021
			Japan	201580041177.9		May 17, 2019
			PRC	10301303		May 28, 2019
			US	2945609		May 23, 2023
2.	Invention	Pharmaceutical composition comprising berberine ursodeoxycholic acid salt for the treatment of various diseases or disorders	US	10988471	Shenzhen HighTide	April 27, 2021
3.	Invention	Solid forms of berberine ursodeoxycholate and compositions and methods thereof	Australia	AU2018264384	Shenzhen	May 19, 2022
			PRC	108864077		HighTide
			US	10959999		March 30, 2021
4.	Invention	Compositions and methods of using islet neogenesis peptides and analogs thereof	Australia	2014231444	Shenzhen	July 19, 2018
			Canada	CA2906240		HighTide
			EPO	2970385		October 3, 2018
			Japan	7075918		May 26, 2022
			PRC	201410096363.X		April 16, 2019
			South Korea	102244349		April 23, 2021
	US	9388215		July 12, 2016		
	US	9738695		August 22, 2017		

APPENDIX IV STATUTORY AND GENERAL INFORMATION

As of the Latest Practicable Date, we filed the following patent applications which we consider to be or may be material to our business:

No.	Type	Patent	Place of Registration	Application Number	Applicant	Date of Application
1.	Invention	Berberine salts, ursodeoxycholic salts and combinations, methods of preparation and application thereof	South Korea	KR2017-7004835	Shenzhen HighTide	July 28, 2015
2.	Invention	Solid forms of berberine ursodeoxycholate and compositions and methods thereof	Canada EPO Japan South Korea	CA3062833 EP2018798004 JP2019562655 KR2019-7036227	Shenzhen HighTide	May 11, 2018

C. FURTHER INFORMATION ABOUT OUR DIRECTORS

1. Particulars of Directors’ service contracts and appointment letters

(a) Executive Directors

Each of our executive Directors, Dr. LIU Liping and Ms. YU Meng, has entered into a service contract with our Company on [●]. The initial term of their service contract shall commence from the date of their appointment as a Director and continue for a period of three years after or until the third annual general meeting of our Company since the [REDACTED], whichever is earlier, and shall be automatically renewed for successive periods of three years (subject always to re-election as and when required under the Articles), until terminated in accordance with the terms and conditions of the service contract or by either party giving to the other not less than three months’ prior notice in writing.

(b) Non-executive Directors and Independent non-executive Directors

Each of our non-executive Directors and independent non-executive Directors has entered into an appointment letter with our Company on [●]. The initial term for their appointment letters shall commence from the date of his appointment as a Director and continue for a period of three years after or until the third annual general meeting of our Company since the [REDACTED], whichever is earlier, and shall be automatically renewed for successive periods of three years (subject always to re-election as and when required under the Articles), until terminated in accordance with the terms and conditions of the appointment letter or by either party giving to the other not less than three months’ prior notice in writing.

2. Remuneration of Directors

Remuneration and benefits in kind of RMB8.8 million, RMB10.9 million and RMB12.6 million in aggregate were paid and granted by our Group to our Directors in respect of the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023, respectively.

Under the arrangements currently in force, our Directors will be entitled to receive remuneration and benefits in kind which, for the year ending December 31, 2023, is expected to be approximately RMB3.91 million in aggregate (excluding discretionary bonus and share-based compensation).

3. Disclosure of interests

(a) Interests and Short Positions of Our Directors and the Chief Executive of Our Company in the Share Capital of our Company and Its Associated Corporations Following Completion of the [REDACTED] and the [REDACTED]

Immediately following completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised), the interests or short positions of our Directors and chief executives in the Shares, underlying shares and debentures of our Company and its associated corporations, within the meaning of Part XV of the SFO, which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he/she is taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to Section 352 of the SFO, to be recorded in the register referred to therein, or which will be required to be notified to our Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers contained in the Listing Rules, will be as, follows:

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Name of Director or Chief Executive	Nature of Interest	Shares Held as of the Latest Practicable Date		Shares Held and Voting Rights Entitled immediately Following the Completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised) ⁽⁸⁾	
		Number	Approximate percentage	Number	Approximate percentage
Dr. Liu.	Founder of a discretionary trust ⁽¹⁾	13,500,000	16.04%	[REDACTED]	[REDACTED]%
	Interest held through voting powers entrusted by other persons and/or vested Shares ⁽²⁾	8,849,294	10.51%	[REDACTED]	[REDACTED]%
Mr. LI Li.	Interest in a controlled corporation ⁽³⁾	20,252,535	24.06%	[REDACTED]	[REDACTED]%
Mr. MA Lixiong . . .	Interest in a controlled corporation ⁽⁴⁾	5,032,359	5.98%	[REDACTED]	[REDACTED]%
	Interest held through voting powers of vested Shares ⁽⁵⁾	nil	nil	[REDACTED]	[REDACTED]%
Ms. YU Meng	Interest held through voting powers of vested Shares ⁽⁶⁾	nil	nil	[REDACTED]	[REDACTED]%
Dr. ZHU Xun	Interest held through voting powers of vested Shares ⁽⁷⁾	nil	nil	[REDACTED]	[REDACTED]%

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Notes:

- (1) Dr. Liu, being the investment advisor of the Family Trust, is entitled to exercise the voting rights attached to the 13,500,000 Shares held by the Founder BVI.
- (2) Dr. Liu was granted power of attorney to exercise the voting rights attached to the Shares held by the 2020 ESOP Platform pursuant to a deed executed by the trustee and the nominee of the 2020 Share Incentive Plan as well as our Company on November 28, 2019. Dr. Liu will not vote with unvested Shares upon [REDACTED] in compliance with Rule 17.05(A) of the Listing Rules.

Based on the vesting schedule of the Awards granted under the 2020 Share Incentive Plan, as of the Latest Practicable Date and immediately after the [REDACTED], Awards with up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares shall be vested (comprising [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) [REDACTED] Vesting Shares and [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares that were granted to Dr. Liu under the 2020 Share Incentive Plan). Pursuant to the voting agreements entered into by certain Grantees and the Company, Dr. Liu was entitled to the voting rights attached to the [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) [REDACTED] Vesting Shares. Immediately after the [REDACTED], Dr. Liu will abstain from voting on the [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) unvested Shares held in the 2020 ESOP Platform for the purpose of compliance with Rule 17.05A of the Listing Rules. As a result, the voting rights in the Company to be exercisable by Dr. Liu immediately after the [REDACTED] will be approximately [REDACTED]%, and the voting rights in the Company exercisable by the AIC Group shall become approximately [REDACTED]% (assuming the [REDACTED] is not exercised) immediately after the [REDACTED]. While the Hepalink Entities will become the single largest group of Shareholders of our Company upon [REDACTED] with approximately [REDACTED]% exercisable voting rights as a result of Dr. Liu having to abstain from voting the approximately [REDACTED]% unvested Shares as aforementioned, the AIC Group remains the group of Shareholders controlling the largest number of voting rights when taking into account the unvested Shares held by the 2020 ESOP Platform, and will continue to have day-to-day control over the management and operation of our Group.

- (3) As at the Latest Practicable Date, Mr. LI Li was interested in approximately 62.90% of the shares in Hepalink, which in turn indirectly wholly-owned Hepalink Biotechnology II Limited. Therefore, Mr. LI Li was deemed to be interested in the Shares held by Hepalink Biotechnology II Limited.
- (4) BAIYI Capital is wholly-owned investment holding company of AIH Capital L.P., which is controlled by Mr. MA Lixiong. Pingtan Rongjing is managed by its general partner, Yuthai Investment Management Co., Ltd., which is owned as to 80% by Mr. MA Lixiong. Therefore, Mr. MA Lixiong is deemed to be interested in the Shares held by BAIYI Capital and Pingtan Rongjing under the SFO.
- (5) On the [REDACTED], Awards with up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares that were granted to Mr. MA Lixiong shall be [REDACTED] Vesting Shares.
- (6) On the [REDACTED], Awards with up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares that were granted to Ms. YU Meng shall be [REDACTED] Vesting Shares.
- (7) On the [REDACTED], Awards with up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares that were granted to Dr. ZHU Xun shall be [REDACTED] Vesting Shares.
- (8) The unvested Shares held in the 2020 ESOP Platform and the 2023 ESOP Platform and the Shares to be repurchased from the 2023 ESOP Platform have been excluded from both the denominator and the numerator when calculating the percentage of the exercisable voting rights immediately upon [REDACTED].

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

(b) *Interests and Short Positions Discloseable under Divisions 2 and 3 of Part XV of the SFO*

For information on the persons who will, immediately following the completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised), having or be deemed or taken to have beneficial interests or short position in our Shares or underlying shares which would fall to be disclosed to our Company under the provisions of 2 and 3 of Part XV of the SFO, or directly or indirectly be interested in 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Company, see the section headed "Substantial Shareholders" in this document.

Save as set out above, as of the Latest Practicable Date, our Directors were not aware of any persons who would, immediately following the completion of the [REDACTED] and the [REDACTED], be interested, directly or indirectly, in 5% or more of the nominal of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group or had option in respect of such capital.

