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## CANbridge Pharmaceuticals Inc.

北海康成製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 1228)

### ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2022

The board of directors (the “**Board**”) of CANbridge Pharmaceuticals Inc. (the “**Company**”) is pleased to announce the audited consolidated annual results of the Company and its subsidiaries (the “**Group**”, “**we**”, “**our**” or “**us**”) for the year ended December 31, 2022 (the “**Reporting Period**”), together with comparative figures for the year ended December 31, 2021 as follows. These consolidated financial statements of the Group for the Reporting Period have been reviewed by the Audit Committee and audited by the Company’s auditors, Ernst & Young.

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

#### BUSINESS HIGHLIGHTS

The Group has made significant progress with respect to its drug pipeline and business operations, including the following milestones and achievements:

***Hunterase® (CAN101)**, targeting MPS II (also known as Hunter syndrome), MPS II has been included in the “First National List of Rare Diseases”<sup>1</sup> in China since May 2018.*

- CANbridge commercial team continues to make good progress in Hunterase®, launched in May 2021 in mainland China as the first and the only enzyme replacement therapy treatment for MPS II. Identification of new patients is accelerating as is the expansion of commercial insurance coverage. Since launch, we have identified 667 patients as of December 31, 2022. In addition, in China, Hunterase has entered into 78 cities’ commercial insurance programme (“**Huiminbao**”) as of December 31, 2022.

1: On May 22, 2018, China’s “First National List of Rare Diseases” was issued jointly by five national authorities, including the National Health Commission of the People’s Republic of China (中華人民共和國國家衛生健康委員會), Ministry of Science and Technology of the People’s Republic of China (中華人民共和國科學技術部), Ministry of Industry and Information Technology of the People’s Republic of China (中華人民共和國工業和信息化部), National Medical Products Administration (國家藥品監督管理局), and National Administration of Traditional Chinese Medicine (國家中醫藥管理局).

**CAN108 maralixibat oral solution/Livmarli®**, an oral, minimally absorbed reversible inhibitor of the ileal bile acid transporter (IBAT) under development to treat rare cholestatic liver diseases. Livmarli is approved to treat Alagille syndrome (ALGS) in the United States (U.S.) and Europe and is under investigation for the treatment of progressive familial intrahepatic cholestasis (PFIC) and biliary atresia (BA). PFIC has been included in the “First National List of Rare Diseases” in China since May 2018. CANbridge has the exclusive rights to develop, commercialize, and under certain conditions, manufacture Livmarli in Greater China.

- The first patient in the Phase 2 EMBARK<sup>1</sup> study of Livmarli in biliary atresia (BA) was dosed in China, at Children’s Hospital of Capital Institute of Pediatrics (CIP), in Beijing. This clinical trial in China is part of the global EMBARK study in BA conducted by Mirum, and supported by CANbridge under the license agreement with Mirum. The multi-center randomized controlled Phase 2 study to evaluate the efficacy and safety of Livmarli in the treatment of patients with BA after Kasai surgery is expected to enroll at least 20 patients in Greater China.
- Livmarli has been approved for the treatment of ALGS under the Early and Pilot Implementation Policy in Boao Lecheng International Medical Tourism Pilot Zone. This allows Livmarli to be imported and used as an urgently needed drug in the region. Livmarli was first prescribed in Boao Lecheng in March 2022.
- The Company filed New Drug Application/Orphan Drug Registration (NDA/ODR) to the China’s National Medical Products Administration (NMPA) and the Taiwan Food and Drug Administration (TFDA) for Livmarli for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. Livmarli was approved in 2021 by the U.S. Food and Drug Administration (FDA) and in December 2022 by the EU Marketing Authority for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS). Livmarli has also been granted priority review by the NMPA with a potential approval in the first half of 2023.
- Mirum realized \$75.1 million in Livmarli net product sales in the first full fiscal year of its U.S. launch.

**CAN106**, a novel, long-acting monoclonal antibody for the treatment of complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria (PNH), myasthenia gravis (MG) and various other complement-mediated diseases that are targeted by anti-C5 antibodies. PNH has been included in the “First National List of Rare Diseases” in China since May 2018.

- In November 2022, the United States Food and Drug administration (FDA) granted CAN106 Orphan Drug Designation for the treatment of myasthenia gravis (MG), an autoimmune neuromuscular disease that causes weakness in skeletal muscles. CAN106 is eligible to receive the benefits provided under the Orphan Drug Act, including 50% tax credit for qualifying clinical trials, waivers for regulatory submission fees, eligibility to receive federal research grants, and upon marketing authorization for MG, 7 years of market exclusivity.
- Presented Phase 1 data at the 17th National Conference on Hematology held in Shanghai, at the 6th Annual Complement Based Drug Development Summit 2022 held in Boston, MA, at the European Hematology Association 2022 Congress in Vienna and at the 14<sup>th</sup> International Conference on Complement Therapeutics, June 17-22, in Rhodes, Greece. Presentations highlighted positive top-line Phase I data from the Singapore trial first reported in February 2022. Results suggest complete blockade of complement function at safe and well-tolerated doses.

1: About the EMBARK Study: EMBARK is a Mirum Pharmaceuticals-sponsored global Phase 2 study to evaluate the efficacy and safety of maralixibat in the treatment of patients with BA after Kasai surgery (NCT04524390). The 26-week randomized controlled trial, to be followed by a 78-week open label extension study, is being conducted at multiple sites in North America, Europe, and Asia, including China. There are currently no pharmacological agents approved for the treatment of patients with biliary atresia.

- We dosed the first patient in the CAN106 Phase 1b/2 trial for treatment of paroxysmal nocturnal hemoglobinuria (PNH) in China in March 2022. The multi-center, open-label, phase 1b/2 study to evaluate the tolerability, efficacy, safety and PK/PD of CAN106 administered intravenously to complement inhibitor treatment-naïve PNH patients, is under the direction of principal investigator, Bing Han, MD, PhD, Chief Physician and Professor in the Department of Hematology at Peking Union Medical College Hospital in Beijing, China. CAN106 was previously shown to be safe and well-tolerated, with dose-dependent and linear pharmacokinetic exposure, in a study of healthy volunteers in Singapore. The data also showed that free C5 and CH50 could be effectively inhibited. Based on these results, the NMPA approved the CAN106 Phase 1b/2 trial for the treatment of patients with PNH. The ongoing Phase 1b part consists of 3 cohorts and the Company plans to announce topline data from phase 1b mid-year 2023.

**CAN008**, a glycosylated CD95-Fc fusion protein being developed for the treatment of glioblastoma multiforme (GBM).

- Enrollment continues in the CAN008 Phase 2 trial in patients with newly diagnosed GBM in China during the reporting period. This multi-center, randomized, double-blind, placebo-controlled trial will evaluate the efficacy and safety of CAN008 and explore the correlation between different biomarkers and treatment outcome. The primary endpoint of the trial is progression-free survival (PFS), and the key secondary endpoint is overall survival (OS). We completed trial enrollment in March 2023 and the potential interim read out is anticipated in the second half of 2023.
- CANbridge expects to commercialize CAN008 in China as a combination therapy with the standard of care for GBM (radiotherapy plus chemotherapy).
- Long-term data from the leading site of the phase 1/2 trial presented in ESMO<sup>1</sup> in Mar 2023 showed
  - 67% five-year OS rate compared to 8.2% in institutional database
  - 83% OS at two years vs. 34.3% OS from institutional database
  - 17.95 months median PFS vs. 5.8 months PFS in historical group
- The Company owns the rights to CAN008 for all potential indications in Greater China, including as a potential novel treatment option to treat COVID-19.

**CAN103**, an enzyme replacement therapy (ERT) for the treatment of Gaucher disease (GD). GD has been included in the “First National List of Rare Diseases” in China since May 2018.

- We dosed the first patient in the CAN103 Phase 1/2 for the treatment of patients with Gaucher disease (GD) Types I and III, in China, in July 2022. The multi-center Phase 1/2 clinical trial consists of two parts: Part A (Phase 1) is an open-label study to evaluate the safety, tolerability and pharmacokinetics of different dose levels of CAN103 in a small number of treatment-naïve subjects with Gaucher disease Type I. Part B (Phase 2) is a study to assess the safety and efficacy of CAN103 in a larger number of subjects with Gaucher disease Type I or III. Part B of the trial will serve as a potential registrational trial. The Company completed Part A and initiated dosing in Part B in the first quarter of 2023. The Company expects to file a NDA by mid 2024.
- CAN103 is the first enzyme replacement therapy for Gaucher disease that is being developed in the clinical trial stage in China.

1: European Society of Medical Oncologists (ESMO) Sarcoma and Rare Cancers Annual Congress

**Gene Therapy**, advanced the world-class CANbridge gene therapy platform, focusing on adeno-associated virus (AAV) as a gene delivery vehicle, with potential as a one-time durable therapy for many genetic diseases. The CANbridge Next-Generation Innovation and Process Development Facility is developing novel, potentially curative, gene therapies for rare genetic diseases, including Pompe disease, Fabry disease, spinal muscular atrophy (SMA) and other neuromuscular conditions. Fabry disease and SMA have been included in the “First National List of Rare Diseases” in China since May 2018.

