HighTide Therapeutics, Inc.

君圣泰医药

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2511)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2024

The board (the "**Board**") of directors (the "**Director(s)**") of HighTide Therapeutics, Inc. (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce the unaudited consolidated interim results of the Group for the six months ended June 30, 2024 (the "**Reporting Period**"), together with the comparative figures for the six months ended June 30, 2023.

In this announcement, "we", "us" and "our" refer to the Company and where the context otherwise requires, the Group. Certain amount and percentage figure included in this announcement have been subject to rounding adjustments or have been rounded to one or two decimal places, as appropriate. Any discrepancies in any table, chart or elsewhere totals and sums of amounts listed therein are due to rounding.

MANAGEMENT DISCUSSION AND ANALYSIS

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, in house, a product pipeline of five candidates, covering eight indications in metabolic and digestive diseases. Two candidates are in clinical-stage across 5 indications. 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. Other product candidates include HTD4010, HTD1804, HTD1805 and HTD2802.

We are dedicated to developing 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. As 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 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.

OUR PRODUCTS AND PRODUCT PIPELINE

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

Candidate	Mechanism/Target	Indication	Right	Designations	Pre-Clinical / Phase I / Phase II / Phase III
HTD1801 ★	Berberine ursodeoxycholate (BUDC)	MASH	Global	FTD	Ph IIa completed in US; Patient enrollment in Ph IIb completed in US, HK and Mainland China
		T2DM	Global		Ph II completed in Mainland China, Ph III trials are ongoing in Mainland China
		SHTG	Global		(1)
		PSC	Global	FTD, ODD	Ph II completed in US and Canada
HTD4010	Polypeptide Drug	AH	Global		Ph I completed in Australia
HTD1804	Undisclosed	Obesity	Global		
HTD1805	Undisclosed	Metabolic Disease	Global		
HTD2802	Undisclosed	IBD	Global		

★ Core Assets

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

Note:

(1) 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 the United States Food and Drug Administration's ("**FDA**") written responses to the pre-investigational new drug 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.

HTD1801

- Our core product, HTD1801, a new molecular entity, is a gut-liver anti-inflammatory metabolic modulator which targets multiple pathways pivotal to treating 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, PSC and SHTG.

MASH

- In March 2024, resmetirom, a thyroid hormone receptor β-selective agonist, became the first drug receiving marketing approval from the FDA for the treatment of fibrosis improvement and MASH resolution in patients with MASH. Given the disease's pathogenetic complexity and heterogeneity, the treatment of MASH is trending toward a multifunctional therapeutic approach.

- We have completed a randomized, double-blind, placebo-controlled Phase IIa study of HTD1801 in patients with MASH and T2DM in the United States in March 2020. 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.

- We presented additional data from the MASH Phase IIa study evaluating the effects of HTD1801 on liver fibroinflammation at the European Association for the Study of the Liver (EASL) in June 2023 and also at NASH-TAG in January 2024. The presentations showed that subjects receiving HTD1801 had significant reductions in fibroinflammatory disease of the liver as assessed by imaging and resulted in more patients achieving clinically relevant thresholds correlated with histologic improvement and lower disease activity.

  At The Liver Meeting of the American Association for the Study of Liver Disease (AASLD) in November 2023, a follow-up analysis to evaluate the characteristics and on-treatment changes in patients achieving MRI-based endpoints (e.g. cT1) associated with improvements in histology was presented. Twice as many patients achieved the MRI response criteria with HTD1801 compared to placebo. Additionally, improvements were observed with HTD1801 treatment in liver biochemistry and key cardiometabolic parameters in both patients who did and did not achieve the response criteria.

  These presentations provide further evidence that HTD1801 may improve liver histology in patients with MASH and T2DM and provides support for the ongoing biopsy-based Phase IIb study.

