

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 globally integrated biopharmaceutical company specializing in the discovery, development and commercialization of first-in-class, 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, 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. HTD1801 is being developed for the indications of nonalcoholic steatohepatitis (“NASH”), type 2 diabetes mellitus (“T2DM”), severe hypertriglyceridemia (“SHTG”), primary sclerosing cholangitis (“PSC”) and primary biliary cholangitis (“PBC”). 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, forming an important barrier to competition. As of the Latest Practicable Date, we held 128 patents and patent applications.

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.

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Candidate	Indication	Right	Designations	Pre-Clinical	Phase I	Phase II	Phase III
Metabolic Disease	NASH	 Global ⁽¹⁾	FTD	Ph IIa completed in US; Ph IIb initiated in US, to be initiated in Hong Kong, Mexico and Mainland China			
	HTD1801 	 Global	T2DM	Ph II completed in Mainland China, Ph III to be initiated in Mainland China			
	SHTG	 Global		Ph II to be initiated in US ⁽²⁾			
	Obesity	 Global					
	Metabolic disease	 Global					
Digestive Disease	PSC	 Global ⁽¹⁾	FTD, ODD	Ph II completed in US and Canada			
	HTD1801 	 Global	PBC	Ph II completed in US			
	HTD4010	 Global	AH	Ph I completed in Australia			
	HTD2802	 Global	IBD				
 Core Product							

Abbreviations: NASH: nonalcoholic steatohepatitis; T2DM: type 2 diabetes mellitus; SHTG: severe hypertriglyceridemia; 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 NASH 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 NASH and PSC; and (iv) import and export HTD1801. For details, see “Business — Collaboration Agreement — HTD1801 License-Out Agreement” and “connected transaction”.
2. We have completed a Phase Ib/IIa trial for hypercholesterolemia in Australia and a Phase IIa trial for NASH 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.

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HTD1801 is a novel salt formed from two active moieties, 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. 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, forming an important barrier to competition. Our clinical results show that HTD1801 delivers a comprehensive therapeutic effect for patients including metabolic improvement, liver protection, anti-inflammation and antioxidative stress. HTD1801 is currently being developed by us for indications across NASH, T2DM, SHTG, PSC and PBC globally, with a focus on comorbidities and a potential for indication expansion. In the United States, we have received fast track designation (“**FTD**”) from the FDA for NASH and PSC indications, as well as orphan drug designation (“**ODD**”) for the PSC indication. 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 NDA for HTD1801 for T2DM in 2025 in China.

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, significantly increasing survival rates, alleviating signs of severe liver injury and reducing systemic inflammation. Our completed Phase I clinical trial demonstrated its favorable safety profile in healthy humans.

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.

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, presently there are significant commercial opportunities across multiple metabolic and digestive diseases including NASH, T2DM, SHTG, PSC and PBC, together representing a large global market size of US\$323 billion in 2022.

NASH 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 NASH 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 NASH. While lifestyle modifications and management of underlying conditions can help slow or stop the

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progression of NASH, there are currently no approved pharmacologic therapies that comprehensively ameliorate the full spectrum of NASH, from inflammation and liver cell damage to fibrosis and cirrhosis. Therefore, there is a significant need for safe and effective pharmacologic therapies to treat NASH, specifically therapies that comprehensively ameliorate the pathologic spectrum of NASH. 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 NASH. 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 NASH.

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 non-alcoholic fatty liver disease (“**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 NAFLD and results in a higher risk of disease progression and outcomes including NASH, cirrhosis and hepatocellular carcinoma. Similarly, NAFLD compounds the severity of T2DM and with an increase in comorbidities such as cardiovascular disease and liver-related outcomes. The worldwide prevalence of NAFLD among people with T2DM is 55.5%; in China the prevalence of T2DM with NAFLD was 64.1 million as of the end of 2022. According to CIC, there are currently no approved drugs which can lead to sufficient and comprehensive therapeutic benefits for both T2DM and NAFLD. 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 NAFLD, thereby reducing the risk of clinical outcomes associated with advanced disease. Therefore, an ideal therapy for patients with T2DM and NAFLD 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, NAFLD/NASH, 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.