- Presented initial data from the CANbridge gene therapy research agreement with the Horae Gene Therapy Center, at the UMass Chan Medical School, at the European Society of Gene and Cell Therapy (ESGCT) 29th Annual Congress in October 2022 and at the 2022 American Society of Gene and Cell Therapy (ASGCT) Annual Meeting in May 2022. Data from a novel second-generation scAAV9 gene therapy, expressing co-hSMN1 from an endogenous hSMN1 promoter, demonstrated superior potency, efficacy and safety in mice with spinal muscular atrophy (SMA), compared to the benchmark vector, scAAV9-CMVen/CB-hSMN1, which is similar to the vector used in the gene therapy approved by the FDA for the treatment of SMA. This is the first data to be presented from the gene therapy research collaboration between CANbridge and the Gao Lab at the Horae Gene Therapy Center.
- The Company announced the license from the UMass Chan Medical School for the global development and commercialization rights to a novel second-generation scAAV9 gene therapy, expressing co-hSMN1 from an endogenous hSMN1 promoter, for the treatment of SMA. CANbridge plans to file a U.S. IND by the fourth quarter of 2024.
- The Company obtained non-exclusive worldwide rights to the LogicBio (a wholly owned subsidiary of Alexion, AstraZeneca Rare Disease) proprietary manufacturing process for Fabry and Pompe gene therapies in the second half of 2022. The Company completed the full technology transfer of gene therapy products under development for the treatment of Fabry and Pompe diseases from LogicBio® Therapeutics by the end of 2022.
- CANbridge has also built up full inhouse gene therapy research and development capabilities.

### **Organizational Updates:**

- Formed a world-class Complement Disease Scientific Advisory Board focused on the global development of CAN106, a novel, long-acting monoclonal antibody directed against C5 complement in July 2022. CANbridge is developing CAN106 for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) and other complement-mediated diseases. CAN106 is currently in a Phase 1b/2 PNH trial in China. The advisory board will offer guidance on the CAN106 clinical development program, as well as explore the potential for CAN106 in other indications.

The members of scientific advisory board are:

- **Anthony Amato, MD**, Brigham and Women’s Hospital Distinguished Chair in Neurology, Chief of the Neuromuscular Division and Director of the Clinical Neurophysiology Laboratory at Brigham and Women’s Hospital, and Professor of Neurology at Harvard Medical School.
- **Robert Colvin, MD**, Pathologist-in-Chief, Emeritus at Massachusetts General Hospital, and the Benjamin Castleman Distinguished Professor of Pathology at Harvard Medical School.
- **Gerald Cox, MD, PhD**, Chief Development Strategist & Interim Chief Medical Officer, Clinical geneticist and pediatrician at Boston Children’s Hospital, Former Chief Medical Officer at Editas Medicine, Vice President, Rare Disease Clinical Development at Sanofi.

- **Jean Francis, MD**, Medical Director of the Kidney Transplant Program at Boston Medical Center and Boston University School of Medicine, Medical Director of the Combined Pancreas Transplant Program at Boston Medical Center and Brigham and Women’s Hospital, and Associate Professor of Medicine at Boston University School of Medicine.
- **Richard Polisson, MD, MHSc**, Clinical Development Consultant and, most recently, former Chief Medical Officer at Artax Biopharma.
- **Sushrut Waikar, MD, MPH**, Chief of Nephrology at Boston Medical Center and the Norman G. Levinsky Professor of Medicine at Boston University School of Medicine, and formerly the Constantine L. Hampers, MD Distinguished Chair in Renal Medicine at Brigham and Women’s Hospital.
- **Brian Weinschenker, MD**, Professor of Neurology at the University of Virginia, and formerly Professor of Neurology at Mayo Clinic.

Appointed Mr. Edward Hu (“**Mr. Hu**”) as a non-executive director of the Company (the “**Director(s)**”) and a member of the remuneration committee of the Board (the “**Remuneration Committee**”), replacing Mr. Xiao Le, effective from July 5, 2022. Mr. Hu brings to the Company a deep and varied C-level biopharmaceutical experience, having served as both Co-Chief Executive Officer and Chief Financial Officer at WuXi AppTec before his current position of Vice Chairman, Global Chief Investment Officer, Executive Director, Strategy Committee Member. Before then, Mr. Hu was Chief Financial Officer and Chief Operating Officer at WuXi PharmaTech. Prior to his roles at WuXi, Mr. Hu held multiple senior management roles, culminating in that of Senior Vice President and Chief Operating Officer at Tanox Inc., a NASDAQ-traded public company, which was acquired by Genentech. Prior to that, Mr. Hu served as business planning manager of Biogen Inc, and before then, as senior financial analyst at Merck. Mr. Hu is currently a non-executive director of CStone Pharmaceuticals and a director of Ambrx Biopharma. Previously, he also served as non-executive director of WuXi Biologics, as well as a director of Viela Bio Inc, which was acquired by Horizon Therapeutics in March 2021. Mr. Hu received a bachelor’s degree in physics from Hangzhou University (currently, Zhejiang University), in Zhejiang province, China. He also has a master’s degree in chemistry and a master’s degree in business administration, both from Carnegie Mellon University, in Pittsburgh, Pennsylvania.

Appointed Dr. Lan Hu (“**Dr. Hu**”), Ph.D. as an independent non-executive Director and a member of the Remuneration Committee, effective from February 16, 2022. Dr. Hu has a rich background in healthcare investment, operations and administrative management and is a seasoned entrepreneur, having founded Beijing Amcare Women’s & Children’s Hospital Co., Ltd. in 2004, where she also served as Director, Chairman of the Board and General Manager. She is currently also serving as the chairman of the board and general manager of Beijing Amcare Medical Management Co., Ltd., the chairman of the board of Beijing Meizhong Airui Tumor Hospital Co., Ltd., the independent director of Beijing Yida Shidai Technology Development Co., Ltd. and the executive director and general manager of Beijing Xuanhe Yazhi Management Consulting Co., Ltd. She obtained a bachelor’s degree in medicine from Peking University in 1993, further obtained a Ph.D. in medical sciences from Medical College of Ohio in 2000 and a master’s degree in business administration from University of Michigan in 2002.

With effect from February 16, 2022, (i) Mr. James Arthur Geraghty (“**Mr. Geraghty**”) has ceased to be a member of the Remuneration Committee; (ii) Dr. Richard James Gregory has ceased to be a member of the audit committee of the Board (the “**Audit Committee**”); and (iii) Mr. Geraghty was appointed as a member of the Audit Committee.

Appointed Dr. Ping Li (“**Dr. Li**”), MD, to the position of Senior Vice President of Clinical Development and Operations in reporting period. Dr. Li brings to CANbridge a wealth of international clinical development experience, in both small molecule and biologic products, across multiple indications and markets. Most recently, she was at Connect Biopharma, where she held the position of Vice President of Clinical Development and was responsible for creating and implementing the clinical development strategy. During her time there, she oversaw five NMPA IND approvals, three FDA IND approvals, eight clinical trial initiations and six clinical trial completions. Before then, she was Executive Director of Clinical Operations at Shanghai Haihe Pharmaceutical Company, Ltd. and Medical & Scientific Affairs Director at Servier China. Earlier, Dr. Li held multiple clinical development and medical roles at leading multinational pharmaceutical companies, including Medical Director at Takeda China, Head of the Medical Affairs at Bayer Healthcare, Senior Medical Manager at Xi’an Janssen and Medical Manager at Shanghai Roche. Dr. Li began her career as a cardiologist at Beijing Fuwai Heart Disease Hospital in Beijing, China.

## **FINANCIAL HIGHLIGHTS**

- Our revenue increased by RMB47.8 million or 153.2%, from RMB31.2 million for the year ended December 31, 2021 to RMB79.0 million for the year ended December 31, 2022, which was mainly attributable to the increase of sales from Hunterase® and Nerlynx®.
- Our research and development (“**R&D**”) expenses decreased by approximately RMB116.5 million or 27.2%, from RMB427.7 million for the year ended December 31, 2021 to RMB311.2 million for the year ended December 31, 2022, which was primarily attributable to decreased upfront and milestone payments made to our licensing partners, partially offset by our increased testing and clinical trial expenses. Our testing and clinical trial expenses increased by RMB37.5 million, from RMB136.8 million for the year ended December 31, 2021 to RMB174.3 million for the year ended December 31, 2022.
- Loss for the year decreased by approximately RMB593.5 million or 55.1% from RMB1,077.0 million for the year ended December 31, 2021 to RMB483.5 million for the year ended December 31, 2022, which was primarily attributable to the decrease of loss on fair value changes of convertible redeemable preferred shares and R&D costs.
- The adjusted loss for the year decreased by RMB124.6 million, or 21.4%, from RMB581.3 million for the year ended December 31, 2021, to RMB456.7 million, for the year ended December 31, 2022. The adjusted loss for the year is arrived at by adjusting the IFRS loss for the year of RMB483.5 million (2021: RMB1,077.0 million) from excluding the effect of (i) a one-time, non-cash, IFRS fair value changes of our pre-IPO convertible redeemable preferred shares and derivative financial instruments, (ii) the share-based payment expenses, and (iii) the listing expenses. Please refer to the section headed “Non-IFRS Measures” of this announcement for details.