- At the EASL Congress in June 2024 multiple post-hoc analyses for the MASH Phase IIa study were presented including an evaluation of ongoing GLP-1 receptor agonists (GLP-1RAs) use compared to newly initiated HTD1801 treatment; analysis of the effects of HTD1801 response based on degree of insulin resistance; and a characterization of the time-course and severity of gastrointestinal (GI) adverse events (AEs) after treatment with HTD1801.

  Key messages from these EASL 2024 presentations are as follows:

  – HTD1801 provides greater benefit across multiple cardiometabolic endpoints compared to ongoing GLP-1RA use and that patients with MASH and T2DM, on concomitant GLP-1RAs, could achieve additional benefit in terms of further glucose and lipid lowering as well as weight loss with HTD1801.

  – Insulin resistance is a significant risk factor for T2DM, obesity and MASH. HTD1801 can alleviate the metabolic inhibitory effects caused by hyperinsulinemia, leading to even greater metabolic benefits in patients with MASH and more severe insulin resistance and therefore may offer a unique therapeutic approach for individuals with MASH and co-morbid T2DM.

  – These data demonstrate that with continued treatment with HTD1801, GI tolerability improves supporting its potential for long-term use for the treatment of chronic disease, such as MASH.

- 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, Hong Kong and Mainland China. The patient enrollment of Phase IIb has been completed in March 2024.

- We currently plan to complete the clinical trial and conduct data readout in the first half of 2025.

T2DM

- T2DM and metabolic dysfunction-associated steatotic liver disease ("**MASLD**", formerly known as nonalcoholic fatty liver disease) 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 cardiovascular diseases ("**CVDs**").

- We completed a Phase I study in healthy subjects in Mainland China in November 2021 and a Phase Ib study in Chinese subjects with T2DM in September 2022. We further completed a Phase II study in Chinese subjects with T2DM in January 2023.

- 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. 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 presented data from the T2DM Phase II study at the Annual Meeting of the European Association for the Study of Diabetes (EASD) in October 2023 demonstrating treatment with HTD1801 resulted in significant reductions hemoglobin A1c, and also achieved clinically important secondary endpoints related to improvements in metabolic and glycemic control. The multifaceted effects demonstrated by HTD1801 in this Phase II study support HTD1801 as a potential and novel oral treatment option for T2DM.

- At the American Diabetes Association's (ADA) 84th Scientific Session held in June 2024, a post-hoc analysis from the Phase II T2DM study presented the effectiveness of HTD1801 in patients with T2DM across the disease spectrum based on baseline HbA1c. Regardless of baseline disease severity, HTD1801 treatment resulted in significant improvements in key glycemic and lipid metabolism markers, as well as indicators of liver injury with a greater improvement in subjects with more severe disease. These data suggest HTD1801 may offer a unique therapeutic approach for individuals with T2DM and other comorbidities (i.e. MASH and dyslipidemia), as managing these conditions effectively is crucial in controlling T2DM and reducing its associated complications.

- 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 MASLD and dyslipidemia.

- The patient enrollments of the two Phase III registration trials of HTD1801 for the treatment of T2DM (SYMPHONY-1 and SYMPHONY-2) have been completed in June 2024.

- We currently plan to complete the clinical trials and conduct data readout in 2025.

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. HTD1801 is precisely engineered to target the disease's complex pathogenic mechanisms through a multifunctional synergistic approach.

- 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 choleretic 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.

- We completed a Phase II clinical trial of HTD1801 for PSC in the United States and Canada in August 2020, 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. We had also held a successful end of Phase II (EOP2) meeting with FDA and was permitted to commence Phase III clinical trial.

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. 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. 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.

- 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, which supports the therapeutic potential of HTD1801 in SHTG.

- We have completed Phase I clinical trial in healthy subjects in Australia. We will continue to evaluate the clinical progress of HTD1801 and, taking into account the overall strategy and resources allocation of the Group, assess the timeframe of initiating the Phase II clinical trial of HTD1801 for the treatment of SHTG.

HTD4010

- Building on our expertise in the development of HTD1801, we have also invested in and developed our pipeline to cover AH, obesity, 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 characterized by acute liver inflammation.