4. Disclaimers

Save as disclosed in this document:

- (a) there are no existing or proposed service contracts (excluding contracts expiring or determinable by the employer within one year without payment of compensation (other than statutory compensation)) between our Directors and any member of our Group;
- (b) none of our Directors or the experts named in the paragraph headed "— E. Other Information — 4. Qualifications and consents of Experts" in this Appendix has any direct or indirect interest in the promotion of, or in any assets which have been, within the two years immediately preceding the date of this document, acquired or disposed of by or leased to any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group;
- (c) save as in connection with the [REDACTED], none of our Directors nor any of the experts named in the paragraph headed "— E. Other Information — 4. Qualifications and consents of experts" in this Appendix is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group as a whole;
- (d) taking no account of any Shares which may be taken up under the [REDACTED] and the [REDACTED], so far as is known to any Director or chief executive of our Company, no other person (other than a Director or chief

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

executive of the Company) will, immediately following completion of the [REDACTED] and the [REDACTED], have interests or short positions in the Shares and underlying Shares which would fall to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or (not being a member of the Group), be interested, directly or indirectly, in 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group;

- (e) none of our Directors or chief executive of our Company has any interests or short positions in the Shares, underlying shares or debentures of the Company or its associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he is taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to Section 352 of the SFO, to be entered into the register referred to therein, or will be required, pursuant to the Model Code for Securities Transaction by Directors of Listed Issuers, to be notified to the Company and the Stock Exchange once the Shares are [REDACTED] thereon;
- (f) save in connection with the [REDACTED], none of the experts named in the paragraph headed “— E. Other Information — 4. Qualifications and consents of experts” in this Appendix: (i) is interested legally or beneficially in any of our Shares or any shares in any of our subsidiaries; or (ii) has any right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group; and
- (g) none of our Directors or their respective close associates or any Shareholders of our Company (who to the knowledge of our Directors owns more than 5% of the number of our issued shares) has any interest in our five largest suppliers or our five largest customers.

D. INCENTIVE PLANS

1. 2020 SHARE INCENTIVE PLAN

The 2020 Share Incentive Plan was originally adopted by the Board on January 22, 2020, amended and restated by the Board on October 18, 2021 and further amended and restated in its entirety on March 4, 2022. The terms of the 2020 Share Incentive Plan are not subject to the provisions of Chapter 17 of the Listing Rules as it does not involve any grant of awards by our Company to subscribe for new Shares after the [REDACTED]. After [REDACTED], no further awards or other type of awards would be granted pursuant to the 2020 Share Incentive Plan. All the Shares underlying the Awards granted under the 2020 Share Incentive Plan have been issued and allotted to the 2020 ESOP Platform for future exercise of the Awards.

The following is a summary of the principal terms of the 2020 Share Incentive Plan.

Summary of Key Terms

(a) *Purpose*

The purpose of the 2020 Share Incentive Plan is to enable the Company to attract and retain the best available personnel, to provide additional incentives to employees, Directors and consultants and to promote the success of the Company's business.

(b) *Who May Join*

Eligible participants ("**Eligible Participants**") means any person belonging to any of the following classes of persons:

- (i) any person who is in the employment of the Group;
- (ii) a member of the Board or the board of directors of any affiliate of the Company; or
- (iii) any person who is engaged by the Group to render consulting or advisory services.

Subject to above classes,

share options (the "**Options**") or restricted share units (the "**RSUs**") shall be granted to the grantee who:

- (i) is department manager, key technical staff of the Group;
- (ii) has made a significant contribution to the Company; or
- (iii) meet such other conditions as determined by Board.

restricted shares ("**Restricted Shares**", together with the Options and the RSUs, the "**Awards**") or RSUs shall be granted to the grantee who is management personnel and:

- (i) has established labor/employment relationship with the Company or its subsidiaries before December 31, 2015 and the continuous service of the grantee is not terminated up to the date of the Award agreement;
- (ii) has made a significant contribution to the Company;
- (iii) is critical to the future development of the Company; or
- (iv) meet such other conditions as determined by Board.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

(c) *Administration of the 2020 Share Incentive Plan*

The 2020 Share Incentive Plan shall be administered by (A) the Board, (B) a committee (the "**Committee**") designated by the Board, which Committee shall be constituted in accordance with the applicable laws and the Articles of Association, or (C) any person appointed by the Board ("**Person**", together with the Board and the Committee, the "**Administrator**"). Once appointed, such Committee or the Administrator shall continue to serve in its designated capacity until otherwise directed by the Board. The Board may authorize one or more officers or Directors to grant the Awards and may limit such authority as the Board determines from time to time.

Subject to applicable laws and the provisions of the 2020 Share Incentive Plan (including any other powers given to the Administrator under the 2020 Share Incentive Plan), and except as otherwise provided by the Board, the Administrator shall have the authority, in its discretion:

- (i) to select Eligible Participants to whom Awards may be granted from time to time;
- (ii) to determine whether and to what extent Awards are granted;
- (iii) to determine the type or the number of Awards to be granted, the number of Shares or the amount of consideration to be covered by each Award granted;
- (iv) to approve forms of Award agreements for use, to amend terms of the Award agreements;
- (v) to determine the terms and conditions of any Award granted under the 2020 Share Incentive Plan (including without limitation the vesting schedule and exercise price set forth in the notice of Award and the Award agreements), including the purchase, exercise or base price, the time or times when Awards may be exercised (which may be based on performance criteria), any forfeiture events, any vesting acceleration or waiver of forfeiture restrictions, and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Administrator determines;
- (vi) to amend the terms of any outstanding Award granted under the 2020 Share Incentive Plan;
- (vii) to construe and interpret the terms of the 2020 Share Incentive Plan and Awards, including without limitation the vesting schedule and exercise price set forth in the notice of Award and the Award agreements;

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- (viii) to require the grantee to provide representation or evidence that any currency used to pay the exercise price of any Award was legally acquired and taken out of the jurisdiction in which the grantee resides in accordance with the applicable laws;
 - (ix) to establish sub-plans or separate program under the Share Incentive Plan, containing such limitations and other terms and conditions as the Administrator determines are necessary or desirable, for the purpose of satisfying blue sky, securities, tax or other laws of various jurisdictions in which the Company intends to grant Awards or qualifying for favorable tax treatment under applicable foreign laws;
 - (x) to correct any defect, omission or inconsistency in the Share Incentive Plan or any Award agreement, in a manner and to the extent it deems necessary or advisable to make the 2020 Share Incentive Plan fully effective;
 - (xi) to authorize any individual to execute, on behalf of the Company, any instrument required to carry out the purpose of the 2020 Share Incentive Plan;
 - (xii) to determine the fair market value;
 - (xiii) to take such other action, not inconsistent with the terms of the 2020 Share Incentive Plan and the applicable laws, as the Administrator deems appropriate.
- (d) *Term and transferability of the Award*

The management personnel should nominate eligible candidates according to the 2020 Share Incentive Plan and advise the conditions of the Award to be granted to such candidates.

The term of each Award shall be the term stated in the Award agreement. Notwithstanding the foregoing, the specified term of any Award shall not include any period for which the grantee has elected to defer the receipt of the Shares of cash issuable pursuant to the Award. In the case of an Option granted to an United States taxpayer who, at the time the Option is granted ("**Grant Date**"), owns (or, pursuant to Section 424(d) of the United States Code, is deemed to own) stock representing more than 10% of the total combined voting power of all classes of Shares of the Company or any subsidiary or affiliate, the term of the Option will not be longer than ten years from the Grant Date. The Grant Date of an Award shall for all purposes be the date on which the Administrator makes the determination to grant such Award, or such other date as is determined by the Administrator.

Subject to the Applicable Laws, Awards shall be transferable by will and by the laws of descent and distribution, only to the extent and in the manner approved by the Administrator. Notwithstanding the foregoing, the grantee may designate one or more

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

beneficiaries of the grantee's Award in the event of the grantee's death on a beneficiary designation form provided by the Administrator.

(e) *Exercise or Purchase Price*

The exercise price of the Options and the purchase price of the RSUs shall be the price determined by the Administrator as of the Grant Date. There is no purchase price for the Restricted Shares. Subject to Applicable Laws, the consideration to be paid for the Shares to be issued upon exercise or purchase of an Award including the method of payment, shall be determined by the Administrator. In addition to any other types of consideration the Administrator may determine, the Administrator is authorized to accept as consideration for Shares issued under the 2020 Share Incentive Plan the following:

- (i) cash;
- (ii) cheque;
- (iii) if the exercise or purchase occurs on or after the [REDACTED], or as otherwise permitted by the Administrator, surrender of Shares or delivery of a properly executed form of attestation of ownership of Shares as the Administrator may require which have a fair market value on the date of surrender or attestation equal to the aggregate exercise price of the Shares as to which said Award shall be exercised;
- (iv) with respect to Options or RSUs, if the exercise occurs on or after the [REDACTED], payment through a broker-dealer sale and remittance procedure pursuant to which the grantee (A) shall provide written instructions to a Company designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (B) shall provide written directives to the Company to deliver the certificates for the purchased Shares directly to such brokerage firm in order to complete the sale transaction; or
- (v) any combination of the foregoing methods of payment.

(f) *Exercise of Award*

Any Award granted under the 2020 Share Incentive Plan shall be exercisable at such times and under such conditions as determined by the Administrator under the terms of the 2020 Share Incentive Plan and specified in the Award agreement.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

An Award shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Award by the person entitled to exercise the Award and full payment for the Shares with respect to which the Award is exercised, including to the extent selected, use of the broker-dealer sale and remittance procedure to pay the purchase price as provided in paragraph (e)(iv).

An Award may not be exercised after the termination date of such Award set forth in the Award agreement and may be exercised following the termination of a grantee's continuous service only to the extent provided in the Award agreement. Where the Award agreement permits a grantee to exercise an Award following the termination of the grantee's continuous service for a specified period, the Award shall terminate to the extent not exercised on the last day of the specified period or the last day of the original term of the Award, whichever occurs first.