**CONSOLIDATED STATEMENTS OF PROFIT OR LOSS***Year ended 31 December 2022*

	<i>Notes</i>	<b>2022</b> <b>RMB'000</b>	2021 <i>RMB'000</i>
<b>REVENUE</b>	4	<b>78,972</b>	31,161
Cost of sales		<u>(30,078)</u>	<u>(12,385)</u>
Gross profit		<b>48,894</b>	18,776
Other income and gains	4	<b>12,883</b>	13,402
Selling and distribution expenses		<b>(86,782)</b>	(100,748)
Administrative expenses		<b>(108,907)</b>	(145,517)
Research and development expenses		<b>(311,174)</b>	(427,658)
Fair value changes of convertible redeemable preferred shares		–	(462,436)
Fair value changes of derivative financial instruments		–	34,454
Finance costs		<b>(6,863)</b>	(3,079)
Other expenses		<u>(31,526)</u>	<u>(4,200)</u>
<b>LOSS BEFORE TAX</b>		<b>(483,475)</b>	(1,077,006)
Income tax expense	5	<u>–</u>	<u>–</u>
<b>LOSS FOR THE YEAR</b>		<b><u>(483,475)</u></b>	<b><u>(1,077,006)</u></b>
Attributable to:			
Owners of the parent		<b><u>(483,475)</u></b>	<b><u>(1,077,006)</u></b>
<b>LOSS PER SHARE</b>			
<b>ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (EXPRESSED IN RMB PER SHARE)</b>			
– Basic and diluted	7	<b><u>(1.14)</u></b>	<b><u>(11.43)</u></b>

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2022

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
<b>LOSS FOR THE YEAR</b>	<b><u>(483,475)</u></b>	<b><u>(1,077,006)</u></b>
<b>OTHER COMPREHENSIVE INCOME</b>		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>(109,485)</u>	<u>16,461</u>
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods	<u>(109,485)</u>	<u>16,461</u>
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of the Company	<u>181,268</u>	<u>29,424</u>
Net other comprehensive income that will not be reclassified to profit or loss in subsequent periods	<u>181,268</u>	<u>29,424</u>
<b>OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX</b>	<b><u>71,783</u></b>	<b><u>45,885</u></b>
<b>TOTAL COMPREHENSIVE INCOME FOR THE YEAR</b>	<b><u>(411,692)</u></b>	<b><u>(1,031,121)</u></b>
Attributable to:		
Owners of the parent	<b><u>(411,692)</u></b>	<b><u>(1,031,121)</u></b>

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION***31 December 2022*

	<i>Notes</i>	<b>2022</b> <b>RMB'000</b>	2021 <b>RMB'000</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		<b>15,003</b>	9,564
Right-of-use assets		<b>129,714</b>	19,978
Intangible assets		<b>49,011</b>	51,269
Other non-current assets		<b>3,157</b>	–
		<hr/>	<hr/>
Total non-current assets		<b>196,885</b>	80,811
		<hr/>	<hr/>
<b>CURRENT ASSETS</b>			
Inventories		<b>9,824</b>	13,448
Trade receivables	<i>8</i>	<b>19,054</b>	9,141
Prepayments, other receivables and other assets		<b>13,175</b>	43,307
Cash and bank balances		<b>463,107</b>	745,815
		<hr/>	<hr/>
Total current assets		<b>505,160</b>	811,711
		<hr/>	<hr/>
<b>CURRENT LIABILITIES</b>			
Trade payables	<i>9</i>	<b>107,540</b>	43,607
Other payables and accruals		<b>130,670</b>	103,423
Interest-bearing bank and other borrowings		<b>26,867</b>	30,868
Lease liabilities		<b>13,028</b>	7,882
		<hr/>	<hr/>
Total current liabilities		<b>278,105</b>	185,780
		<hr/>	<hr/>
<b>NET CURRENT ASSETS</b>		<b>227,055</b>	625,931
		<hr/>	<hr/>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<b>423,940</b>	706,742
		<hr/>	<hr/>
<b>NON-CURRENT LIABILITIES</b>			
Interest-bearing bank and other borrowings		<b>10,779</b>	–
Lease liabilities		<b>104,606</b>	13,351
		<hr/>	<hr/>
Total non-current liabilities		<b>115,385</b>	13,351
		<hr/>	<hr/>
Net assets		<b>308,555</b>	693,391
		<hr/> <hr/>	<hr/> <hr/>
<b>EQUITY</b>			
<b>Equity attributable to owners of the parent</b>			
Share capital		<b>28</b>	28
Reserves		<b>308,527</b>	693,363
		<hr/>	<hr/>
<b>Total equity</b>		<b>308,555</b>	693,391
		<hr/> <hr/>	<hr/> <hr/>

## 1. CORPORATE AND GROUP INFORMATION

The Company was incorporated as an exempted company with limited liability in the Cayman Islands on 30 January 2018. The registered office address of the Company is 89 Nexus Way, Camana Bay, Grand Cayman, KY1-9009, Cayman Islands.

The Company is an investment holding company. During the year, the Group was principally engaged in the research and development and commercialisation of medical products.

The shares of the Company have been listed on the Main Board of the Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) effective from 10 December 2021.

## 2. BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards (“**IFRSs**”) (which include all International Financial Reporting Standards, International Accounting Standards (“**IASs**”) and Interpretations) issued by the International Accounting Standards Board (“**IASB**”) and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention. These financial statements are presented in Renminbi (“**RMB**”) and all values are rounded to the nearest thousand except when otherwise indicated.

The financial statements has been prepared on the assumption that the Group will continue as a going concern, which assumes that the Group will be able to meet its obligations and continue its operations for the coming twelve months notwithstanding that as at 31 December 2022, the Group had net assets of RMB308,555,000 and accumulated losses of RMB3,410,605,000. In the opinion of the directors of the Company, the Group will have the necessary liquid funds to finance its working capital and capital expenditure requirements for the next twelve months after 31 December 2022. This is due to the following considerations:

- (a) The Group had net current assets of RMB227,055,000 as at 31 December 2022; and
- (b) The Group has performed a working capital forecast for the next twelve months and will have sufficient liquid funds to finance its operations and can operate as a going concern in the foreseeable future.

## 3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following revised IFRSs for the first time for the current year’s financial statements.

Amendments to IFRS 3	<i>Reference to the Conceptual Framework</i>
Amendment to IFRS 16	<i>Covid-19-Related Rent Concessions beyond 30 June 2021</i>
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use</i>
Amendments to IAS 37	<i>Onerous Contracts – Cost of Fulfilling a Contract</i>
<i>Annual Improvements to IFRS Standards 2018-2020</i>	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41

The nature and the impact of the revised IFRSs that are applicable to the Group are described below:

- (a) Amendments to IFRS 3 replace a reference to the previous *Framework for the Preparation and Presentation of Financial Statements* with a reference to the *Conceptual Framework for Financial Reporting* (the “**Conceptual Framework**”) issued in March 2018 without significantly changing its requirements. The amendments also add to IFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or IFRIC 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group has applied the amendments prospectively to business combinations that occurred on or after 1 January 2022. As there were no business combinations during the year, the amendments did not have any impact on the financial position and performance of the Group.

- (b) Amendment to IFRS 16 issued in March 2021 extends the availability of the practical expedient for lessees to elect not to apply lease modification accounting for rent concessions arising as a direct consequence of the COVID-19 pandemic by 12 months. Accordingly, the practical expedient applies to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022, provided the other conditions for applying the practical expedient are met. The Group has adopted the amendment on 1 January 2022 and applied the practical expedient during the current year to all covid-19-related rent concessions granted by the lessors that affected only payments originally due on or before 30 June 2022.

A reduction in the lease payments arising from the rent concessions of RMB1,788,000 has been accounted for as a variable lease payment by derecognising part of the lease liabilities and crediting to profit or loss for the year ended 31 December 2022. There was no impact on the opening balance of equity as at 1 January 2022.

- (c) Amendments to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items as determined by IAS 2 *Inventories*, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2022. Since there was no sale of items produced prior to the property, plant and equipment being available for use, the amendments did not have any impact on the financial position or performance of the Group.
- (d) Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.
- (e) *Annual Improvements to IFRS Standards 2018-2020* sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendment that is applicable to the Group are as follows:
- *IFRS 9 Financial Instruments*: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively from 1 January 2022. As there was no modification or exchange of the Group's financial liabilities during the year, the amendment did not have any impact on the financial position or performance of the Group.

#### 4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Revenue from contracts with customers	<u>78,972</u>	<u>31,161</u>

(a) Disaggregated revenue information

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
<b>Type of goods</b>		
Sale of medical products	<u>78,972</u>	<u>31,161</u>
<b>Timing of revenue recognition</b>		
Goods transferred at a point in time	<u>78,972</u>	<u>31,161</u>

(b) Performance obligation

The performance obligation is satisfied upon delivery of the goods and payment is generally due within 30 to 90 days from the invoice date.

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
<u>Other income</u>		
Bank interest income	3,893	2,607
Government grants*	<u>8,454</u>	<u>405</u>
	<u>12,347</u>	<u>3,012</u>
<u>Gains</u>		
Gain on disposal of an intangible asset	–	9,727
Foreign exchange gains, net	–	633
Gain on disposal of right-of-use assets for early terminated leases	435	–
Others	<u>101</u>	<u>30</u>
	<u>536</u>	<u>10,390</u>
	<u>12,883</u>	<u>13,402</u>

\* Government grants have been received from the local government authorities to support the subsidiaries' research and development activities and other operation activities. There are no unfulfilled conditions related to these government grants.

## 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.

### Hong Kong

Hong Kong profits tax has been provided at the rate of 16.5% (2021: 16.5%) on the estimated assessable profits arising in Hong Kong during the year, 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 (2021: HK\$2,000,000) of assessable profits of this subsidiary are taxed at 8.25% (2021: 8.25%) and the remaining assessable profits are taxed at 16.5% (2021: 16.5%).

### Taiwan

The subsidiary incorporated in Taiwan is subject to income tax at a rate of 20% (2021: 20%) on the estimated assessable profits arising in Taiwan during the year.

### Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% (2021: 25%) on the taxable income.

### United States of America

The subsidiary incorporated in Delaware, the United States was subject to statutory United States federal corporate income tax at a rate of 21% (2021: 21%) during the year.