- 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. HTD4010 is a Toll-like receptor 4 inhibitor potentially capable of modulating the innate immune response and the resulting liver inflammation, a major contributor to AH pathogenesis.

HTD1804

- 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 CVDs and T2DM.

- 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

- HTD1805, another drug candidate in our pipeline, is a multifunctional small molecule drug for the treatment of metabolic diseases. It 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.

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 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.

Looking forward, we will continue to advance our pipeline of drug candidates through clinical development and continue to seek to expand indication coverage of our pipeline. With respect to commercialization, based on the expected approval timeline of each indication of HTD1801 in our pipeline, we expect to file new drug application 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, PSC and SHTG in multiple jurisdictions, including but not limited to the United States, European Union and China.

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

RESEARCH AND DEVELOPMENT CAPABILITY

We believe that our continued research and development ("**R&D**") is the key driver of our business growth and competitiveness.

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 is generally responsible for the global development of our pipeline products. 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 contract research organizations ("**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. Our R&D team is led by a team of world-class scientists with years of drug development experience.

Drug Discovery

We have worked on our product candidates' advancement for more than ten years and developed product candidates in-house. Our drug discovery team members have expertise in biology, medicinal chemistry, drug metabolism and pharmacokinetics, chemistry and early clinical areas, which support our product development.

Clinical Development

As of June 30, 2024, the clinical development team consisted of more than thirty 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 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. 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.

FINANCIAL OVERVIEW

The following discussion is based on, and should be read in conjunction with, the financial information and notes included elsewhere in this announcement.

Other Income and Gains

Our other income and gains increased by RMB15.6 million from RMB22.7 million for the six months ended June 30, 2023 to RMB38.3 million for the six months ended June 30, 2024, representing an increase of 68.7%.

The increase in the other income and gains was primarily because of the increase of approximately RMB15.1 million in government grants.

Fair Value Losses on Convertible Redeemable Preferred Shares

Our fair value changes of convertible redeemable preferred shares decreased from a loss of RMB399.6 million for the six months ended June 30, 2023 to nil for the six months ended June 30, 2024. The changes in 2023 are non-recurring after the completion of the listing (the "**Listing**") of the ordinary shares of the Company (the "**Share(s)**") on the Main Board of The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") on December 22, 2023 (the "**Listing Date**") as all of the Company's preferred shares were converted to ordinary shares upon the Listing Date.

Research and Development Costs

Our research and development costs primarily consist of (i) third-party contracting expenses primarily including early stage discovery expenses, preclinical expenses, and clinical development expenses for our drug candidates; (ii) staff costs, primarily consisting of salaries and benefits for our R&D team; (iii) expenses under the employee long-term incentive plans, representing expenses associated with share options 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 68.2% from RMB120.1 million for the six months ended June 30, 2023 to RMB202.0 million for the six months ended June 30, 2024. The increase was mainly attributable to an increase of approximately RMB70.8 million in third-party contracting expenses and an increase of approximately RMB12.0 million in the expenses under the employee long-term incentive plans.

The following table sets forth a breakdown of our research and development costs for the periods indicated:

	For the six months ended June 30,			
	2024		2023	
	RMB'000	***%***	*RMB'000*	*%*
Third-party contracting expenses	**146,294**	**72**	75,526	63
Staff costs	**21,056**	**10**	20,338	17
Expenses under the employee long-term incentive plans	**31,560**	**16**	19,548	16
Others	**3,064**	**2**	4,676	4
Total	**201,974**	**100**	120,088	100

Administrative Expenses

Our administrative expenses decreased by 11.3% from RMB52.0 million for the six months ended June 30, 2023 to RMB46.1 million for the six months ended June 30, 2024. The decrease in administrative expenses was primarily attributable to the decrease in professional service fees.

Loss for the Period

As a result of the above, we recorded a loss of RMB210.9 million for the six months ended June 30, 2024, as compared to RMB549.7 million for the six months ended June 30, 2023.

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 maximize value to the holders of the Shares (the "**Shareholders**").