Notwithstanding the foregoing, regardless of whether an Award has otherwise become exercisable, the Award shall not be exercised if the Administrator (in its sole discretion) determines that an exercise would violate any applicable laws. Shares shall not be issued pursuant to the exercise of an Award unless the exercise of such Award and the issuance and delivery of such Shares pursuant thereto shall comply with all applicable laws (including all relevant filings, approvals and registrations (if any) required under the laws PRC) with respect to the exercise of such Award including without limitation, those required with the PRC State Administration of Foreign Exchange as determined to be necessary or desirable by the Board of Directors in its discretion), and shall be further subject to the approval of counsel for the Company with respect to such compliance.

(g) Termination

An Award shall lapse automatically and not be exercisable (to the extent not already exercised):

- (i) in the event the grantee's continuous service terminates as a result of his/her retirement, death, permanent disability prevents from working, resignation or company terminates his/her employment;
- (ii) in the event the grantee's continuous service terminates due to bad faith causes;
- (iii) in the event change in control of the Company or corporate transaction as defined as below:
 - (as determined by the Administrator acting reasonably) a change in ownership or control of the Company effected through the direct or indirect acquisition by any person or related group of persons (other than an acquisition from or by the Company or by a Company sponsored employee benefit plan or by an affiliate of the Company) of beneficial ownership of securities possessing

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's shareholders which a majority of the Directors who are not affiliates or associates of the offeror do not recommend such shareholders accept;

- (as determined by the Administrator acting reasonably) a merger, amalgamation, consolidation or other business combination of the Company with or into any person, in which the Company is not the surviving entity, or any other transaction or series of transactions, as a result of which the Shareholders of the Company immediately prior to such transaction or series of transactions will cease to own a majority of the voting power of the surviving entity immediately after consummation of such transaction or series of transactions, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated;
- the sale, transfer, exclusive license or other disposition of all or substantially all of the assets of the Group;
- the complete liquidation or dissolution of the Company;
- any reverse merger or series of related transactions culminating in a reverse merger (including, but not limited to, a tender offer followed by a reverse merger) in which the Company is the surviving entity but (A) the ordinary Shares outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (B) in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger or the initial transaction culminating in such merger, but excluding any such transaction or series of related transactions that the Administrator determines shall not be a corporate transaction; or
- acquisition in a single or series of related transactions by any person or related group of persons of beneficial ownership of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities, but excluding any such transaction or series of related transactions that the Administrator determines shall not be a corporate transaction.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

(h) Maximum Number of Shares

The maximum number of Shares in respect of which Awards may be granted under the 2020 Share Incentive Plan is 8,849,294 ([REDACTED] as adjusted after the [REDACTED]) Shares (the "2020 Scheme Limit"). All 8,849,294 Shares underlying the Awards granted under the 2020 Share Incentive Plan have been issued and allotted to the 2020 ESOP Platform for future exercise of the Awards.

Any Shares covered by an Award (or portion of an Award) which is forfeited, canceled or expires (whether voluntarily or involuntarily) shall be deemed not to have been issued for purposes of determining the maximum aggregate number of Shares which may be issued under the 2020 Share Incentive Plan. Shares that actually have been issued under the 2020 Share Incentive Plan pursuant to an Award shall not be returned to the 2020 Share Incentive Plan and shall not become available for future issuance under the 2020 Share Incentive Plan, except that if the Shares subject to an outstanding Award are not issued or delivered or are returned to the Company by reason of (i) expiration, termination, cancellation or forfeiture of such Award, (ii) the settlement of such Award in cash, (iii) the delivery or withholding of Shares to pay all or a portion of the exercise price of an Award, if any, or to satisfy all or a portion of the tax withholding obligations relating to an Award, such Shares shall revert to and become available for future grant under the 2020 Share Incentive Plan. To the extent not prohibited by the applicable law and the listing requirements of the applicable stock exchange or national market system on which the Shares are traded, any Shares covered by an Award which are surrendered (i) in payment of the Award exercise or purchase price or (ii) in satisfaction of tax withholding obligations incident to the exercise of an Award shall be deemed not to have been issued for purposes of determining the maximum number of Shares which may be issued pursuant to all Awards under the 2020 Share Incentive Plan, unless otherwise determined by the Administrator.

(i) Adjustments upon Changes in Capitalization

Subject to any required action by Shareholders of the Company, the number of Shares covered by each outstanding Award, the number of Shares which have been authorized for issuance under the 2020 Share Incentive Plan but as to which no Awards have yet been granted or which have been returned to the 2020 Share Incentive Plan, the exercise or purchase price of each such outstanding Award, the maximum number of Shares with respect to which Awards may be granted to any Grantee in any fiscal year of the Company, as well as any other terms that the Administrator determines require adjustment shall be proportionately adjusted for (i) any increase or decrease in the number of issued Shares resulting from a share split, reverse share split, share dividend, combination or reclassification of the Shares, or similar transaction affecting the Shares, (ii) any other increase or decrease in the number of issued Shares effected without receipt of consideration by the Company, or (iii) as the Administrator may determine in its discretion, any other transaction with respect to Shares including a corporate merger, consolidation, acquisition of property or equity, separation (including a spin-off or other distribution of shares or property),

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

reorganization, liquidation (whether partial or complete) or any similar transaction; provided, however that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Administrator and its determination shall be final, binding and conclusive. Except as the Administrator determines, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, shall affect, and no adjustment by reason hereof shall be made with respect to, the number or price of Shares subject to an Award. In the event of a spin-off transaction, the Administrator may in its discretion make such adjustments and take such other action as it deems appropriate with respect to outstanding Awards under the 2020 Share Incentive Plan, including but not limited to: (i) adjustments to the number and kind of Shares, the exercise or purchase price per Share and the vesting periods of outstanding Options, (ii) prohibit the exercise of Awards during certain periods of time prior to the consummation of the spin-off transaction, or (iii) the substitution, exchange or grant of Awards to purchase securities of the subsidiary; provided that the Administrator shall not be obligated to make any such adjustments or take any such action under the 2020 Share Incentive Plan.

(j) Amendment, Suspension or Termination of the 2020 Share Incentive Plan

The Board may at any time amend, suspend or terminate the 2020 Share Incentive Plan; provided, however, that no such amendment shall be made without the approval of the Shareholders to the extent such approval is required by applicable laws or if such amendment would change the provision of this paragraph:

(k) Dividend and voting rights

Unless and until the Shares underlying an Award are actually issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to receive dividends or other distributions will exist with respect to the Shares underlying such Award, notwithstanding the exercise of the Award. If any such dividends or distributions are paid in Shares, such Shares will be subject to the same restrictions on transferability and forfeitability as the Restricted Shares with respect to which they were paid. The dividends and distributions shall be held by the 2020 ESOP Platform and distributed to the Grantees, unless the Grantee has held relevant Shares of the Company as permitted by the Administrator.

Except as otherwise provided in the 2020 Share Incentive Plan or the applicable Award agreement, no Grantee will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any Shares underlying an Award which has not been vested and exercised. All the rights of a holder with respect to any such Shares shall be exercised by the 2020 ESOP Platform prior to the [REDACTED].

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Details of the Awards granted, including Awards exercised or outstanding, under this scheme shall be disclosed in the circular to shareholders of the Company seeking approval of the new scheme established after the termination of this scheme.

Outstanding Awards

As of the Latest Practicable Date, all the Awards available for granting under the 2020 Share Incentive Plan have been granted, and therefore the aggregate number of underlying Shares pursuant to the outstanding Awards granted under the 2020 Share Incentive Plan is 8,849,294 ([REDACTED] as adjusted after the [REDACTED]) Shares, representing all Shares held by the 2020 ESOP Platform. Upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised), the aggregate number of Shares underlying all Awards granted represents approximately [REDACTED]% of the issued Shares immediately following the completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED].

As of the Latest Practicable Date, the outstanding Awards which have been granted under the 2020 Share Incentive Plan for an aggregate of 8,849,294 ([REDACTED] as adjusted after the [REDACTED]) Shares have been granted to a total of 55 Eligible Participants, 13 of whom are Directors or members of the senior management or connected persons of our Company or consultants of our Group. The outstanding Awards granted under the 2020 Share Incentive Plan were granted at nil consideration to each of the relevant Eligible Participant with an exercise price of US\$0.81 to US\$2.82 per Share. The exercise period of the Awards granted is ten years commencing from the date upon which the Awards are deemed to be granted and accepted pursuant to the terms of the 2020 Share Incentive Plan.

All the Shares subject to the Awards have been allotted and issued and are held by the 2020 ESOP Platform as of the Latest Practicable Date. Accordingly, if all the Awards granted under the 2020 Share Incentive Plan are exercised, there will not be any dilution effect on the shareholdings of our Shareholders nor any impact on the earnings per Share arising from the exercise of the outstanding Awards. The Shares underlying the Awards under the 2020 Share Incentive Plan that have not been granted to any specific grantee prior to [REDACTED] will be repurchased and cancelled.

An [REDACTED] has been made to the Stock Exchange for the [REDACTED] of, and permission to deal in, the Shares held by the 2020 ESOP Platform for the purpose of the 2020 Share Incentive Plan. Unvested Shares under the 2020 Share Incentive Plan will abstain from voting upon [REDACTED] in compliance with Rule 17.05(A) of the Listing Rules.

APPENDIX IV STATUTORY AND GENERAL INFORMATION

The table below shows the details of Awards (all being Options) granted under the 2020 Share Incentive Plan that are outstanding as of the Latest Practicable Date.