A reconciliation of the tax expense applicable to loss before tax at the statutory rate for the jurisdictions in which the majority of the Group’s subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Loss before tax	<u>(483,475)</u>	<u>(1,077,006)</u>
Tax at the statutory tax rate of 25%	(120,869)	(269,252)
Effect of tax rate differences in other jurisdictions	20,180	145,958
Expenses not deductible for tax	7,056	34,084
Additional deductible allowance for qualified research and development costs	(8,677)	(2,600)
Tax losses utilised from previous periods	(950)	–
Tax losses not recognised	<u>103,260</u>	<u>91,810</u>
Tax charge at the Group’s effective tax rate	<u>–</u>	<u>–</u>

## 6. DIVIDENDS

No dividends have been declared and paid by the Company for the year ended 31 December 2022 (2021: Nil).

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

The calculation of the basic loss per share amounts is based on the loss for the year attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares of 424,210,824 in issue during the year (2021: 94,241,487). The share subdivision in 2021 was treated as having been in issue for the whole year.

No adjustment has been made to the basic loss per share amounts presented for the year ended 31 December 2022 (2021: Nil) as the impact of the share options and share awards outstanding had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted earnings per share are based on:

	<b>2022</b> <i>RMB'000</i>	2021 <i>RMB'000</i>
<b>Loss</b>		
Loss attributable to owners of the parent, used in the basic loss per share calculation:	<u><u>(483,475)</u></u>	<u><u>(1,077,006)</u></u>
	<b>Number of shares</b>	
	<b>2022</b>	2021
<b>Shares</b>		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	<u><u>424,210,824</u></u>	<u><u>94,241,487</u></u>

## 8. TRADE RECEIVABLES

An ageing analysis of the trade receivables as at the end of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	<b>2022</b> <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 3 months	<u><u>19,054</u></u>	<u><u>9,141</u></u>

## 9. TRADE PAYABLES

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

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 6 months	63,645	43,607
Over 6 months	43,895	–
	<u>107,540</u>	<u>43,607</u>

The trade payables are non-interest-bearing and are normally settled in less than six months.

## MANAGEMENT DISCUSSION AND ANALYSIS

### OVERVIEW

Founded in 2012, we are a global biopharmaceutical company, with a foundation in China, committed to the research, development and commercialization of transformative therapies to treat rare diseases and oncology. As of December 31, 2022, we have a comprehensive pipeline of 14 drug assets with significant market potential targeting some of the most prevalent rare diseases, as well as rare oncology indications. These include three marketed products, four drug candidates at clinical stage, one at IND-enabling stage, two at preclinical stage and four gene therapy programs at lead-identification stage. Given the challenging macro environment, including volatile capital markets and limited biotech funding, CANbridge has adjusted its cost structure to optimize the development of key products that have significant development and regulatory milestones in the coming year.

We are led by a management team with significant industry experience in rare diseases, spanning R&D, clinical development, regulatory affairs, business development and commercialization. We are supported by a talent pool of 117 employees of which 15 have a Ph.D. and/or M.D. degree. And more than 80% of our employees have prior experience working at multinational biopharmaceutical companies as of December 31, 2022. Our management team has a track record of successfully achieving approval and commercializing of rare disease therapies across the key markets, including China, the United States, Europe, Latin America and Southeast Asia. We leverage this expertise to play an active role in advancing the rare disease industry and shaping the rare disease ecosystem in China. For example, our founder, Dr. James Qun Xue (“**Dr. Xue**”), Ph. D., is currently serving as the Deputy Director General of China’s Alliance for Rare Disease (CHARD).

Since our inception in 2012, we have built a comprehensive portfolio of therapeutics, consisting of biologics, small molecules and gene therapies that target diseases with validated mechanisms of action. We will continue to enrich our pipeline through business partnerships and collaborations with academic institutions, as well as with in-house research and development.

In the rare disease area, we have seven biologics and small molecule products and product candidates for multiple indications. These include MPS II (Hunter syndrome) and other lysosomal storage disorders (LSDs), complement mediated disorders, hemophilia A, metabolic disorders and rare cholestatic liver diseases including, Alagille syndrome (ALGS), Progressive familial intrahepatic cholestasis (PFIC) and biliary atresia (BA). We received marketing approval for Hunterase® (CAN101) for MPS II in mainland China in September 2020. We initiated a Phase 1 clinical trial in healthy volunteers for CAN106 in Singapore in February 2021; obtained the IND approval from the China's National Medical Products Administration (NMPA) for a CAN106 study in paroxysmal nocturnal hemoglobinuria (PNH) in July 2021; and reported positive top-line CAN106 Phase 1 data for the single ascending dose study in Singapore in February 2022. Results suggest complete blockade of complement function. CAN106 was shown to be safe and well-tolerated. In addition, the Livmarli NDA for ALGS was accepted and granted priority review by NMPA in January 2022. The first patient was dosed in Livmarli Phase 2 Study in biliary atresia in China in July 2022. In addition, the first patient was dosed in CAN103 phase 1/2 trial for the treatment of Gaucher disease in China in July 2022 and the first patient was dosed in phase 2 trial for the treatment of Gaucher disease in China in January 2023.

In the rare oncology area, we are developing CAN008 for the treatment of glioblastoma multiforme (GBM). In 2018, we completed a Phase 1 clinical trial for CAN008 in Taiwan in newly diagnosed patients. We received IND approval from the NMPA to commence first-line Phase 2 clinical trial of CAN008, dosed the first patient in a Phase 2 clinical trial of CAN008 for the first-line treatment of GBM patients in mainland China, in October 2021, and completed phase 2 clinical trial patient enrolment in March 2023.

In addition to biologics and small molecules, we are investing in next-generation technology for gene therapies. Gene therapies provide a potentially one-time durable treatment for rare genetic diseases that have limited treatment options. As of December 31, 2022, we are using an AAV sL65 capsid vector for the development of treatments for Fabry disease and Pompe disease, which we licensed from LogicBio Therapeutics. The license is for the development of two gene therapy products. In January 2023, we announced that we have exercised our option to secure the exclusive global rights to develop, manufacture and commercialize a novel second-generation gene therapy to treat spinal muscular atrophy (SMA) from UMass Chan Medical School. In addition, we are internally developing an adeno-associated virus (AAV) delivery platform targeting different tissues, such as the central nervous system (CNS) and muscle.

### **Market opportunities in the rare disease industry**

The global rare disease industry is a sector of the biopharmaceutical market focusing on the discovery and commercialization of medicines for the treatment of diseases which affect a small number of people, as compared to other more prevalent diseases in the general population. The unique characteristics of rare diseases create a highly efficient market for rare disease therapeutic development. According to Frost & Sullivan, most rare diseases are caused by genetic mutations with a well-defined pathology. This leads to higher probability of technical and regulatory success (“PTRS”) in the R&D of rare disease drugs. In addition, certain rare disease patients are treated at a limited number of specialized hospitals, therefore sales efforts for rare disease drugs can be much more targeted. The unique nature of rare diseases has also led to a favorable regulatory environment in various countries, such as the Orphan Drug Act in the United States, which helps accelerate the development and commercialization process of rare disease drugs.

The global rare disease drug market has grown rapidly since 1983, when the Orphan Drug Act was first enacted in the United States, setting standards for regulatory pathways that have been followed by other jurisdictions. The size of global rare disease drug market grew from USD109.0 billion, in 2016, to USD135.1 billion, in 2020, representing a CAGR of 5.5%. It is estimated to further grow to USD383.3 billion by 2030, at a CAGR of 11.0%, from 2020 to 2030. Growing awareness of rare disease has augmented the demand for special treatments while expenditure on healthcare is also rising, positively impacting the rare disease treatment market growth. The US and Europe are the largest rare diseases markets globally.

The rare disease markets in developing countries are relatively underpenetrated, due to limited access to rare disease diagnosis and treatments.

The market size of rare disease drugs in China was approximately USD1.3 billion in 2020, far below that in the U.S, or Europe. The high prevalence of rare diseases in China in 2019, as defined by the FDA, indicates a patient pool potentially more than four times greater than in the U.S, according to Frost & Sullivan. The discrepancy between patient population and market size suggests significant room for rare disease drug growth in China. According to Frost & Sullivan, the rare disease drug market in China is expected to grow dramatically from USD1.3 billion, in 2020, to USD25.9 billion, in 2030, at a CAGR of 34.5%. In comparison, markets in the U.S. and the rest of the world are expected to grow at a CAGR of 10.5% and 10.0%, respectively, for the same time period. The China rare disease drug market accounted for 0.4% and 1.0% of the global rare disease market in 2016 and 2020, respectively, and is expected to account for 6.8% in 2030, indicating a favorable rare disease market outlook. With a population of untreated rare disease patients larger than that of the U.S. and Europe, China offers great opportunities for rare disease pharmaceutical companies to capture a massive market at potentially lower costs than other disease areas. In response to such significant market opportunity, many leading pharmaceutical companies, such as Sanofi, AstraZeneca and Roche, have launched products in China and other developing countries. We believe that CANbridge is uniquely positioned to provide sustainable solutions to the medical needs of global rare disease patients in an efficient manner.

In addition, the rare disease industry in China is expected to benefit from various regulatory initiatives. In recognition of the urgency for effective rare disease treatment development, and the unique clinical challenges associated with such development, authorities in the U.S. and Europe have provided regulatory incentives, and adopted special regulatory frameworks, to encourage development and commercialization of drugs to treat rare diseases and support companies that focus on rare disease treatment. In 2018, China published the first edition of the National List of Rare Disease that includes 121 rare diseases. As in the U.S. and Europe, China has simplified the rare disease treatment application process and instituted other reforms that streamline the regulatory and post-regulatory environment, including allowing for the submission of clinical data from global trials. China is also moving towards a more favorable rare disease treatment reimbursement policy. After years of local-level rare disease insurance mechanisms, more and more provinces and cities have joined forces to implement insurance policies for rare disease under various reimbursement models. In 2021, National Health Commission of the People's Republic of China (PRC) announced that it is developing the second edition of the National List of Rare Disease, which is expected to include more rare diseases, according to Frost & Sullivan.