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 the 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 Reporting Period.

Liquidity and Capital Resources

The Group has always adopted a prudent treasury management policy. The Group places strong emphasis on having funds readily available and accessible and is in a stable liquidity position with sufficient funds in standby banking facilities to cope with daily operations and meet its future development demands for capital.

As of June 30, 2024, the current assets of the Group were RMB594.4 million, of which cash and bank balances amounted to RMB392.4 million and other current assets amounted to RMB202.0 million. The Group's cash and bank balances decreased by 35.5% from RMB608.2 million as at December 31, 2023 to RMB392.4 million as at June 30, 2024. The decrease was mainly due to expenditure on research and development cost and administrative expenses. As at June 30, 2024, cash and bank balances were mainly denominated in United States dollars, Renminbi and Hong Kong dollars.

As of June 30, 2024, the current liabilities of the Group were RMB54.6 million, including trade payables of RMB38.7 million, other payables and accruals of RMB10.9 million and lease liabilities of RMB5.0 million.

Bank Borrowings

As of June 30, 2024, the Group did not have any outstanding interest-bearing bank borrowings (December 31, 2023: RMB3.5 million).

Charges on Group Assets

As of June 30, 2024, there were no charges on assets of the Company (December 31, 2023: nil).

Key Financial Ratios

The following table sets forth the key financial ratios for the dates indicated:

	As at June 30, 2024	**As at December 31,** 2023
Gearing Ratio [(1)]	**Nil**	0.5%
Current Ratio [(2)]	**10.9**	9.8

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.

Significant Investments

During the six months ended June 30, 2024, the Group held investments through two structured entities, Apollo Multi-Asset Growth Fund and Chaince Capital Fund LP (together the "**Funds**"), that the Group invested with initial capital contribution of US$12.5 million each. Such investments were made before the Listing Date. As at June 30, 2024, the underlying assets purchased by Apollo Multi-Asset Growth Fund and Chaince Capital Fund LP mainly included listed equity investments, which were classified as financial instruments at FVTPL of RMB85.5 million and RMB85.5 million (representing 13.8% and 13.8% of the Group's total assets as at June 30, 2024), respectively. The listed equity investments are non-principal guaranteed with floating return. During the six months ended June 30, 2024, the underlying assets purchased by the Funds generated an investment income of approximately RMB1.0 million.

Save as disclosed above, the Group did not have any significant investments and did not have other plans for significant investments or capital assets as at the date of this announcement.

Material Acquisitions and Disposals

The Group did not have any material acquisitions or disposals of subsidiaries, associates and joint ventures for the six months ended June 30, 2024.

Contingent Liabilities

The Group did not have any material contingent liabilities as at June 30, 2024.

Capital Commitments

As of December 31, 2023 and June 30, 2024, the Group had capital commitments contracted for but not yet provided of RMB2.6 million and RMB1.8 million, respectively, primarily in connection with property, plant and equipment.

Foreign Currency Risk

We have transactional currency exposures. Our Group's transactions were primarily denominated in US dollars, Renminbi and Hong Kong dollars. Certain of our cash and bank balances and trade and other payables are denominated in non-functional currency of the Company and exposed 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.

Non-IFRS Measures

To supplement our consolidated statements of profit or loss which are presented in accordance with IFRS, we also use adjusted net loss as non-IFRS measures, which are not required by, or presented in accordance with, IFRS. We believe that the presentation of non-IFRS measures when shown in conjunction with the corresponding IFRS measures provides useful information to investors and management in facilitating a comparison of our operating performance from period to period by eliminating potential impacts of certain non-operational or one-off expenses that do not affect our ongoing operating performance, including changes in fair value of convertible redeemable preferred shares, expenses under the employee long-term incentive plans and listing expenses. Such non-IFRS measures allow investors to consider metrics used by our management in evaluating our performance. Changes in fair value of convertible redeemable preferred shares represent the changes in fair value of various rights associated with the preferred shares, which is non-recurring and non-operational in nature. Expenses under the employee long-term incentive plans are non-operational expenses arising from granting options to selected directors, employees and consultants of the Company, the amount of which may not directly correlate with the underlying performance of our business operations, and is also affected by non-operating performance related factors that are not closely or directly related to our business activities. With respect to share awards, determining its fair value involves a high-degree of judgment. Historical occurrence of expenses under the employee long-term incentive plans is not indicative of any future occurrence. Listing expenses are one-off expenses in relation to the Listing. Therefore, we do not consider