Grantee	Position/ Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price <i>(US\$ per Share)</i>	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
Directors								
Dr. Liu	Founder, executive Director and chief executive officer of our Company	703, Building 4, Jiixin Garden,	545,642	December 17, 2020	Four years ⁽²⁾	0.81	Nil	[REDACTED]%
		Longcheng Street, Longgang District, Shenzhen,	272,821	December 30, 2021	Four years ⁽²⁾	1.06	Nil	[REDACTED]%
		Guangdong, PRC	849,031	April 1, 2023	Four years ⁽²⁾	2.82	Nil	[REDACTED]%
Ms. YU Meng (于萌)	Executive Director, deputy general manager of our Company	6-2-506 Wendelford Garden,	280,182	March 31, 2022	Four years ⁽²⁾	1.06	Nil	[REDACTED]%
		Houhai Avenue, Nanshan District, Shenzhen, Guangdong, PRC	325,246	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Dr. ZHU Xun (朱迅)	Non-executive Director	Room 402, Building 33,	174,126	December 30, 2021	Four years ⁽²⁾	1.06	Nil	[REDACTED]%
		Yumingbiyuan Guangsheng Road, Jiangang Hill, Bao'an District, Shenzhen, Guangdong, PRC	48,692	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Mr. MA Lixiong (馬立雄)	Non-executive Director	Room 1608, International Chamber of Commerce Center, No. 168	71,932	December 30, 2021	Four years ⁽²⁾	1.06	Nil	[REDACTED]%
		Fuhua 3rd Road, Futian District, Shenzhen, Guangdong, PRC	515,832	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Subtotal			3,083,504					[REDACTED]%

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Grantee	Position/ Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price <i>(US\$ per Share)</i>	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
Senior management of our Company who are not Directors								
Dr. Leigh Anne MACCONNELL	Chief development officer of our Company	773 Corinia Court, Olivenhain, CA 92024 United States	240,000 248,031	February 1, 2021 April 1, 2023	Four years ⁽²⁾ Four years ⁽²⁾	0.81 2.82	Nil Nil	[REDACTED] % [REDACTED] %
Mr. SIM Koon Yin Edmund (沈觀賢)	Chief financial officer of our Company	Flat F, 6/F, Tower 16, South Horizons, Ap Lei Chau, Hong Kong	800,000	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED] %
Dr. MA Tianwei (馬天偉)	Vice president of discovery research	Room 901, No. 6 Lane 288, Yupan North Road, Pudong New Area, Shanghai, PRC	206,960	April 1, 2023	Four years ⁽²⁾	2.82	Nil	[REDACTED] %
Ms. BAI Ru (白茹)	Director of non-clinical development	Room 4603, Building 1, Baolan Yayuan, No. 1 Cuiqing Road, Baolong Street, Longgang District, Shenzhen, Guangdong, PRC	234,387 122,067	March 31, 2022 April 1, 2023	Four years ⁽²⁾ Four years ⁽²⁾	1.06 1.97	Nil Nil	[REDACTED] % [REDACTED] %
Ms. YU Li (于莉)	Vice president	Room 1618, Building 16, Zhonghaixin Innovation Industrial City, Ganli 2nd Road, Jihua Street, Longgang District, Shenzhen, Guangdong, PRC	762,088 365,851 970,175	March 31, 2022 April 1, 2023 September 1, 2023	Four years ⁽²⁾ Four years ⁽²⁾ Four years ⁽²⁾	1.06 1.97 1.97	Nil Nil Nil	[REDACTED] % [REDACTED] % [REDACTED] %
Subtotal			3,949,559					[REDACTED] %
Connected person of our Company who is not a Director								
Mr. YANG Feng (楊鋒)	Former director of our Company ⁽⁵⁾	Block 10-2B, Xi'Gu Garden, Xicheng Villa, Bao'an District, Shenzhen, Guangdong, PRC	39,999	December 30, 2021	Four years ⁽²⁾	1.06	Nil	[REDACTED] %
Subtotal			39,999					[REDACTED] %

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Grantee	Position/ Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price <i>(US\$ per Share)</i>	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
Consultants of our Group⁽⁶⁾								
Dr. Adrian M. DI BISCEGLIE . . .	Medical advisor of our Group	3005 Salena Street, St. Louis, MO 63118 United States	68,393	January 1, 2021	Four years ⁽²⁾	0.81	Nil	[REDACTED]%
Ms. Gwen A. MELINCOFF . . .	Business Advisor of our Group	262 South 16th Street, Unit 4, Philadelphia, PA 19102 United States	18,860	December 17, 2020	Four years ⁽²⁾	0.81	Nil	[REDACTED]%
Mr. LI Chun (李春)	Organization Advisor of our Group	Room 1001, No. 29 Baihuiyuan, Lane 183, Yunjin Road, Xuhui District, Shanghai, PRC	50,951	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Subtotal			138,204					[REDACTED]%
Other employees of our Group								
FU Xinxiang (付鑫祥)	Director ⁽⁴⁾	B2102, Yaxuan, Tianyue No. 1, Section 25, Bao'an District, Shenzhen, Guangdong, PRC	141,372	March 31, 2022	Four years ⁽²⁾	1.06	Nil	[REDACTED]%
			88,891	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Myleen Ignacio LEONCAVA . . .	Senior vice president	630 Elk River Drive, Ormond Beach, FL 32174 USA	50,000	March 31, 2022	Four years ⁽²⁾	1.72	Nil	[REDACTED]%
FU Wenjun (付文俊)	Director ⁽⁴⁾	703, Building 2, Nanshan Jian Gong Village, Nantou Street, Nanshan District, Shenzhen, Guangdong, PRC	92,244	March 31, 2022	Four years ⁽²⁾	1.06	Nil	[REDACTED]%
			52,028	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Jeffrey J. DAO . . .	Head of U.S. Operations	726 Barneson Avenue, San Mateo, CA 94402 U.S.	64,775	March 31, 2021	Four years ⁽²⁾	0.81	Nil	[REDACTED]%
			40,299	April 1, 2023	Four years ⁽²⁾	2.82	Nil	[REDACTED]%
XIE Liming (谢黎明)	Clinical Quality assurance Manager	5H, Unit 2, Building 3, North Zone, Zuotingyuyuan, Nanwan Street, Longgang District, Shenzhen, Guangdong, PRC	91,176	March 31, 2022	Four years ⁽²⁾	1.06	Nil	[REDACTED]%
			40,680	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%

APPENDIX IV STATUTORY AND GENERAL INFORMATION

Grantee	Position/ Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price <i>(US\$ per Share)</i>	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
Jin CHEN	Senior vice president	6 Tulip Lane Randolph, NJ 07869, U.S.	130,084	December 30, 2021	Four years ⁽²⁾ for Awards underlying which are 70,084 Shares; vesting per milestone for remaining Awards ⁽⁷⁾	1.72	Nil	[REDACTED]%
Cathryn M. BENNETT	Vice president	5295 Oswego Circle, Palm Springs, CA 92264 U.S.	71,792	December 17, 2020	Four years ⁽²⁾	1.72	Nil	[REDACTED]%
LIU Kui (劉奎)	Senior director ⁽⁴⁾	Room 101, No. 22 Lane 1169, Kongjiang Road, Yangpu District, Shanghai, PRC	48,228	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
GAO Liping (高麗萍)	Director ⁽⁴⁾	No. 299 Xuanhua Road, Changning District, Shanghai, PRC	49,457	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Alexander LIBERMAN	Associate director ⁽⁴⁾	836 West Pennsylvania Ave Apt 307, San Diego, CA 92103, U.S.	23,423 12,256	December 30, 2021 April 1, 2023	Four years ⁽²⁾ Four years ⁽²⁾	1.06 2.82	Nil Nil	[REDACTED]%, [REDACTED]%
ZHANG Yanli (張曉麗)	Regulatory affairs department manager	Unit 607, Building 4, Unit 1, Blue Diamond Tiancheng, No. 969 Moganshan Road, Xiangfu Street, Gongshu District, Hangzhou, Zhejiang, PRC	19,254 26,740	March 31, 2022 April 1, 2023	Four years ⁽²⁾ Four years ⁽²⁾	1.06 1.97	Nil Nil	[REDACTED]%, [REDACTED]%
ZHANG Lin (張琳)	Director ⁽⁴⁾	Room 308, Building 10, Huilong Garden, No. 30 Kaifeng Road, Futian District, Shenzhen, Guangdong, PRC	23,423 12,952	March 31, 2022 April 1, 2023	Four years ⁽²⁾ Four years ⁽²⁾	1.06 1.97	Nil Nil	[REDACTED]%, [REDACTED]%
CHEN Zhaobin (陳兆斌)	Formulation manager	Room 1519, Building 8, Xinge District, No. 9 Linyuan East Road, Futian District, Shenzhen, Guangdong, PRC	14,209 15,694	March 31, 2022 April 1, 2023	Four years ⁽²⁾ Four years ⁽²⁾	1.06 1.97	Nil Nil	[REDACTED]%, [REDACTED]%
ZHOU Haoran (周皓然)	Director ⁽⁴⁾	Room 2205, Weijian Building, No. 1005, Fuqiang Road, Futian District, Shenzhen, Guangdong, PRC	26,774	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%