Enabled by new technologies, gene therapies are become an emerging solution for rare diseases. Approximately 80% of rare diseases result from genetic disorders, according to Frost & Sullivan. Gene therapies serve as a promising solution for a broad spectrum of rare diseases as they have the potential to address the underlying cause of the diseases and be curative. Recent advances in genetic engineering and recombinant viral vector development have ignited interest in the field and several gene therapy products have been approved. The success of several pioneering gene therapy products, such as Zolgensma<sup>®</sup>, developed by Novartis, have made a targeted treatment available for spinal muscular atrophy (SMA), and validate the potential of gene therapies to provide solutions to rare diseases.

On May 9, 2022, the NMPA issued the “Regulations for the Implementation of the Drug Administration Law of the People’s Republic of China (Revised Draft for Comment)”. The Revised Draft for Comment proposes that in respect to pediatric drugs, the draft proposed that the first new molecular entities (NMEs), dosage, and formulations approved for marketing for pediatrics, as well as those drugs adding indications or increasing dosage for pediatrics, should be granted a market exclusive period for a maximum of no more than 12 months, during which the period drugs of the same entity will not be approved for marketing.

In respect to rare diseases, the draft proposed that the new drugs for rare diseases approved for marketing should be granted a market exclusivity period of no more than seven years, during which the period drugs of the same entity will not be approved for marketing, as long as the drug marketing license holder agrees to ensure supply of the drug in this period.

# PIPELINE

## Our Comprehensive and Diversified Pipeline

A portfolio of biologics, small molecules and gene therapy solutions with validated mechanisms of action, targeting some of the most prevalent rare diseases and rare oncology indications with significant market potential. CANbridge owns global rights for 8 of the 14 drug assets

Candidate	Mechanism	Discovery	IND-enabling	Ph 1	Ph 2/3	NDA	Marketed	Dev Strategy	Partner	Commercial Rights
<b>Rare Onc.</b> CAN008 (Asumarecept) Hunterase® (dursulfase beta)	CD95- Fc fusion protein ERT IDS	Glioblastoma Multiforme Hemangioendothelioma (Type II) Alagille Syndrome (US /EU)						In China for China	apogenix GC Pharma	Greater China Greater China
<b>Rare Disease</b> CAN 108 (Lysymart®) CAN 106 CAN 103 CAN 107 CAN 104 CAN 105 CAN 201 CAN 202 CAN 203 Undisclosed	IBAT inhibitor Anti-C5 mAb ERT GBA Anti-FGF23 mAb ERT GLA Anti-Factor IXa/ XbsAb AAV sL65 GLA AAV sL65 GAA AAV9 SMN1 AAV Calcium phosphate rimse	Progressive Familial Intrahepatic Cholestasis Biliary Atresia Paroxysmal Nocturnal Hemoglobinuria Gaucher Disease XLH Fabry Disease Hemophilia A Fabry Disease Pompe Disease SMA DMD						In China for Global In China for China Global for Global	mirum WuXi Biologics / Privus WuXi Biologics WuXi Biologics / Privus WuXi Biologics WuXi Biologics AstraZeneca / LogicBio AstraZeneca / LogicBio UMass Chan Medical School LW Medicine Scripta EUSA Pharma	Greater China Greater China Global Global Global Global Greater China Global Global Global Global Global Global China
<b>Other Onc.</b> Caphosol™ Nerlynx® (Neratinib)	Tyrosine kinase inhibitor	Oral Mucositis HER2+ Breast Cancer							Pierre Fabre	Hong Kong, Taiwan, Macau

Small Molecule 
 Biologic 
 Gene Therapy 
 Medical Device

Clinical trials performed by license partner



## **BUSINESS REVIEW**

The Company was listed on the Stock Exchange on December 10, 2021. Since then, the Company has made significant progress with respect to its drug pipeline and business operations, including the following milestones and achievements.

### **HUNTERASE® (CAN101)**

- Hunterase® is the first ERT approved for the treatment of Hunter syndrome (MPS II) in China. Given that ERT is the standard of care for Hunter syndrome, and that there is currently no other drug treatment available in China, we believe there is a significant market opportunity for Hunterase® (CAN101).
- We received the marketing approval from the NMPA for Hunterase® (CAN101) in September 2020 as the first and the only treatment for MPS II. Hunterase® (CAN101) is currently marketed in over 10 countries worldwide by GC Pharma. In a head-to-head Phase 1 study, Hunterase® (CAN101) demonstrated favorable efficacy as compared to Elaprase®, a drug commonly used to treat Hunter syndrome globally.
- We commercially launched Hunterase® (CAN101) in China in May 2021 in a non-reimbursed market. Since launch, commercial penetration in mainland China has gone well, and we've experienced accelerated the expansion of the patient market and reimbursement coverage. Focus remains on expanding the number of patients by creating a stronger diagnostic network.
- The Company plans to strengthen its dedicated, in-house commercialization team and expects to assemble a full-fledged rare disease commercialization team in China with the ability to commercial multiple rare disease products.

### **CAN108 (MARALIXIBAT ORAL SOLUTION/LIVMARLI®)**

- Livmarli is an oral, minimally absorbed reversible inhibitor of the ileal bile acid transporter (IBAT) and is under development to treat rare cholestatic liver diseases, including Alagille syndrome (ALGS, approved by PDA), progressive familial intrahepatic cholestasis (PFIC) and biliary atresia (BA). Livmarli possesses an extensive safety dataset, having been evaluated in more than 1,600 human subjects. Livmarli has been studied in a number of completed and ongoing clinical trials in ALGS and PFIC with over 120 children treated and some on study for over seven years. A Phase 2b placebo-controlled randomized withdrawal period clinical trial with open-label extension in children (aged 1-18 years) conducted for ALGS by Mirum Pharmaceuticals, Inc. (“**Mirum**”), our collaboration partner in the U.S., shows that patients receiving Livmarli experienced significant reductions in serum bile acids and pruritus compared to placebo, improvements in quality of life and xanthomas and accelerated long-term growth. In addition, Mirum has completed PFIC Phase 3 study of Livmarli, which is the largest randomized, placebo-controlled study with 93 patients across a range of genetic PFIC subtypes, including PFIC1, PFIC2, PFIC3, PFIC4, PFIC6 and unidentified mutational status. The results of this Phase 3 study have demonstrated that Livmarli-treated patients had statistically significant improvements in pruritus, serum bile acids, bilirubin and growth as measured by weight z-score in the cohort evaluating combined genetic subtypes. Mirum has submitted a NDA for Livmarli for the treatment of cholestatic pruritus in patients two months of age and older with PFIC. Mirum obtained FDA approval for Livmarli for ALGS in September 2021 and EU marketing approval in December 2022.

- CANbridge and Mirum have an exclusive license agreement for the development, commercialization and manufacture, under certain conditions, of Livmarli in Greater China. Under the terms of the agreement, CANbridge has the right to develop and commercialize Livmarli for three indications: ALGS, PFIC and BA in Greater China.
- Under the license agreement with CANbridge, Mirum dosed the first patient in the Phase 2 EMBARK study of Livmarli in biliary atresia (BA) in China, at Children's Hospital of Capital Institute of Pediatrics (CIP), in Beijing. The clinical trial in China is part of the global EMBARK study in BA. The multi-center randomized controlled Phase 2 study to evaluate the efficacy and safety of Livmarli in the treatment of patients with BA after Kasai surgery is expected to enroll at least 20 patients in Greater China.

EMBARK is a Mirum Pharmaceuticals-sponsored global Phase 2 study to evaluate the efficacy and safety of maralixibat in the treatment of patients with BA after Kasai surgery (NCT04524390). The 26-week randomized controlled trial, to be followed by a 78-week open label extension study, is being conducted at multiple sites in North America, Europe, and Asia, including China. There are currently no pharmacological agents approved for the treatment of patients with biliary atresia.

- Livmarli has been approved for the treatment for ALGS under the Early and Pilot Implementation Policy in Boao Lecheng International Medical Tourism Pilot Zone which allows Livmarli to be imported and used as an urgently needed drug in the region. Livmarli was first prescribed in Boao Lecheng in March 2022.
- The Company filed New Drug Application/Orphan Drug Registration (NDA/ODR) to the China's National Medical Products Administration (NMPA) and the Taiwan Food and Drug Administration (TFDA) for Livmarli for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. Livmarli has also been granted priority review by China's NMPA with a potential approval in the first half of 2023.
- Mirum realized net product sales of US\$75.1 million in Livmarli in the first full fiscal year of its U.S. launch.

## **CAN106**

- CAN106 is a novel long-acting monoclonal antibody directed against C5 complement being developed for the treatment of complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria (PNH), other complement mediated diseases that are targeted by approved anti-C5 antibodies and other new potential indications. We obtained global rights to develop, manufacture and commercialize this drug candidate from WuXi Biologics and Privus in 2019 and 2020 respectively. Based on preclinical data, CAN106 has demonstrated a favorable PK/PD profile, safety and tolerability, indicating that CAN106 has the potential to effectively inhibit C5 in patients with PNH and potentially with reduced dosing frequency.