changes in fair value of convertible redeemable preferred shares, expenses under the employee long-term incentive plans and Listing expenses to be indicative of our ongoing core operating performance and exclude them in reviewing our financial results. From time to time in the future, there may be other items that we may exclude in reviewing our financial results.

The use of the non-IFRS measures has limitations as an analytical tool, and you should not consider it in isolation from, or as a substitute for or superior to analysis of, our results of operations or financial condition as reported under IFRS. In addition, the non-IFRS financial measures may be defined differently from similar terms used by other companies and therefore may not be comparable to similar measures presented by other companies.

The following table shows reconciliation of net loss for the period to our adjusted net loss for the periods indicated:

	For the six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Net loss for the period	**(210,945)**	(549,744)
Added:		
Fair value changes on convertible redeemable preferred shares	**–**	399,635
Expenses under the employee long-term incentive plans	**54,036**	28,445
Listing expenses	**–**	16,315
Adjusted net loss	**(156,909)**	(105,349)

Employees and Remuneration Policy

As at June 30, 2024, we had 68 employees in total. The following table sets forth the number of our employees categorized by function as of June 30, 2023 and June 30, 2024.

	Number of employees as at June 30, 2024	Number of employees as at June 30, 2023
Discovery and Clinical Development	**42**	38
Regulatory Affairs	**6**	6
Management Operations	**20**	24
Total	**68**	68

The total employee benefit expense (excluding Directors' and chief executive's remuneration) incurred by the Group was RMB62.6 million for the six months ended June 30, 2024 (six months ended June 30, 2023: RMB45.3 million). The increase in remuneration cost was primarily attributable to the grants of options under the 2020 and 2023 share incentive plans of the Company (employee long term incentive plans adopted by the Company on January 22, 2020 and May 24, 2023, respectively) in the second half of 2023.

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.

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.

The Company has adopted share incentive plans on January 22, 2020 and May 24, 2023, respectively. For further details, please refer to the paragraph headed "D. Incentive Plans" in Appendix IV to the prospectus of the Company dated December 14, 2023 (the "**Prospectus**").

OTHER INFORMATION

Compliance with the Corporate Governance Code

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the Shareholders as a whole. The Company has adopted the Corporate Governance Code (the "**Corporate Governance Code**") contained in Part 2 of Appendix C1 to the Rules Governing the Listing of Securities on the Stock Exchange (the "**Listing Rules**") as its own code of corporate governance. The Directors are of the view that throughout the Reporting Period, the Company has complied with all applicable code provisions of the Corporate Governance Code save and except for the following deviation from code provision C.2.1 of the Corporate Governance Code.

Under code provision C.2.1 of the Corporate Governance Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Dr. Liu Liping ("**Dr. Liu**") has been serving as the chairwoman of the Board since the Listing and Chief Executive Officer since February 2018. 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, three non-executive Directors and three independent non-executive Directors, and therefore has a strong independence element in its composition.

The Board will continue to review the effectiveness of the corporate governance structure of the Group in order to assess whether separation of the roles of chairperson and the chief executive officer is necessary.

Compliance with the Model Code for Securities Transactions by Directors of Listed Issuers (the "Model Code")

The Company has adopted the Model Code set out in Appendix C3 to the Listing Rules as its own code of conduct regarding dealings in the securities of the Company by the Directors and the Company's employees who, because of his/her office or employment, is likely to possess inside information in relation to the Company or its securities.