APPENDIX IV STATUTORY AND GENERAL INFORMATION

Grantee	Position/ Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price <i>(US\$ per Share)</i>	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
Kjersti SWEARINGEN	Associate director ⁽⁴⁾	3210 219th Avenue SE, Snohomish, WA 98290, U.S.	23,423	December 30, 2021	Four years ⁽²⁾	1.06	Nil	[REDACTED]%
WANG Niwen (王妮文)	Executive assistant, administrative manager	Room 309, Building 7, Phase 1, Chengxiang Garden, No. 28 Zhonghao 2nd Road, Longgang District, Shenzhen, Guangdong, PRC	10,833 8,918	March 31, 2022 April 1, 2023	Four years ⁽²⁾ Four years ⁽²⁾	1.06 1.97	Nil Nil	[REDACTED]%, [REDACTED]%
Rochelle Rubik S. BARLIS	Manager	1778 Paterna Drive, Chula Vista, CA 91913 U.S.	17,552	December 17, 2020	Four years ⁽²⁾	0.81	Nil	[REDACTED]%
WANG Rong (王璐)	Director ⁽⁴⁾	1103, Building B1, Ganglongcheng, Baomin 2nd Road, Xixiang Street, Bao'an District, Shenzhen, Guangdong, PRC	15,238	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
LI Yingzi (李英姿)	Director ⁽⁴⁾	B1-18b, Tianji Mansion, No. 45 Longguan East Road, Longhua Stage, Longhua District, Shenzhen, Guangdong, PRC	15,238	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
FAN Ziqi (範子琦)	Senior project manager	Room 604, Unit C, Building 3, Phase 2, Shiwufeng Garden, Longzhu 6th Road, Nanshan District, Shenzhen, Guangdong, PRC	14,457	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
LIU Haowen (劉浩文)	Project manager	Room 1405, Building 1, Phase I, Bantian Chengxiang Garden, Longgang, Shenzhen, Guangdong, PRC	7,708	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
HUANG Weixin (黃偉鑫)	Project manager	Room 1412, No. 63, East Sixth Lane, Fenghuanggang Village, Xixiang, Bao'an District, Guangdong, PRC	7,641	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
HUANG Yi (黃宜)	Senior project manager	9A401, Langju Homeland, No. 3355, Liuxian Avenue, Nanshan District, Shenzhen, Guangdong, PRC	10,638	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%

APPENDIX IV STATUTORY AND GENERAL INFORMATION

Grantee	Position/ Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price <i>(US\$ per Share)</i>	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
LI Youlan (李有蘭)	Senior project manager	Chengxiang Garden Phase I, Xiangjiaotang Community, Bantian Street, Longgang District, Shenzhen, Guangdong, PRC	7,569	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
ZHONG Lijun (鐘麗君)	Quality assurance manager	4A1003, Shangshui Tiancheng Community, Xiashui Path, Jihua Street, Longgang District, Guangdong, PRC	5,562	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
SONG Yanqin (宋曉琴)	Office manager	Room 901, No. 179, Lane 6130, Jiasang North Road, Jiading District, Shanghai, PRC	5,000	March 31, 2022	Four years ⁽²⁾	1.72	Nil	[REDACTED]%
			2,180	April 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
JOSEPH GUGLIOTTA . .	Clinical operation manager	1383 Oakridge Court, Thousand Oaks, CA 91362 U.S.	4,000	March 31, 2022	Four years ⁽²⁾	1.72	Nil	[REDACTED]%
LEI Fen (雷芬)	Vice president of corporate affairs	Room 1405, Biyue Pavilion, Biling Huating, Taibai Road, Luohu District, Shenzhen, Guangdong, PRC	220,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
LI Guodong (李國棟)	Drug metabolism and pharmacokinetics project director	Room 801, No. 18, Lane 1978, Yuqiao Road, Beicai Town, Pudong New Area, Shanghai, PRC	11,455	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
SHEN Zhengnan (沈錚男)	Principal scientist	Room 301, No. 20, Lane 1296, Gaosi Road, Pudong New Area, Shanghai, PRC	15,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[0.02]%
XIA Guoping (夏郭平)	Director of discovery pharmacokinetic/ pharmacodynamic	Room 301, No. 29, Lane 31, Shouguang Road, Pudong New Area, Shanghai, PRC	11,455	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[0.01]%
JIANG Lidan (薑力丹)	Deputy medical director	Room 1304, No. 10, Shuirong Street One, Haizhu District, Guangzhou, Guangdong, PRC	11,455	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[0.01]%

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Grantee	Position/ Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price <i>(US\$ per Share)</i>	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
Tian Yu LIU	Office manager	Room 707, Building 16, Zhonghaixin Apartment, Jihua Street, Longgang District, Shenzhen, Guangdong, PRC	11,455	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
SONG Heng (宋恒)	Formulation project manager	Room 221, Xintaozhijia, No. 6 Xinwucun Industrial Zone, Taoyuan Street, Nanshan District, Shenzhen, Guangdong, PRC	7,500	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
ZHANG Liyang (張力揚)	Clinical operations project manager	Room 806, Phase 2, Faraway Home, Yongfeng Community, Xixiang Street, Bao'an District, Shenzhen, Guangdong, PRC	7,500	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
CHENG Junwei (成君偉)	Preclinical assistant project manager	Room 703, Building 1, Gushu Garden Complex Building, Xixiang, Bao'an District, Shenzhen, Guangdong, PRC	7,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
ZHU Simin (朱思敏)	Registered assistant project manager	Room 103, Mezzanine, No. 21 Xinde East Lane Two, Fuhai Street, Bao'an District, Shenzhen, Guangdong, PRC	7,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
YUAN Xiaojing (袁曉菁)	Registered assistant project manager	Room 2801, Building 55, Xiyuanshanyuan, Minzhi Street, Longhua District, Shenzhen, Guangdong, PRC	7,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
HUANG Mengjiao (黃夢嬌)	Clinical registration project manager	B803, Huatong Smart Park Apartment Building, No. 7, Ganli Road Two, Jihua Street, Longgang District, Shenzhen, Guangdong, PRC	7,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
ZHANG Jingxiao (張靜瀾)	Assistant researcher	Room 201, Building 117, Landsea Future Tree, Lane 88, Qiuting Road, Zhuqiao Town, Pudong New Area, Shanghai, PRC	7,500	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Grantee	Position/ Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price (US\$ per Share)	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
LIU Haiqing (劉海清)	Financial officer	Room 704, Building 92, Hebei Village, Xiameilin, Futian District, Shenzhen, Guangdong, PRC	7,500	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
LIU Weijian (劉偉健)	Laboratory supervisor	No. 605, No. 5, Yixue Street, Nantou Street, Nanshan District, Shenzhen, Guangdong, PRC	7,500	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Subtotal			<u>1,638,028</u>					[REDACTED]%
Total			<u><u>8,849,294⁽⁸⁾</u></u>					[REDACTED]%

Notes:

- (1) Refers to any consideration of the acceptance of grant, other than exercise price to be paid by grantees.
- (2) The Awards shall vest in four years subject to the [REDACTED]. The Awards representing 25% of the Awards granted shall vest in equal, yearly installments at each anniversary date commencing from the vesting commencement date set forth in the notice of Award and the Award agreements. For the avoidance of doubt, no Awards shall be vested if the [REDACTED] has not occurred on or prior to the applicable vesting date of the individual Awards. The vesting of the Awards that become ready to be vested according to their respective designated vesting schedule in the notice of Award on a date prior to the [REDACTED] will be deferred and only effected on the [REDACTED]. For details, please refer to “History, Reorganization and Corporate Structure — Adoption of the Incentive Plans — 2020 ESOP Platform”. The vesting of the Awards is also subject to other vesting conditions, including the Grantee’s provision of continuous service to the Company or its affiliates and the performance criteria to be satisfied by each of the Grantees set forth in their respective notice of Award and Award agreements. The performance criteria comprise a mixture of attaining satisfactory key performance indicators of the Company, the department of the Company and the individual Grantee, respectively. Based on the vesting schedule of the Awards granted under the 2020 Share Incentive Plan, Awards with up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares shall be be vested on the date of [REDACTED], Awards with up to [1,978,382] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares shall be be vested by December 31, 2023, Awards with up to [3,617,972] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares shall be be vested on or before April 1, 2024, Awards with up to [5,785,697] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares shall be be vested on or before April 1, 2025, Awards with up to [7,180,594] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares shall be be vested on or before April 1, 2026, and Awards with up to [8,520,170] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares shall be be vested on or before April 1, 2027. Awards with [361,009] ([REDACTED] as adjusted after the [REDACTED]) underlying Shares had lapsed as of the Latest Practicable Date due to the termination of the employment of the Grantees.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- (3) The table above assumes (i) the [REDACTED] becomes unconditional and the [REDACTED] are issued pursuant to the [REDACTED], (ii) the [REDACTED] is not exercised and (iii) each Series A Preferred Share, Series B Preferred Share, Series B+ Preferred Share, Series C Preferred Shares and Series C+ Preferred Share will be converted into ordinary Shares at the conversion ratio of 1:1 by way of re-designation immediately prior to the completion of the [REDACTED] and the [REDACTED].
- (4) The term “director” refers to the working title of employee, not member of the Board.
- (5) Mr. YANG Feng resigned from our Company on May 11, 2023 for the reason that he would like to devote more time to his investment businesses.
- (6) The Company granted Shares under the 2020 Share Incentive Plan to the consultants of the Company to recognize their contribution to the business development of the Company and to incentivize them to continue to cooperate with the Company and contribute to the Company. The consultants that were granted Shares under the 2020 Share Incentive Plan include Dr. Adrian M. Di BISCEGLIE, Ms. Gwen A. MELINCOFF and Mr. LI Chun. Pursuant to the consulting agreement entered into between our Company and Dr. Adrian M. DI BISCEGLIE (“**Dr. Di Bisceglie**”), Dr. Di Bisceglie has been providing medical support to Company’s clinical studies since May 2019. Pursuant to a consulting agreement, Ms. Gwen A. MELINCOFF (“**Ms. MELINCOFF**”) has been providing business development consulting services to the Company since January 2019. Pursuant to the consulting agreement entered into between our Company and Mr. LI Chun, Mr. LI Chun has been providing corporate strategy and human resource consulting services to the Company since February 2022. Each of Dr. DI BISCEGLIE, Ms. MELINCOFF and Mr. LI Chun is independent from our Group, the Shareholders, Directors and/or senior management other than the services provided by them to our Group.
- (7) Subject to the [REDACTED], Awards underlying 30,000 Shares have been vested as at the Latest Practicable Date, as the proposed global clinical pharmacology and drug metabolism and pharmacokinetics plan for HTD1801 has been finalized on or before December 31, 2022. Subject to the [REDACTED], the remaining Awards underlying 30,000 Shares shall be vested on December 31, 2023 only if the Grantee has been continuously serving in certain position responsible for specified programs which are successfully executed throughout 2022 and 2023. For the avoidance of doubt, no Awards shall be vested until and unless the [REDACTED] occurs. For details please see “History, Reorganization and Corporate Structure — Adoption of the Incentive Plans — 2020 ESOP Platform”.
- (8) As of the Latest Practicable Date, up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) Shares underlying the granted Awards under the 2020 Share Incentive Plan will be subject to lock-up of six months commencing from the [REDACTED] and up to [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) Shares underlying the granted Awards under the 2020 Share Incentive Plan will be subject to lock-up of 180 days commencing from the [REDACTED].