- We reported data from the Phase 1 trial of CAN106, conducted in Singapore in February 2022 which demonstrated that CAN106 is able to achieve potent and rapid reduction of C5 levels and completely block terminal complement activity for up to four weeks, suggesting the possibility of an extended dosing regimen. CAN106 was safe and well-tolerated with mostly mild or moderate adverse events and no drug-related serious adverse events in this first-in-human single ascending dose study in healthy subjects. Furthermore, CAN106 led to rapid (within 24 hours), dose-dependent reductions in free C5 and in CH50, a measure of serum hemolytic activity that reflects complement pathway activity. At the two highest doses (8 and 12 mg/kg), CAN106 achieved complete and sustained blockade of terminal complement activity, with all subjects showing a >99% reduction in free C5 and ≥90% inhibition of CH50. In addition, the half-life of circulating CAN106 in healthy volunteers was 31 days, which is similar to that of the approved anti-C5 agent, ravulizumab, which is dosed every eight weeks in patients. The C5 protein is a component of the complement system, part of the innate immune system. Dysregulation or over-activity of the complement pathway is implicated in various complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria (PNH).

We presented Phase 1/2 trial data at the 17th National Conference on Hematology held in Shanghai, and at the 6th Annual Complement Based Drug Development Summit 2022 held in Boston, MA, at the European Hematology Association 2022 Congress in Vienna and at the 14<sup>th</sup> International Conference on Complement Therapeutics, June 17-22, in Rhodes, Greece. Presentations highlighted positive top-line Phase 1 data from the trial conducted in Singapore, which was first reported in February 2022. Results suggest complete blockade of complement function at safe and well-tolerated doses.

- Dosed the first patient in the CAN106 Phase 1b/2 trial for treatment of paroxysmal nocturnal hemoglobinuria (PNH) in China. The multi-center, open-label, phase 1b/2 study to evaluate the tolerability, efficacy, safety and PK/PD of CAN106 administered intravenously to complement inhibitor treatment-naïve PNH patients, is under the direction of principal investigator, Bing Han, MD, PhD, Chief Physician and Professor in the Department of Hematology at Peking Union Medical College Hospital in Beijing, China. CAN106 was previously shown to be safe and well-tolerated, with dose-dependent and linear pharmacokinetic exposure in a study of healthy volunteers in Singapore. The data also showed that free C5 and CH50 could be effectively inhibited. Based on these results, the NMPA approved the CAN106 Phase 1b/2 trial for the treatment of patients with PNH. The ongoing Phase 1b part consists of 3 cohorts and the Company plans to announce topline data from phase 1b mid-year 2023.
- In November 2022 announced that the United States Food and Drug administration (FDA) granted CAN106 Orphan Drug Designation for the treatment of myasthenia gravis (MG), an autoimmune neuromuscular disease that causes weakness in skeletal muscles. CAN106 is eligible to receive the benefits provided under the Orphan Drug Act, including 50% tax credit for qualifying clinical trials, waivers for regulatory submission fees, eligibility to receive federal research grants, and upon marketing authorization for MG, 7 years of market exclusivity.

## **CAN008**

- CAN008 is a recombinant, antibody-like, fully-human CD95-Fc fusion protein that is being developed as a first line treatment for patients with newly diagnosed GBM. Acting as a soluble receptor, CAN008 binds to the endogenous CD95L on tumor cells and blocks its interaction with the endogenous CD95 receptor, thereby preventing tumor cell growth and metastasis. CAN008 also blocks the interaction of CD95L and CD95 on T cells, thereby preventing apoptosis and restoring immune function. As our core product, CAN008 has demonstrated promising efficacy and a favorable safety profile in completed and ongoing clinical trials, providing a new potential first-line treatment option for GBM. A Phase 2 pivotal trial conducted by Apogenix showed statistically significant and clinically meaningful improvements of more than 50% in 4-month to 6-month progression-free survival and quality of life as well as a positive trend in overall survival in patients with relapsed GBM.
- Completed a Phase 1 dose comparison (200 vs 400 mg) trial in patients with newly diagnosed GBM in Taiwan, and the results showed that CAN008 was generally safe and well tolerated. No dose-limiting toxicity was observed, and no treatment-related serious adverse events were reported. The 400 mg dose was associated with 57% (4/7) progression-free survival at 12 months and was selected as the Phase 2 dose.
- Received CDE approval in April 2021 to conduct a Phase 2 trial of CAN008 as a first-line treatment for patients with newly diagnosed GBM in China. The first patient was dosed in October 2021. We completed trial enrollment in March 2023 and the potential interim read out is anticipated in the second half of 2023.

## **CAN103**

- CAN103, a recombinant, human glucocerebrosidase (acid  $\beta$ -glucosidase), an enzyme replacement therapy (ERT) for the treatment of Gaucher disease (GD). CANbridge maintains global proprietary rights to develop and commercialize the product.
- Dosed the first patient in the CAN103 Phase 1/2 trial being developed for the treatment of patients with Gaucher disease (GD) Types I and III in China. Bing Han MD, PhD, Chief Physician and Professor in the Department of Hematology at Peking Union Medical College Hospital in Beijing, China, is the principal investigator for the trial. Gaucher disease (GD), a lysosomal storage disorder, is caused by a genetic enzyme deficiency leading to an accumulation of a cellular sphingolipid called glucocerebroside in macrophages residing in liver, spleen, and bone marrow, resulting in hepatosplenomegaly, anemia, thrombocytopenia, skeletal disease (infarction, osteoporosis, and pain), and death. CAN103 is an enzyme replacement therapy (ERT) under development by CANbridge, as part of its rare disease partnership with WuXi Biologics (2269.HK), for the long-term treatment of adults and children with Gaucher disease Types I and III. Many GD patients in China do not have access to approved treatments due to cost barriers.

- The multi-center Phase 1/2 clinical trial consists of two parts: Part A (Phase 1) is an open-label study to evaluate the safety, tolerability and pharmacokinetics of different dose levels of CAN103 in a small number of treatment-naïve subjects with Gaucher disease Type I. Part B (Phase 2) is a study to assess the safety and efficacy of CAN103 in a larger number of subjects with Gaucher disease Type I or III. Part B of the trial will serve as a potential registrational trial. The Company has completed Part A and initiated dosing in Part B in the first quarter of 2023. The Company expects to file NDA by mid 2024.
- CAN103 is the first enzyme replacement therapy for Gaucher disease in the clinical development stage trial in China.

## GENE THERAPY

- Presented initial data from our gene therapy research agreement with the Horae Gene Therapy Center, at the UMass Chan Medical School, at the 2022 American Society of Gene and Cell Therapy (ASGCT) Annual Meeting. These data encourage us to continue development of this second-generation vector as a potential best-in-class gene therapy for SMA. This next-generation gene therapy leverages the advances in gene therapy that have occurred since the first gene therapy was developed, over a decade ago. Data shared at ASGCT highlights the potential of this novel, second-generation scAAV9 that expresses co-hSMN1 from an endogenous hSMN1 promoter, to treat SMA. The data, demonstrated superior potency, efficacy and safety in mice with SMA, compared to the benchmark vector, scAAV9-CMVen/CB-hSMN1, which is similar to the vector used in the gene therapy approved by the FDA for the treatment of SMA.
- The Company announced a license from the UMass Chan Medical School for the global development and commercialization rights to a novel second-generation scAAV9 gene therapy, expressing co-hSMN1 from an endogenous hSMN1 promoter, for the treatment of SMA. CANbridge plans to file a U.S. IND by the fourth quarter of 2024.
- The Company obtained non-exclusive worldwide rights to the LogicBio (a wholly owned subsidiary of Alexion, AstraZeneca Rare Disease) proprietary manufacturing process for Fabry and Pompe gene therapies in the second half of 2022. The Company completed the full technology transfer of gene therapy products under development the treatment of Fabry and Pompe diseases from LogicBio® Therapeutics by the end of the year.
- CANbridge has also built up full inhouse gene therapy research and development capabilities.

## WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT CANDIDATE, OR ANY OF OUR PIPELINE PRODUCTS

### Corporate Development

- Formed a Complement Disease Scientific Advisory Board focused on the global development of CAN106, a novel long-acting monoclonal antibody directed against C5 complement. CANbridge is developing CAN106 for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) and other complement-mediated diseases. CAN106 is currently in a Phase 1b/2 PNH trial in China. The advisory board will offer guidance on the CAN106 clinical development program, as well as explore the potential for CAN106 in other indications.

The members of scientific advisory board are:

- **Anthony Amato, MD**, Brigham and Women's Hospital Distinguished Chair in Neurology, Chief of the Neuromuscular Division and Director of the Clinical Neurophysiology Laboratory at Brigham and Women's Hospital, and Professor of Neurology at Harvard Medical School.

- **Robert Colvin, MD**, Pathologist-in-Chief, Emeritus at Massachusetts General Hospital, and the Benjamin Castleman Distinguished Professor of Pathology at Harvard Medical School.
- **Gerald Cox, MD, PhD**, Chief Development Strategist & Interim Chief Medical Officer, Clinical geneticist and pediatrician at Boston Children’s Hospital, Former Chief Medical Officer at Editas Medicine, Vice President, Rare Disease Clinical Development at Sanofi.
- **Jean Francis, MD**, Medical Director of the Kidney Transplant Program at Boston Medical Center and Boston University School of Medicine, Medical Director of the Combined Pancreas Transplant Program at Boston Medical Center and Brigham and Women’s Hospital, and Associate Professor of Medicine at Boston University School of Medicine.
- **Richard Polisson, MD, MHSc**, Clinical Development Consultant and, most recently, former Chief Medical Officer at Artax Biopharma.
- **Sushrut Waikar, MD, MPH**, Chief of Nephrology at Boston Medical Center and the Norman G. Levinsky Professor of Medicine at Boston University School of Medicine, and formerly the Constantine L. Hampers, MD Distinguished Chair in Renal Medicine at Brigham and Women’s Hospital.
- **Brian Weinschenker, MD**, Professor of Neurology at the University of Virginia, and formerly Professor of Neurology at Mayo Clinic.
- Appointed Mr. Edward Hu (“**Mr. Hu**”) as a non-executive Director and a member of the Remuneration Committee, replacing Mr. Xiao Le, effective from July 5, 2022. Mr. Hu brings to the Company a deep and varied C-level biopharmaceutical experience, having served as both Co-Chief Executive Officer and Chief Financial Officer at WuXi AppTec before his current position of Vice Chairman, Global Chief Investment Officer, Executive Director, Strategy Committee Member. Before then, Mr. Hu was Chief Financial Officer and Chief Operating Officer at WuXi PharmaTech. Prior to his roles at WuXi, Mr. Hu held multiple senior management roles, culminating in that of Senior Vice President and Chief Operating Officer at Tanox Inc., a NASDAQ-traded public company, which was acquired by Genentech. Prior to that, Mr. Hu served as business planning manager of Biogen Inc, and before then, as senior financial analyst at Merck. Mr. Hu is currently a non-executive director of CStone Pharmaceuticals and a director of Ambrx Biopharma. Previously, he also served as non-executive director of WuXi Biologics, as well as a director of Viela Bio Inc, which was acquired by Horizon Therapeutics in March 2021. Mr. Hu received a bachelor’s degree in physics from Hangzhou University (currently, Zhejiang University), in Zhejiang province, China. He also has a master’s degree in chemistry and a master’s degree in business administration, both from Carnegie Mellon University, in Pittsburgh, Pennsylvania.