Upon specific enquiry, all Directors confirmed that they have complied with the Model Code throughout the Reporting Period. In addition, the Company is not aware of any non-compliance of the Model Code by the employees of the Company who are likely to be in possession of inside information of the Company throughout the Reporting Period.

Purchase, Sale or Redemption of the Company's Listed Securities

Neither the Company nor any of its subsidiaries purchased, redeemed or sold any of the Company's listed securities (including sale of treasury shares, as defined in the Listing Rules) during the Reporting Period. The Company did not hold any treasury shares (as defined in the Listing Rules) as of June 30, 2024.

Material Litigation

The Company was not involved in any material litigation or arbitration during the Reporting Period which could have a material and adverse effect on our financial condition or results of operations. The Directors are also not aware of any material litigation or claims that are pending or threatened against the Company during the Reporting Period which could have a material and adverse effect on our financial condition or results of operations.

Use of Net Proceeds from the Listing

The total net proceeds from the issue of shares by the Company in its Listing amounted to approximately HK$194.1 million, after deducting the underwriting commission and other expenses payable by the Company in connection with the Listing. During the Reporting Period, the net proceeds were used according to the intentions previously disclosed by the Company in the Prospectus. The balance of unutilized net proceeds amounted to approximately HK$156.1 million as at the end of the Reporting Period and the Company intends to use them in the same manner and proportions as described in the Prospectus and proposes to use the unutilized net proceeds in accordance with the expected timetable disclosed in the table below.

	Use of proceeds in the same manner and proportion as stated in the Prospectus	Net proceeds unutilized as at the beginning of the Reporting Period	Actual use of proceeds during the Reporting Period	Actual use of proceeds as at the end of the Reporting Period	Net proceeds unutilized as at the end of the Reporting Period	Expected time frame for utilizing the remaining unutilized net proceeds[Note]
	HK$ in million	*HK$ in million*	*HK$ in million*	*HK$ in million*	*HK$ in million*	
Approximately 80.0% to fund the continuing clinical research and development activities of our HTD1801	155.2	155.2	36.2	36.2	119.0	December 2025
Approximately 5.0% to fund the ongoing research and development including R&D personnel costs and third party contracting expenses for HTD1804 for obesity	9.7	9.7	0.2	0.2	9.5	December 2025
Approximately 10.0% for the early drug discovery and development of other drug candidates from continuously upgrading and enhancing our FUSIONTX™ development approach	19.5	19.5	1.8	1.8	17.7	December 2025
Approximately 5.0% for working capital and other general corporate purposes	9.7	9.7	–	–	9.7	December 2025
Total	194.1	194.1	38.2	38.2	155.9	

Note: The expected timeframe for utilizing the remaining unutilized net proceeds is based on the best estimation of the factual business needs and future business development of the Group. It will be subject to change based on the current and future developments of market conditions and future business needs of the Group.

Review of Interim Results

The audit committee of the Board (the "**Audit Committee**"), comprising three independent non-executive Directors, being Mr. TAN Bo (譚擘) (chairman of the Audit Committee with the appropriate professional qualifications), Dr. Jin LI (李靖) and Mr. HUNG Tak Wai (孔德偉), together with the management of the Company, have considered and reviewed the Group's unaudited interim results for the Reporting Period, the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters, and are of the view that the interim results of the Group are prepared in compliance with the relevant accounting standards, laws and regulations and the Company has made appropriate disclosures thereof. The interim condensed consolidated financial information of the Group for the Reporting Period has not been audited. The Company's independent auditor, Ernst & Young, has performed an independent review of the Group's interim financial information for the Reporting Period 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 Hong Kong Institute of Certified Public Accountants. There is no disagreement by the Audit Committee or the auditor of the Company with the accounting treatment adopted by the Company.

Events after the Reporting Period

There were no important events affecting the Group occurred since June 30, 2024 and up to the date of this announcement.

Interim Dividend

The Board did not recommend the distribution of an interim dividend for the six months ended June 30, 2024 (six months ended June 30, 2023: nil).