2. 2023 SHARE INCENTIVE PLAN

The 2023 Share Incentive Plan was adopted by the Board on May 24, 2023. The terms of the 2023 Share Incentive Plan are not subject to the provisions of Chapter 17 of the Listing Rules as it does not involve any grant of awards by our Company to subscribe for new Shares after [REDACTED]. After the [REDACTED], no further awards would be granted pursuant to this 2023 Share Incentive Plan. All the Shares underlying the Awards granted under the 2023 Share Incentive Plan have been issued and allotted to the 2023 ESOP Platform for future exercise of the Awards.

The following is a summary of the principal terms of the 2023 Share Incentive Plan.

Summary of Key Terms

(a) Purpose

The purpose of the 2023 Share Incentive Plan is to enable the Company to attract and retain the best available personnel, to provide additional incentives to employees, Directors and consultants and to promote the success of the Company's business.

(b) Who May Join

Eligible participants ("**Eligible Participants**") means any person belonging to any of the following classes of persons:

- (i) any person who is in the employment of the Group;
- (ii) a member of the Board or the board of directors of any affiliate of the Company; or
- (iii) any person who is engaged by the Group to render consulting or advisory services.

Subject to above classes,

share options (the "**Options**"), restricted share units ("**RSUs**") or restricted shares ("**Restricted Shares**", together with the Options and the RSUs, the "**Awards**") shall be granted to the grantee who:

- (i) is department manager, key technical staff of the Group;
- (ii) has made a significant contribution to the Company; or
- (iii) meet such other conditions as determined by the Administrator (as defined below).

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

(c) *Administration of the 2023 Share Incentive Plan*

The 2023 Share Incentive Plan shall be administered by (A) the Board or (B) a committee (the "**Committee**") designated by the Board (the "**Administrator**"), which Committee shall be constituted in accordance with the applicable laws and the Articles of Association, or (C) any person appointed by the Board (the "**Person**"), together with the Board and the Committee, the "**Administrator**"). Once appointed, such Committee or the Administrator shall continue to serve in its designated capacity until otherwise directed by the Board. The Board may authorize one or more officers or Directors to grant the Awards and may limit such authority as the Board determines from time to time.

Subject to applicable laws and the provisions of the 2023 Share Incentive Plan (including any other powers given to the Administrator under the 2023 Share Incentive Plan), and except as otherwise provided by the Board, the Administrator shall have the authority, in its discretion:

- (i) to select Eligible Participants to whom Awards may be granted from time to time;
- (ii) to determine whether and to what extent Awards are granted;
- (iii) to determine the type or the number of Awards to be granted, the number of Shares or the amount of consideration to be covered by each Award granted;
- (iv) to approve forms of Award agreements for use, to amend terms of the Award agreements;
- (v) to determine the terms and conditions of any Award granted under the 2023 Share Incentive Plan (including without limitation the vesting schedule and exercise price set forth in the notice of Award and the Award agreements), including the purchase, exercise or base price, the time or times when Awards may be exercised (which may be based on performance criteria), any forfeiture events, any vesting acceleration or waiver of forfeiture restrictions, and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Administrator determines;
- (vi) to amend the terms of any outstanding Award granted under the 2023 Share Incentive Plan;
- (vii) to construe and interpret the terms of the 2023 Share Incentive Plan and Awards, including without limitation the vesting schedule and exercise price set forth in the notice of Award and the Award agreements;

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- (viii) to require the grantee to provide representation or evidence that any currency used to pay the exercise price of any Award was legally acquired and taken out of the jurisdiction in which the grantee resides in accordance with the applicable laws;
- (ix) to establish sub-plans or separate program under the Share Incentive Plan, containing such limitations and other terms and conditions as the Administrator determines are necessary or desirable, for the purpose of satisfying blue sky, securities, tax or other laws of various jurisdictions in which the Company intends to grant Awards or qualifying for favorable tax treatment under applicable foreign laws;
- (x) to correct any defect, omission or inconsistency in the Share Incentive Plan or any Award agreement, in a manner and to the extent it deems necessary or advisable to make the 2023 Share Incentive Plan fully effective;
- (xi) to authorize any individual to execute, on behalf of the Company, any instrument required to carry out the purpose of the 2023 Share Incentive Plan;
- (xii) to determine the fair market value;
- (xiii) to take such other action, not inconsistent with the terms of the 2023 Share Incentive Plan and the applicable laws, as the Administrator deems appropriate.

(d) Term and transferability of the Award

The management personnel should nominate eligible candidates according to the 2023 Share Incentive Plan and advise the conditions of the Award to be granted to such candidates.

The term of each Award shall be the term stated in the Award agreement. Notwithstanding the foregoing, the specified term of any Award shall not include any period for which the grantee has elected to defer the receipt of the Shares of cash issuable pursuant to the Award. In the case of an Option granted to an United States taxpayer who, at the time the Option is granted ("**Grant Date**"), owns (or, pursuant to Section 424(d) of the United States Code, is deemed to own) stock representing more than 10% of the total combined voting power of all classes of Shares of the Company or any subsidiary or affiliate, the term of the Option will not be longer than ten years from the Grant Date. The Grant Date of an Award shall for all purposes be the date on which the Administrator makes the determination to grant such Award, or such other date as is determined by the Administrator.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Subject to the Applicable Laws, Awards shall be transferable by will and by the laws of descent and distribution, only to the extent and in the manner approved by the Administrator. Notwithstanding the foregoing, the grantee may designate one or more beneficiaries of the grantee's Award in the event of the grantee's death on a beneficiary designation form provided by the Administrator.

(e) Exercise or Purchase Price

The exercise or purchase price shall be the price determined by the Administrator as of the Grant Date. Subject to Applicable Laws, the consideration to be paid for the Shares to be issued upon exercise or purchase of an Award including the method of payment, shall be determined by the Administrator. In addition to any other types of consideration the Administrator may determine, the Administrator is authorized to accept as consideration for Shares issued under the 2023 Share Incentive Plan the following:

- (i) cash;
- (ii) cheque;
- (iii) if the exercise or purchase occurs on or after the [REDACTED], or as otherwise permitted by the Administrator, surrender of Shares or delivery of a properly executed form of attestation of ownership of Shares as the Administrator may require which have a fair market value on the date of surrender or attestation equal to the aggregate exercise price of the Shares as to which said Award shall be exercised;
- (iv) with respect to Options or RSUs, if the exercise occurs on or after the [REDACTED], payment through a broker-dealer sale and remittance procedure pursuant to which the grantee (A) shall provide written instructions to a Company designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (B) shall provide written directives to the Company to deliver the certificates for the purchased Shares directly to such brokerage firm in order to complete the sale transaction; or
- (v) any combination of the foregoing methods of payment.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

(f) Exercise of Award

Any Award granted under the 2023 Share Incentive Plan shall be exercisable at such times and under such conditions as determined by the Administrator under the terms of the 2023 Share Incentive Plan and specified in the Award agreement.

An Award shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Award by the person entitled to exercise the Award and full payment for the Shares with respect to which the Award is exercised, including to the extent selected, use of the broker-dealer sale and remittance procedure to pay the purchase price as provided in paragraph (e)(iv).

An Award may not be exercised after the termination date of such Award set forth in the Award agreement and may be exercised following the termination of a grantee's continuous service only to the extent provided in the Award agreement. Where the Award agreement permits a grantee to exercise an Award following the termination of the grantee's continuous service for a specified period, the Award shall terminate to the extent not exercised on the last day of the specified period or the last day of the original term of the Award, whichever occurs first.

Notwithstanding the foregoing, regardless of whether an Award has otherwise become exercisable, the Award shall not be exercised if the Administrator (in its sole discretion) determines that an exercise would violate any applicable laws. Shares shall not be issued pursuant to the exercise of an Award unless the exercise of such Award and the issuance and delivery of such Shares pursuant thereto shall comply with all applicable laws (including all relevant filings, approvals and registrations (if any) required under the laws PRC) with respect to the exercise of such Award including without limitation, those required with the PRC State Administration of Foreign Exchange as determined to be necessary or desirable by the Board of Directors in its discretion), and shall be further subject to the approval of counsel for the Company with respect to such compliance.