- Appointed Dr. Lan Hu (“**Dr. Hu**”), Ph.D. as an independent non-executive Director and a member of the Remuneration Committee, effective from February 16, 2022. Dr. Hu has a rich background in healthcare investment, operations and administrative management and is a seasoned entrepreneur, having founded Beijing Amcare Women’s & Children’s Hospital Co., Ltd. in 2004, where she also served as Director, Chairman of the Board and General Manager. She is currently also serving as the chairman of the board and general manager of Beijing Amcare Medical Management Co., Ltd., the chairman of the board of Beijing Meizhong Airui Tumor Hospital Co., Ltd., the independent director of Beijing Yida Shidai Technology Development Co., Ltd. and the executive director and general manager of Beijing Xuanhe Yazhi Management Consulting Co., Ltd. She obtained a bachelor’s degree in medicine from Peking University in 1993. She further obtained a Ph.D. in medical sciences from Medical College of Ohio in 2000 and a master’s degree in business administration from University of Michigan in 2002.
- With effect from February 16, 2022, (i) Mr. James Arthur Geraghty (“**Mr. Geraghty**”) has ceased to be a member of the Remuneration Committee; (ii) Dr. Richard James Gregory has ceased to be a member of the Audit Committee; and (iii) Mr. Geraghty was appointed as a member of the Audit Committee.
- Appointed Dr. Ping Li (“**Dr. Li**”), MD, to the position of Senior Vice President of Clinical Development and Operations in the Reporting Period. Dr. Li brings to CANbridge a wealth of international clinical development experience, in both small molecule and biologic products, across multiple indications and markets. Most recently, she was at Connect Biopharma, where she held the position of Vice President of Clinical Development and was responsible for creating and implementing the clinical development strategy. During her time there, she oversaw five NMPA IND approvals, three FDA IND approvals, eight clinical trial initiations and six clinical trial completions. Before then, she was Executive Director of Clinical Operations at Shanghai Haihe Pharmaceutical Company, Ltd. and Medical & Scientific Affairs Director at Servier China. Earlier, Dr. Li held multiple clinical development and medical roles at leading multinational pharmaceutical companies, including Medical Director at Takeda China, Head of the Medical Affairs at Bayer Healthcare, Senior Medical Manager at Xi’an Janssen and Medical Manager at Shanghai Roche. Dr. Li began her career as a cardiologist at Beijing Fuwai Heart Disease Hospital in Beijing, China.

## **Manufacturing**

We have secured manufacturing capacity for selected in-licensed programs, including from third party collaboration partners such as WuXi Biologics, GC Pharma and Mirum. We aim to balance cost-efficiency and control over quality of our drug products. In an effort to scale up our gene therapy development, we anticipate entering into a CDMO partnership to enable the further development of our gene therapy products.

## **Commercialization**

With our late-stage drug candidates entering into the commercialization stage, we have established our key operation hubs in both Beijing and Shanghai, with offices in other locations in Greater China, and plan to expand to each of the key target provinces with local offices in mainland China. We have set up a commercialization team dedicated to our late-stage drug candidates, that can be quickly expanded in line with our business growth, comprising three major functions, including marketing and sales, medical affairs and patient advocacy and assistance, with the mission to execute medical engagement plan for key opinion leader (KOL) development, promote community awareness and explore industry insights for better drug development and marketing strategy.

## **KEY EVENTS AFTER THE REPORTING PERIOD**

Save as disclosed in this announcement, the Company has no key events after the Reporting Period that need to be brought to the attention of the shareholders of the Company (the “**Shareholders**”).

## **THE IMPACT OF COVID-19**

The management of the Company expected that clinical trials in and outside mainland China will not be significantly affected by the outbreak of COVID-19. The Directors believe that, based on the information available as of the date of this announcement, the outbreak of COVID-19 would not result in a material disruption to the Group’s business operations or a material impact on the financial position or financial performance of the Group. Due to the outbreak of COVID-19, we have taken various measures, including but not limited to reducing face-to-face meetings by means of telephone or video conferences; avoiding unnecessary travels and trips for interviews as well as providing face masks, hand sanitizers and other sanitation supplies.

## **FINANCIAL REVIEW**

### **Overview**

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

### **Revenue**

Our revenue increased by RMB47.8 million from RMB31.2 million for the year ended December 31, 2021 to RMB79.0 million for the year ended December 31, 2022, which was primarily attributable to the increase in sales of Nerlynx<sup>®</sup> (CAN030) in Taiwan and sales of Hunterase<sup>®</sup> (CAN101) in mainland China.

### **Cost of Sales**

Our cost of sales increased by RMB17.7 million from RMB12.4 million for the year ended December 31, 2021 to RMB30.1 million for the year ended December 31, 2022, which was primarily attributable to the increase in sales of commercialized products.

## **Gross Profit and Gross Profit Margin**

Our gross profit increased by RMB30.1 million from RMB18.8 million for the year ended December 31, 2021 to RMB48.9 million for the year ended December 31, 2022. Our gross profit margin for the year ended December 31, 2022 was 61.9% (2021: 60.3%).

## **Other Income and Gains**

Our other income and gains decreased by RMB0.5 million from RMB13.4 million for the year ended December 31, 2021 to RMB12.9 million for the year ended December 31, 2022, which was primarily attributable to the decrease in gain on disposal of an intangible asset which was partially offset by the increase in subsidies received from local government for the year ended December 31, 2022.

## **Selling and Distribution Expenses**

Our selling and distribution expenses decreased by RMB13.9 million from RMB100.7 million for the year ended December 31, 2021 to RMB86.8 million for the year ended December 31, 2022, which was primarily due to the decrease in employee costs and marketing expenses as a result of the reduction of marketing activities during the year ended December 31, 2022 due to the increased effectiveness in sales activities during the year ended December 31, 2022.

## **Administrative Expenses**

Our administrative expenses decreased by RMB36.6 million from RMB145.5 million for the year ended December 31, 2021 to RMB108.9 million for the year ended December 31, 2022. Such decrease was primarily attributable to the decrease in our listing expenses and professional fees.

## **Research and Development Expenses**

Our research and development expenses decreased by RMB116.5 million from RMB427.7 million for the year ended December 31, 2021 to RMB311.2 million for the year ended December 31, 2022. Such decrease was primarily attributable to (i) decreased license fees from RMB213.8 million for the year ended December 31, 2021 to RMB59.5 million for the year ended December 31, 2022, which was partially offset by (ii) increased testing and clinical trial expenses from RMB136.8 million for the year ended December 31, 2021 to RMB174.3 million for the year ended December 31, 2022.

## **Fair Value Changes of Convertible Redeemable Preferred Shares**

Our fair value changes of convertible redeemable preferred shares decreased from a loss of RMB462.4 million for the year ended December 31, 2021 to nil for the year ended December 31, 2022, as all of the Company's preferred shares were converted to ordinary shares upon the listing on December 10, 2021, and no such fair value losses were incurred since then.

## **Fair Value Changes of Derivative Financial Instruments**

Our fair value changes of derivative financial instruments decreased from a gain of RMB34.5 million for the year ended December 31, 2021 to nil for the year ended December 31, 2022, as the Group had no derivative financial instruments during the Reporting Period.

## **Finance Costs**

Our finance costs increased from RMB3.1 million for the year ended December 31, 2021 to RMB6.9 million for the year ended December 31, 2022. Such increase was primarily due to the increase in interest on lease liabilities.

## **Non-IFRS Measures**

In addition to the Group's consolidated financial statements, which are presented in accordance with IFRSs, the Company also uses adjusted loss for the year as an additional financial measure, which is not required by, or presented in accordance with IFRSs. We present this financial measure because it is used by our management to evaluate our financial performance by eliminating the impacts of items that we do not consider indicative of our performance results. The Company believes that these adjusted measures provide additional information to investors and others, helping them to understand and evaluate our consolidated results of operations in the same manner as our management, and thus, facilitate comparisons of operating performance from period to period and company to company to the extent applicable.

We define adjusted loss for the year as loss for the year excluding the effect of share-based payment expenses, listing expenses and non-cash items and one-time events, namely fair value changes on convertible redeemable preferred shares and fair value changes of derivative financial instruments. The term adjusted loss for the year is not defined under the IFRSs. The use of this non-IFRS measure has limitations as an analytical tool, and you should not consider it in isolation from, or as substitute for analysis of, the Group's results of operations or financial condition as reported under IFRSs.