Publication of Interim Results Announcement and Interim Report

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.hightidetx.com). The interim report for the six months ended June 30, 2024 containing all the information required by the Listing Rules will be dispatched to the Shareholders (if appropriate) in accordance with the Listing Rules and published on the websites of the Stock Exchange and the Company in due course.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the six months ended 30 June 2024

	Notes	**2024** ***RMB'000*** **(Unaudited)**	2023 *RMB'000* (Audited)
Other income and gains	4	**38,273**	22,722
Fair value losses on convertible redeemable preferred shares		**–**	(399,635)
Other expenses		**(171)**	(502)
Research and development costs		**(201,974)**	(120,088)
Administrative expenses		**(46,054)**	(52,014)
Finance costs		**(481)**	(201)
LOSS BEFORE TAX		**(210,407)**	(549,718)
Income tax expenses	5	**(538)**	(26)
LOSS FOR THE PERIOD		**(210,945)**	(549,744)
Attributable to:			
Owners of the parent		**(210,945)**	(549,744)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	7		
Basic and diluted			
For loss for the period (RMB per share)		**(0.47)**	(2.16)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME

For the six months ended 30 June 2024

	2024	2023
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
LOSS FOR THE PERIOD	**(210,945)**	(549,744)
OTHER COMPREHENSIVE INCOME/(LOSS)		
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of the financial statements of subsidiaries	**(1,317)**	(8,896)
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of the financial statements of the Company	**4,114**	(27,703)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD, NET OF TAX	**2,797**	(36,599)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	**(208,148)**	(586,343)
Attributable to:		
Owners of the parent	**(208,148)**	(586,343)

INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	30 June 2024 *RMB'000* (Unaudited)	31 December 2023 *RMB'000* (Audited)
NON-CURRENT ASSETS			
Property, plant and equipment		**1,729**	2,410
Right-of-use assets		**21,671**	12,571
Other non-current assets		**3,997**	1,302
Total non-current assets		**27,397**	16,283
CURRENT ASSETS			
Prepayments, other receivables and other assets		**30,934**	43,052
Financial assets at fair value through profit or loss ("**FVTPL**")		**171,046**	127,489
Cash and bank balances		**392,395**	608,212
Total current assets		**594,375**	778,753
CURRENT LIABILITIES			
Trade payables	8	**38,747**	30,507
Other payables and accruals		**10,865**	43,336
Interest-bearing bank borrowings		**–**	3,500
Lease liabilities		**5,009**	2,468
Total current liabilities		**54,621**	79,811
NET CURRENT ASSETS		**539,754**	698,942
TOTAL ASSETS LESS CURRENT ASSETS		**567,151**	715,225
NON-CURRENT LIABILITIES			
Lease liabilities		**18,100**	10,464
Deferred income		**389**	1,987
Total non-current liabilities		**18,489**	12,451
Net assets		**548,662**	702,774
EQUITY			
Equity attributable to owners of the parent			
Share capital		**364**	364
Treasury shares		**(44)**	(44)
Reserves		**548,342**	702,454
Total equity		**548,662**	702,774

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

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. During the reporting periods, the Company and its subsidiaries were involved in the research and development of pharmaceutical products.

2.1. BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended 30 June 2024 has been prepared in accordance with IAS 34 Interim Financial Reporting. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual consolidated financial statements for the year ended 31 December 2023.

This interim condensed consolidated financial information is presented in Renminbi ("**RMB**") and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

2.2. CHANGES IN ACCOUNTING POLICIES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group's annual consolidated financial statements for the year ended 31 December 2023, except for the adoption of the following revised International Financial Reporting Standards ("**IFRSs**") for the first time for the current period's financial information.

Amendments to IFRS 16	Lease Liability in a Sale and Leaseback
Amendments to IAS 1	Classification of Liabilities as Current or Non-current (the "**2022 Amendments**")
Amendments to IAS 1	Non-current Liabilities with Covenants (the "**2022 Amendments**")
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements

The adoption of the revised standards has no significant financial effect on the Group's interim condensed consolidated financial information.