(g) Termination

An Award shall lapse automatically and not be exercisable (to the extent not already exercised):

- (i) in the event the grantee's continuous service terminates as a result of his/her retirement, death, permanent disability prevents from working, resignation or company terminates his/her employment;
- (ii) in the event the grantee's continuous service terminates due to bad faith causes;

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

(iii) in the event change in control of the Company or corporate transaction as defined as below:

- (as determined by the Administrator acting reasonably) a change in ownership or control of the Company effected through the direct or indirect acquisition by any person or related group of persons (other than an acquisition from or by the Company or by a Company sponsored employee benefit plan or by an affiliate of the Company) of beneficial ownership of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's shareholders which a majority of the Directors who are not affiliates or associates of the offeror do not recommend such shareholders accept;
- (as determined by the Administrator acting reasonably) a merger, amalgamation, consolidation or other business combination of the Company with or into any person, in which the Company is not the surviving entity, or any other transaction or series of transactions, as a result of which the Shareholders of the Company immediately prior to such transaction or series of transactions will cease to own a majority of the voting power of the surviving entity immediately after consummation of such transaction or series of transactions, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated;
- the sale, transfer, exclusive license or other disposition of all or substantially all of the assets of the Group;
- the complete liquidation or dissolution of the Company;
- any reverse merger or series of related transactions culminating in a reverse merger (including, but not limited to, a tender offer followed by a reverse merger) in which the Company is the surviving entity but (A) the ordinary Shares outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (B) in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger or the initial transaction culminating in such merger, but excluding any such transaction or series of related transactions that the Administrator determines shall not be a corporate transaction; or

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- acquisition in a single or series of related transactions by any person or related group of persons of beneficial ownership of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities, but excluding any such transaction or series of related transactions that the Administrator determines shall not be a corporate transaction; or
- (iv) in the event that the Company incurs an insolvency event as defined as below:
- circumstances under which the Company (a) has a receiver or similar officer appointed over all or a material part of its assets or business; (b) passes a resolution for winding-up of all or a material part of its assets or business (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court enters an order to that effect; (c) has entered against it an order for relief recognizing it as a debtor under any insolvency or bankruptcy laws (or any equivalent order in any jurisdiction); or (d) enters into any composition or arrangement with its creditors with respect to all or a material part of its assets or business (other than relating to a solvent restructuring).
- (h) *Additional Conditions of Lapse*
- (i) Any Award granted under the 2023 Share Incentive Plan shall lapse and be cancelled automatically if the Company's [REDACTED] (the "[REDACTED]") to the Stock Exchange has been rejected in writing or if the Company has otherwise withdrawn or not renewed within six months after the lapse of the [REDACTED].
 - (ii) The Awards granted under the 2023 Share Incentive Plan to any Grantee shall be subject to the Company completing an [REDACTED] of a final [REDACTED] size (the "**Final [REDACTED] Size**") of US\$130 million or above. To the extent the Final [REDACTED] Size falls below US\$130 million, a corresponding portion of each of the Awards granted under this Plan shall lapse and be cancelled automatically. With respect to any Awards granted but automatically lapsed in accordance with such condition, the underlying Shares shall be repurchased and cancelled before the [REDACTED].
- (i) *Maximum Number of Shares*

The maximum number of Shares in respect of which Awards may be granted under the 2023 Share Incentive Plan is 4,000,000 ([REDACTED] as adjusted after the [REDACTED]) Shares (the "**2023 Scheme Limit**"). All 4,000,000 Shares underlying the Awards granted under the 2023 Share Incentive Plan have been issued and allotted to the 2023 ESOP Platform for future exercise of the Awards.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Any Shares covered by an Award (or portion of an Award) which is forfeited, canceled or expires (whether voluntarily or involuntarily) shall be deemed not to have been issued for purposes of determining the maximum aggregate number of Shares which may be issued under the 2023 Share Incentive Plan. Shares that actually have been issued under the 2023 Share Incentive Plan pursuant to an Award shall not be returned to the 2023 Share Incentive Plan and shall not become available for future issuance under the 2023 Share Incentive Plan, except that if the Shares subject to an outstanding Award are not issued or delivered or are returned to the Company by reason of (i) expiration, termination, cancellation or forfeiture of such Award, (ii) the settlement of such Award in cash, (iii) the delivery or withholding of Shares to pay all or a portion of the exercise price of an Award, if any, or to satisfy all or a portion of the tax withholding obligations relating to an Award, such Shares shall revert to and become available for future grant under the 2023 Share Incentive Plan. To the extent not prohibited by the applicable law and the listing requirements of the applicable stock exchange or national market system on which the Shares are traded, any Shares covered by an Award which are surrendered (i) in payment of the Award exercise or purchase price or (ii) in satisfaction of tax withholding obligations incident to the exercise of an Award shall be deemed not to have been issued for purposes of determining the maximum number of Shares which may be issued pursuant to all Awards under the 2023 Share Incentive Plan, unless otherwise determined by the Administrator.

(j) Adjustments upon Changes in Capitalization

Subject to any required action by Shareholders of the Company, the number of Shares covered by each outstanding Award, the number of Shares which have been authorized for issuance under the 2023 Share Incentive Plan but as to which no Awards have yet been granted or which have been returned to the 2023 Share Incentive Plan, the exercise or purchase price of each such outstanding Award, the maximum number of Shares with respect to which Awards may be granted to any Grantee in any fiscal year of the Company, as well as any other terms that the Administrator determines require adjustment shall be proportionately adjusted for (i) any increase or decrease in the number of issued Shares resulting from a share split, reverse share split, share dividend, combination or reclassification of the Shares, or similar transaction affecting the Shares, (ii) any other increase or decrease in the number of issued Shares effected without receipt of consideration by the Company, or (iii) as the Administrator may determine in its discretion, any other transaction with respect to Shares including a corporate merger, consolidation, acquisition of property or equity, separation (including a spin-off or other distribution of shares or property), reorganization, liquidation (whether partial or complete) or any similar transaction; provided, however that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Administrator and its determination shall be final, binding and conclusive. Except as the Administrator determines, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, shall affect, and no adjustment by reason hereof shall be made with respect to, the number or price of Shares subject to an Award. In the event of a spin-off transaction, the Administrator may in its discretion make such adjustments and take such other

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

action as it deems appropriate with respect to outstanding Awards under the 2023 Share Incentive Plan, including but not limited to: (i) adjustments to the number and kind of Shares, the exercise or purchase price per Share and the vesting periods of outstanding Options, (ii) prohibit the exercise of Awards during certain periods of time prior to the consummation of the spin-off transaction, or (iii) the substitution, exchange or grant of Awards to purchase securities of the subsidiary; provided that the Administrator shall not be obligated to make any such adjustments or take any such action under the 2023 Share Incentive Plan.

(k) Amendment, Suspension or Termination of the 2023 Share Incentive Plan

The Board may at any time amend, suspend or terminate the 2023 Share Incentive Plan; provided, however, that no such amendment shall be made without the approval of the Shareholders to the extent such approval is required by applicable laws or if such amendment would change the provision of this paragraph:

Details of the Awards granted, including Awards exercised or outstanding, under this scheme shall be disclosed in the circular to shareholders of the Company seeking approval of the new scheme established after the termination of this scheme.

(l) Dividend and voting rights

Unless and until the Shares underlying an Award are actually issued or transferred (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to receive dividends or other distributions will exist with respect to the Shares underlying such Award, notwithstanding the exercise of the Award. If any such dividends or distributions are paid in Shares, such Shares will be subject to the same restrictions on transferability and forfeitability as the Restricted Shares with respect to which they were paid. The dividends and distributions which the grantees who are PRC citizens or otherwise designated by the Company as PRC grantees (the "**PRC Grantee(s)**") are entitled to shall be held by the 2023 ESOP Platform and distributed to the PRC Grantees, unless the PRC Grantee has held relevant Shares of the Company as permitted by the Administrator.

No Award gives the Grantee any of the rights of a shareholder of the Company unless and until Shares are in fact issued or transferred to such Grantee upon vesting and exercising of such Award. Except as otherwise provided in the 2023 Share Incentive Plan or the applicable Award agreement, no PRC Grantee will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any Shares unless and until the Shares underlying an Award are actually issued or transferred (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). All the rights of a PRC Grantee with respect to any Trust Shares shall be exercised by the 2023 ESOP Platform.

Outstanding Awards

As of the Latest Practicable Date, all the Awards available for granting under the 2023 Share Incentive Plan have been granted, and therefore the aggregate number of underlying Shares pursuant to the outstanding Awards granted under the 2023 Share Incentive Plan is 4,000,000 ([REDACTED] as adjusted after the [REDACTED]) Shares. Upon completion of the [REDACTED], the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] (assuming the [REDACTED] is not exercised), the aggregate number of Shares underlying all Awards granted represents approximately [REDACTED]% of the issued Shares.

As of the Latest Practicable Date, the outstanding Awards which have been granted under the 2023 Share Incentive Plan for an aggregate of 4,000,000 ([REDACTED] as adjusted after the [REDACTED]) Shares have been granted to a total of four Eligible Participants, all of whom are Directors or members of the senior management of our Company. The outstanding Awards granted under the 2023 Share Incentive Plan were granted at nil consideration to each of the relevant Eligible Participants with an exercise price of US\$1.97 per Share. The exercise period of the Awards granted is ten years commencing from the date upon which the Awards are deemed to be granted and accepted pursuant to the terms of the 2023 Share Incentive Plan.

All the Shares subject to the Awards have been allotted and issued and are held by the 2023 ESOP Platform as of the date of this document. Accordingly, if all the Awards granted under the 2023 Share Incentive Plan are exercised, there will not be any dilution effect on the shareholdings of our Shareholders nor any impact on the earnings per Share arising from the exercise of the outstanding Awards. The Shares underlying the Awards under the 2023 Share Incentive Plan that have not been granted to any specific grantee prior to [REDACTED] will be repurchased and cancelled.