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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 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.

STRENGTHS

We believe the following strengths differentiate us from our competitors:

- Global leader in developing novel multifunctional, multi-target therapies for metabolic and digestive diseases to treat patients as a whole
- HTD1801, a “pipeline-in-a-product” first-in-class new molecular entity with the potential to become a blockbuster backbone therapy for NASH, T2DM, and other metabolic and digestive diseases
- Robust pipeline of new molecular entities with a therapeutic profile to address unmet needs in metabolic and digestive diseases
- Significant 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

STRATEGIES

We plan to pursue the following significant 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 robust 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

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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.

As of the Latest Practicable Date, the clinical development team consisted of 29 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, we recorded R&D costs of RMB84.0 million and RMB182.7 million, respectively. In 2021 and 2022, we recorded R&D costs of RMB76.0 million and RMB173.7 million, respectively, for our Core Product HTD1801.

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INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we hold 128 patents and patent applications. 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, Mexico, Singapore, United States, South Africa	Granted	2035	Ownership
		Canada, Mainland China, EAPO, Israel, India, 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 China)	Ownership
		Australia, Canada, EPO, 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	PCT, United States, EPO	Pending	–	Ownership
	Compositions of Berberine Ursodeoxycholate and Methods for Treating Primary Sclerosing Cholangitis	PCT	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 hold 41 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.

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”.

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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 NASH 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 for indications other than for NASH 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 NASH 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 double-digit percentage 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 HTD1801 Agreement shall continue in full force until the last applicable royalty term (the patent expiration date or the expiration date of the patent exclusivity period, whichever is earlier) of HTD1801 in Europe expires or unless otherwise terminated earlier in accordance with the terms therein. For details, please refer to “Business — Collaboration Agreement — HTD1801 License-Out Agreement.”

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, our purchases from our five largest R&D suppliers in each year in the aggregate accounted for 44.5% and 54.2% of our total corresponding purchases, respectively, and our purchases from the largest R&D supplier accounted for 12.0% and 17.9% 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 four 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 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

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CMC know-hows in production, packaging, transportation, and storage of our products through technology transfer. 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.

COMMERCIALIZATION

Commercialization Strategy

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.

Product 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 National Reimbursement Drug List (“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.

OUR SINGLE LARGEST GROUP OF SHAREHOLDERS

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, each of which is a party to the Concert Party Agreement, which provided that (i) such parties had acted 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.

Immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised and no Share is repurchased from the ESOP Platforms before the [REDACTED]), our Single Largest Group of Shareholders will be collectively entitled to exercise the voting rights attached to approximately [REDACTED]% of the total issued Shares of our Company. Therefore, they will not be regarded as our controlling Shareholders upon [REDACTED] as defined under the Listing Rules but will remain as our Single Largest Group of Shareholders upon [REDACTED].

OUR [REDACTED] INVESTORS

Our [REDACTED] Investors include certain Sophisticated Investors, such as dedicated healthcare funds and biotech funds as well as established funds with a focus on investments in the healthcare sector. Our [REDACTED] Investors include Hepalink, Qianhai Haichuang, Goldlink,

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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. 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 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,	
	2021	2022
	<i>(RMB in thousands)</i>	
Other income and gains	13,821	20,581
Fair value (losses)/gains on convertible redeemable preferred shares	(93,656)	23,242
Other expenses	(1)	(7,518)
Fair value losses on financial liabilities at FVTPL	(4,609)	—
Research and development costs	(84,012)	(182,651)
Administrative expenses	(48,064)	(43,433)
Finance costs	(4,528)	(426)
Loss before tax	(221,049)	(190,205)
Total comprehensive loss for the year	(217,410)	(223,888)

We have incurred operating losses during the Track Record Period. Our loss before tax was RMB221.0 million and RMB190.2 million for 2021 and 2022, respectively. Substantially all of our loss resulted from research and development costs and administrative expenses, as a result of the expansion of our business operations.