3. 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

During the reporting period, since almost all of the Group's non-current assets were located in Chinese Mainland, no geographical segment information in accordance with IFRS 8 Operating Segments is presented.

Information about major customers

No revenue was derived during the six months ended 30 June 2024 and 2023. Therefore, no information about major customer is presented.

4. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	For the six months ended 30 June	
	2024	2023
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Other income and gains		
Government grants related to expense items*	**23,938**	8,875
Government grants related to assets**	**98**	67
Bank interest income	**2,465**	696
Investment income from short-term time deposits	**7,961**	12,931
Other investment income from financial assets at FVTPL	**420**	120
Foreign exchange gains, net	**3,047**	–
Fair value gain on financial assets at FVTPL	**137**	–
Others	**207**	33
	38,273	22,722

* 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 Development and Reform Commission of Shenzhen Municipality. 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.

5. 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

Hong Kong profits tax has been provided at the rate of 16.5% (2023: 16.5%) on the estimated assessable profits arising in Hong Kong during the period, except for one subsidiary of the Group which is a qualifying entity under the two-tiered profits tax rates regime. The first HK$2,000,000 (2023: HK$2,000,000) of assessable profits of this subsidiary are taxed at 8.25% (2023: 8.25%) and the remaining assessable profits are taxed at 16.5% (2023: 16.5%). Taxes on profits assessable elsewhere have been calculated at the rates of tax prevailing in the jurisdictions in which the Group operates.

Chinese Mainland

No provision for Chinese Mainland 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 Chinese Mainland 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 2022 and Shenzhen HighTide is entitled a preferential income tax rate of 15% from 2022 to 2024.

JSK Consumer Healthcare Ltd, Shanghai HighTide Biopharmaceutical Ltd., Shanghai Fusion Therapeutics Inc., Hebei Puhui Pharmaceutical Co., Ltd 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 annual taxable income was entitled to be included in the actual taxable income at reduced rates of 25% during the period (2023: 25%).

Australia

The subsidiary incorporated in Australia was subject to income tax at the rate of 25% on the estimated assessable profits arising in Australia during the period.

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 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 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 period.

The income tax expense of the Group during the period is analysed as follows:

	For the six months ended 30 June	
	2024	2023
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Current tax:		
Charge for the period	**162**	26
Adjustments in respect of current tax of previous periods	**376**	–
Total tax expense for the period	**538**	26

6. DIVIDENDS

No dividend was paid or declared by the Company during the reporting periods.

7. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss for the period attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares of 452,074,904 (30 June 2023:254,825,232) in issue (excluding shares reserved for share incentive scheme) during the year.

In the calculation of the weighted average number of ordinary shares outstanding for the period ended 30 June 2023, the shares issued to existing shareholders before public offering through the Capitalisation Issue had been adjusted retrospectively as if those shares have been issued since 1 January 2023.

No adjustment was made to the basic loss per share amounts presented for the periods ended 30 June 2024 and 2023 in respect of a dilution as the impact of the convertible redeemable preferred shares and share-based payment had an anti-dilutive effect on the basic loss per share amounts presented.

Loss per share (basic and diluted) (RMB per share) during the period is (0.47).

8. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of the reporting periods, based on the invoice date, is as follows:

	30 June 2024	31 December 2023
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Within one year	**38,747**	30,507

The trade payables are non-interest-bearing and are normally settled within one month after the receipt of the invoice.

By order of the Board
HighTide Therapeutics, Inc.
Dr. LIU Liping
Executive Director and Chief Executive Officer

Hong Kong, August 28, 2024

As at the date of this announcement, the Board comprises Dr. LIU Liping and Ms. YU Meng as executive Directors; Dr. ZHU Xun, Mr. MA Lixiong and Mr. JIANG Feng as non-executive Directors; and Mr. TAN Bo, Dr. Jin LI and Mr. HUNG Tak Wai as independent non-executive Directors.