An [REDACTED] has been made to the Stock Exchange for the [REDACTED] of, and permission to deal in, the Shares held by the 2023 ESOP Platform for the purpose of the 2023 Share Incentive Plan. Unvested Shares under the 2023 Share Incentive Plan will abstain from voting upon [REDACTED] in compliance with Rule 17.05(A) of the Listing Rules.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

The table below shows the details of Awards (all being Options) granted under the 2023 Share Incentive Plan that are outstanding as of the Latest Practicable Date.

Grantee	Position/Relationship	Address	Number of Shares under outstanding Awards granted before the completion of the [REDACTED]	Date of Grant	Vesting Period	Exercise price	Consideration paid by the Grantee ⁽¹⁾	Approximate percentage of enlarged issued Shares following the completion of the [REDACTED] the repurchase of Shares from the 2023 ESOP Platform and the [REDACTED] ⁽³⁾
<i>(US\$ per Share)</i>								
Directors								
Ms. YU Meng (于萌)	Executive Director, deputy general manager of our Company	6-2-506 Wendelford Garden, Houhai Avenue, Nanshan District, Shenzhen, Guangdong, PRC	1,000,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Mr. MA Lixiong (馬立雄)	Non-executive Director	Room 1608, International Chamber of Commerce Center, No. 168 Fuhua 3rd Road, Futian District, Shenzhen, Guangdong, PRC	1,000,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Subtotal			2,000,000					[REDACTED]%
Senior management of our Company who are not Directors								
Mr. SIM Koon Yin Edmund (沈觀賢)	Chief financial officer of our Company	Flat F, 6/F, Tower 16, South Horizons, Ap Lei Chau, Hong Kong	1,000,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Ms. YU Li (于莉)	Vice president	Room 1618, Building 16, Zhonghaixin Innovation Industrial City, Ganli 2nd Road, Jihua Street, Longgang District, Shenzhen, Guangdong, PRC	1,000,000	September 1, 2023	Four years ⁽²⁾	1.97	Nil	[REDACTED]%
Subtotal			2,000,000					[REDACTED]%
Total			4,000,000⁽⁴⁾					[REDACTED]%

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Notes:

- (1) Refers to any consideration of the acceptance of grant, other than exercise price to be paid by grantees.
- (2) The Awards representing 25% of the Awards granted shall vest in equal, yearly installments at each of the first anniversary date, the second anniversary date, the third anniversary date and the fourth anniversary date commencing from the [REDACTED]. The vesting of the Awards is also subject to other vesting conditions, including the Grantee's provision of continuous service to the Company or its affiliates and the performance criteria to be satisfied by each of the Grantees set forth in their respective notice of Award and Award agreements. The performance criteria comprise a mixture of attaining satisfactory key performance indicators of the Company, the department of the Company and the individual Grantee, respectively.
- (3) The table above assumes (i) the [REDACTED] becomes unconditional and the [REDACTED] are issued pursuant to the [REDACTED], (ii) the [REDACTED] is not exercised and (iii) each Series A Preferred Share, Series B Preferred Share, Series B+ Preferred Share, Series C Preferred Shares and Series C+ Preferred Share will be converted into ordinary Shares at the conversion ratio of 1:1 by way of re-designation immediately prior to the completion of the [REDACTED] and the [REDACTED].
- (4) As of the Latest Practicable Date, up to [4,000,000] ([REDACTED] as adjusted after the [REDACTED]) Shares underlying the granted Awards under the 2023 Share Incentive Plan will be subject to lock-up of 12 months commencing from the [REDACTED].

E. OTHER INFORMATION

1. 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.

2. Litigation

As of the Latest Practicable Date, our Directors were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us or our Directors which may have a material adverse impact on our business, financial condition or results of operations.

3. Joint Sponsors

The Joint Sponsors have made an [REDACTED] on our behalf to the Listing Committee for the [REDACTED] of, and permission to deal in, the Shares in issue (including the Shares to be converted from the Preferred Shares), the Shares to be issued pursuant to the [REDACTED] and the [REDACTED] (including the additional Shares which may fall to be issued pursuant to exercise of the [REDACTED] (if any) and the share options granted under the Incentive Plans. All necessary arrangements have been made to enable such Shares to be admitted into [REDACTED].

The Joint Sponsors will be paid by our Company an aggregate fee of US\$1,000,000 to act as the joint sponsors to the Company in connection with the [REDACTED].

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

4. Qualifications and consents of experts

The following experts have each given and have not withdrawn their respective written consents to the issue of this document with copies of their reports, letters, opinions or summaries of opinions (as the case may be) and the references to their names included herein in the form and context in which they are respectively included.

<u>Name</u>	<u>Qualification</u>
UBS Securities Hong Kong Limited	Licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 6 (advising on corporate finance) and Type 7 (providing automated trading services) regulated activities as defined under the SFO
Huatai Financial Holdings (Hong Kong) Limited	Licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 6 (advising on corporate finance), Type 7 (providing automated trading services) and Type 9 (asset management) of the regulated activities as defined under the SFO
Han Kun Law Offices	Legal advisor as to PRC law
Conyers Dill & Pearman	Cayman Islands attorneys-at-law
Ernst & Young	Certified Public Accountants and Registered Public Interest Entity Auditor
China Insights Industry Consultancy Limited	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.

5. Binding effect

This document shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of Sections 44A and 44B of the Companies Ordinance so far as applicable.

6. No material and adverse change

Our Directors confirm that, save as disclosed in the document, as far as they are aware, there had been no material adverse change in our financial, trading position or prospects since December 31, 2022, being the date of our consolidated financial statements as set out in “Appendix I — Accountants’ Report” of this document, up to the date of this document.

7. Bilingual document

The English language and Chinese language versions of this document are being published separately in reliance upon the exemption provided by Section 4 of Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

8. Preliminary expenses

As of the Latest Practicable Date, our Company has not incurred any material preliminary expenses.

9. Promoters

We have no promoter for the purpose of the Listing Rules. Save as disclosed in this document, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given nor are any proposed to be paid, allotted or given to any promoters in connection with the [REDACTED] and the related transactions described in this document.

10. Disclaimers

- (a) Save as disclosed in this document:
- (i) within the two years immediately preceding the date of this document, neither we nor any of our subsidiaries has issued or agreed to issue any share or loan capital fully or partly paid up either for cash or for a consideration other than cash;
 - (ii) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;
 - (iii) within the two years immediately preceding the date of this document, no commissions, discounts, brokerage or other special terms have been granted in connection with the issue or sale of any shares or loan capital of any member of the Group;

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- (iv) within the two years immediately preceding the date of this document, no commission has been paid or payable to any persons for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription of any shares of the Company or any of its subsidiaries;
 - (v) no founder, management or deferred shares of the Company or any of its subsidiaries have been issued or agreed to be issued;
 - (vi) the Company has no outstanding convertible Preferred Shares;
 - (vii) there is no arrangement under which future dividends are waived or agreed to be waived or is agreed conditionally or unconditionally to be put under option; and
 - (viii) there has not been any interruption in the business of our Group which may have or have had a significant effect on the financial position of our Group in the 12 months immediately preceding the date of this document.
- (b) The principal register of members of our Company will be maintained by our [REDACTED], Conyers Trust Company (Cayman) Limited, in the Cayman Islands and our Hong Kong register of members will be maintained by our Hong Kong [REDACTED], in Hong Kong. Unless our Directors otherwise agree, all transfer and other documents of title of Shares must be lodged for registration with and registered by our Hong Kong [REDACTED] and may not be lodged in the Cayman Islands.
- (c) No company within our Group is presently listed on any stock exchange or traded on any trading system and no listing or permission to deal is being or is proposed to be sought.

APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND ON DISPLAY

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to the copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) the written consents referred to in the section headed “Statutory and General Information — E. Other information — 4. Qualifications and consents of Experts” in Appendix IV to this document; and
- (b) a copy of each of the material contracts referred to in the section headed “Statutory and General Information — B. Further Information about our business — 1. Summary of material contracts” in Appendix IV to this document.

DOCUMENTS ON DISPLAY

Copies of the following documents will be published on the Stock Exchange’s website at www.hkexnews.hk and our Company’s website at www.hightidetx.com during a period of 14 days from the date of this document:

- (a) the Memorandum of Association and Articles of our Company;
- (b) the Accountants’ Report of our Group prepared by Ernst & Young, the texts of which are set out in Appendix I;
- (c) the report from Ernst & Young on the unaudited [REDACTED] financial information of our Group, the texts of which are set out in Appendix II;
- (d) the audited financial statements of the companies comprising our Group for the years ended December 31, 2021 and 2022 and the six months ended June 30, 2023;
- (e) the legal opinion issued by Han Kun Law Offices, our PRC Legal Advisor in respect of general matters and property interests of our Group in the PRC;
- (f) the letter of advice from Conyers Dill & Pearman, our legal advisor on Cayman Islands law, summarizing certain aspects of the Cayman Islands company law referred to in Appendix III to this document;
- (g) the industry report prepared by China Insights Industry Consultancy Limited;
- (h) the material contracts referred to in the section entitled “B. Further Information about Our Business — 1. Summary of Material Contracts” in Appendix IV to this document;
- (i) the written consents referred to in the section entitled “E. Other Information — 4. Qualifications and consents of Experts” in Appendix IV to this document;

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND ON DISPLAY**

- (j) the service contracts and letters of appointment referred to in the section headed “C. Further Information about Our Directors — 1. Particulars of Directors’ service contracts and appointment letters” in Appendix IV to this document;
- (k) the terms of the 2020 Share Incentive Plan and the 2023 Share Incentive Plan; and
- (l) the Cayman Companies Act.