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. Our other expenses increased significantly from approximately RMB one thousand in 2021 to RMB7.5 million in 2022, primarily attributable to the foreign exchange losses of RMB7.5 million in 2022 due to fluctuations in foreign currency exchange rates and currency translation.

Our research and development costs primarily consist of (i) third-party contracting expense which primarily includes the early stage discovery expenses, 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. Our research and development costs increased by 117.5% 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.

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

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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.

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,	
	2021	2022
	(RMB in thousands)	
Total non-current assets	3,450	4,806
Total current assets	775,182	851,018
Total assets	778,632	855,824
Total current liabilities	28,534	1,319,720
Total non-current liabilities	1,022,360	6,632
Total liabilities	1,050,894	1,326,352
Net current assets/(liabilities)	746,648	(468,702)

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.

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

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,	
	2021	2022
	(RMB in thousands)	
Net cash flows used in operating activities	(90,546)	(172,379)
Net cash flows from/(used in) investing activities	1,588	(415,661)
Net cash flows from financing activities	493,982	46,034
Net increase/(decrease) in cash and cash equivalents	405,024	(542,006)
Cash and cash equivalents at beginning of year	367,252	765,290
Effects of foreign exchange rate changes, net	(6,986)	49,763
Cash and cash equivalents at end of year	765,290	273,047

SUMMARY

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.

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.

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 1.9 times the level in 2022, we estimate that our total cash balance as of December 31, 2022 (including cash and bank balances and the amount of financial assets at amortized cost as of December 31, 2022), will be able to maintain our financial viability for approximately 31 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 and no Share is repurchased from the ESOP Platforms before the [REDACTED]) from the [REDACTED], for at least 55 months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

Key Financial Ratios

	As of December 31,	
	2021	2022
Gearing Ratio ⁽¹⁾	(3%)	(2%)

Note:

(1) Equals bank loans and other borrowings divided by total equity as of the same date.

[REDACTED]

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. The declaration and payment of any dividends in the future will be determined by our Board of Directors, in its discretion, 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 or share premium account, provided that in no circumstances may a dividend be paid 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.

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], for FUSIONTX™ development approach, the early drug discovery and development and enhancement of other drug candidates;
- Approximately HK\$[REDACTED], representing [REDACTED]% of the net [REDACTED], will be used for working capital and other general corporate purposes.

SUMMARY

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:

- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may be unable to commercialize our drug candidates on a timely basis.
- 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 approval, filing or other requirements of the China Securities Regulatory Commission or other PRC government authorities may be required under PRC laws.

[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 [[REDACTED]%) of the gross [REDACTED] from the [REDACTED], including HK\$[REDACTED] that we have incurred for the years ended December 31, 2021 and 2022, of which HK\$[REDACTED] was charged to our consolidated statements of profit or loss, while the remaining amount of HK\$[REDACTED] was capitalized as other current assets as of December 31, 2022 and will be subsequently charged to equity upon completion of the [REDACTED], and HK\$[REDACTED] that we expect to further incur after December 31, 2022, 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) non-[REDACTED]-related expenses of HK\$[REDACTED], including (a) fee paid and payable to

SUMMARY

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

Recent Developments in Clinical Development

For NASH, we initiated our Phase IIb study (HTD1801.PCT014) in the United States in December 2022 and we are actively enrolling patients in this study in the United States. We expect to initiate the same study in Hong Kong, Mexico and Mainland China in the second half of 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.

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 NASH 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.

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. We are also proactively following up changes in laws and regulatory development and will carry out relevant work to ensure compliance with laws and regulations with the aid of external counsels.

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 December 31, 2022, being the end of the period reported on as set out in the Accountants’ Report included in Appendix I to this document.