The table below sets forth a reconciliation of the adjusted loss for the year during the years indicated:

	<b>For the year ended</b>	
	<b>December 31,</b>	
	<b>2022</b>	2021
	<b>RMB'000</b>	RMB'000
Loss for the year	<b>(483,475)</b>	(1,077,006)
Add:		
Loss on fair value changes of convertible redeemable preferred shares	–	462,436
Gain on fair value changes of derivative financial instruments	–	(34,454)
Share-based payment expenses	<b>26,822</b>	30,510
Listing expenses	–	37,192
	<hr/>	<hr/>
Adjusted loss for the year	<b><u>(456,653)</u></b>	<b><u>(581,322)</u></b>

## **Capital Management**

The primary objectives of the Group's capital management are to safeguard the Group's ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise Shareholders' value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. There is no material seasonality of borrowing requirements for the Group.

## **Liquidity and Financial Resources**

On December 10, 2021, 56,251,000 shares of USD0.00001 each were issued at a price of HKD12.18 per share in connection with the Company's listing on the Main Board of the Stock Exchange. The proceeds of HKD4,386.46 representing the par value, were credited to the Company's share capital. The remaining proceeds of HKD685,132,793.54, (before deduction of the legal and other professional fees in relation to the listing) were credited to the share premium account.

Our cash and bank balances as of December 31, 2022 were RMB463.1 million, of which RMB41.6 million, RMB413.0 million, RMB2.8 million and RMB5.7 million, were denominated in RMB, USD, HKD and TWD, respectively. As compared to RMB745.8 million as of December 31, 2021, the decrease of cash and bank balances was primarily attributable to the net cash outflows used in operations. Our primary uses of cash are to fund research and development efforts, milestone payments and working capital and for other general corporate purposes.

## **Funding and Treasury Policy**

The Group adopts a prudent funding and treasury policy, aiming to maintain an optimal financial position and minimal financial risks. The Group regularly reviews its funding requirements to maintain adequate financial resources in order to support its business operations as well as its research and development, business operation and expansion plans. For the year ended December 31, 2022, we funded our operations primarily through revenue generated from sales of commercialized products, net proceeds raised from the global offering (the “**Global Offering**”) as set out in the prospectus of the Company dated November 30, 2021 (the “**Prospectus**”) and debt financing. With the continuing expansion of our business and development of new drug candidates, we may require further funding through public or private equity offerings, debt financing and other sources.

## **Bank Loans and Other Borrowings**

Our bank loans and other borrowings as of December 31, 2022 were RMB37.6 million (December 31, 2021: RMB30.9 million), of which RMB5.0 million and RMB32.6 million, were denominated in RMB and USD, respectively and carried fixed nominal interest rates ranging from 4.0% to 4.2% per annum.

## **Current ratio**

Current ratio (calculated by current assets divided by current liabilities) of the Group as at December 31, 2022 was 181.6% (December 31, 2021: 436.9%). The decrease in current ratio was primarily due to the decrease of cash and cash equivalents, and the increase of trade payables, other payables and accruals as of December 31, 2022.

## **Gearing ratio**

The gearing ratio (calculated by total interest-bearing borrowings divided by total assets) of the Group as at December 31, 2022 was 5.4% (December 31, 2021: 3.5%).

## **Foreign Currency Risk**

We have transactional currency exposures. Certain of our cash and bank balances, trade receivables and other receivables and trade and other payables are denominated in non-functional currencies and exposed to foreign currency risk.

We currently do not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

## **Contingent Liabilities**

As of December 31, 2022, we did not have any material contingent liabilities.

## Capital Expenditure and Commitments

The Group's capital expenditures in the year ended December 31, 2022 were primarily related to the purchase of property, plant and equipment, land use rights and other intangible assets. In the year ended December 31, 2022, the Group incurred RMB33.3 million in relation to capital expenditures as compared to RMB8.5 million in the year ended December 31, 2021. The increase in capital expenditures was primarily due to the increase in the purchase of property, plant and equipment and land use rights during the Reporting Period.

## Charges on Group Assets

As of December 31, 2022, CANbridge Biomed Limited and CANbridge Care Pharma HongKong Limited, two subsidiaries of the Company, have charged all of their assets in favour of a commercial bank incorporated in the PRC ("Bank") by way of first fixed charge and floating charge as security for the payment of the bank borrowings from the Bank. As of December 31, 2022, the Group pledged deposits of RMB12.0 million in commercial banks held as collateral for issuance of letters of credit for lease.

Saved as disclosed above, as of December 31, 2022, the Group did not have other charges over its assets.

## Significant Investment Held

During the Reporting Period, the Group did not have any significant investments.

## Material Acquisition and Disposal of Subsidiaries, Associates and Joint Ventures

On June 10, 2022, the Company's wholly-owned subsidiary CANbridge (Suzhou) Bio-Pharma Co., Ltd (北海康成(蘇州)生物製藥有限公司) (the "WFOE") entered into contractual arrangements (the "Contractual Arrangements") with CANbridge Care Pharma (Suzhou) Biotechnology Co., Ltd (康成諾愛(蘇州)生物科技有限公司) (the "VIE"), a company incorporated in the PRC, to gain the economic benefit and control of the VIE. The VIE will engage in businesses which involve research, development and commercialization of gene therapy and related products, which falls under the "prohibited" category of the Negative List in the PRC according to the Foreign Investment Law. Details of the Contractual Arrangements are disclosed in the announcement of the Company dated July 8, 2022. Through the Contractual Arrangements, the WFOE has effective control over the finance and operation of the VIE, and can enjoy the economic interests and benefits generated by the VIE. Upon the entering into of the Contractual Arrangements, the financial results of the VIE are consolidated into the consolidated financial statements of the Group and the VIE is treated as a subsidiary of the Company.

Save as disclosed above, during the Reporting Period, the Group did not have any material acquisitions and disposals of subsidiaries, associates and joint ventures. Save as otherwise disclosed in the Prospectus, the Group does not have any specific future plan on material investments or capital assets as of the date of this announcement.

## Share Schemes

### *Pre-IPO Equity Incentive Plan*

The Company adopted the 2019 equity incentive plan (the “**Pre-IPO Equity Incentive Plan**”) on July 25, 2019 and amended it on June 11, 2021.

The maximum number of Shares that may be subject to the awards granted and sold under the Pre-IPO Equity Incentive Plan is 54,549,230 Shares and share options (including those have subsequently lapse or been fully exercised) to subscribe for 55,708,000 Shares thereof had been granted. No share options were granted under the Pre-IPO Equity Incentive Plan after the Company’s listing.

During the year ended December 31, 2022, 100,000 options were exercised, and 5,715,394 options were forfeited. As at December 31, 2022, the Company has 40,529,786 options outstanding.

### *Post-IPO RSU Scheme*

The Company has conditionally adopted the post-IPO RSU scheme by Shareholders’ resolution dated November 18, 2021 (the “**Post-IPO RSU Scheme**”).

The aggregate number of Shares underlying all grants made pursuant to the Post-IPO RSU Scheme (excluding awards which have been forfeited in accordance with the Post-IPO RSU Scheme) will not exceed 5% of the issued share capital of the Company as at the date of the approval of the Post-IPO RSU Scheme and further subject to an annual limit of 5% of the total number of issued share capital of the Company at the relevant time.

On November 11, 2022, the Company granted a total of 5,800,000 RSUs to 31 grantees (including Dr. Xue and 30 other grantees who are not connected persons of the Company under the Listing Rules) under the Post-IPO RSU Scheme. The 5,800,000 RSUs represents 5,800,000 underlying Shares, and approximately 1.37% of the issued share capital of the Company as of the date of this announcement. Each RSU is granted for nil consideration and the vesting period of the RSUs will be no more than four years pursuant to the terms of the award agreement entered into between the Company and each RSU grantee. The closing price of the Shares on the date of grant was HK\$2.15 per Share.

### *Post-IPO Share Option Scheme*

The Company has conditionally adopted the post-IPO share option scheme by Shareholders’ resolution dated November 18, 2021 (the “**Post-IPO Share Option Scheme**”).

The maximum number of Shares in respect of which options may be granted under the Post-IPO Share Option Scheme when aggregated with the maximum number of Shares in respect of which options may be granted under any other option scheme over Shares shall not exceed 10% of the issued share capital of the Company as of the date of approval of the Post-IPO Share Option Scheme.

On June 27, 2022, the Company granted a total of 4,465,000 share options under the Post-IPO Share Option Scheme of which none of the grantees is a connected person of the Company under the Listing Rules.

On November 11, 2022, the Company granted a total of 7,405,000 share options to 40 grantees (including Dr. Xue and 39 other grantees who are not connected persons of the Company under the Listing Rules) under the Post-IPO Share Option Scheme, among which 1,000,000 share options are granted to Dr. Xue. The grant of share options to Dr. Xue had been approved by the independent non-executive Directors in accordance with Rule 17.04(1) of the Listing Rules. Dr. Xue had abstained from voting on the resolutions relating to the share options granted to himself and had not been counted towards the quorum of the Board meeting in respect of such resolutions.

During the year ended December 31, 2022, none of share options were exercised, and 930,000 share options were forfeited. As at December 31, 2022, the Company has 10,940,000 share options outstanding.

## **CORPORATE GOVERNANCE AND OTHER INFORMATION**

### **Compliance with the Corporate Governance Code (“CG Code”)**

The Company is committed to maintaining high standard of corporate governance to safeguard the interests of the Shareholders, enhance corporate value, formulate its business strategies and policies, and enhance its transparency and accountability. The Company has complied and adopted the principles and the code provisions of the CG Code as set out in Appendix 14 to the Listing Rules as its own code of corporate governance. The CG Code has been applicable to the Company with effect from the Listing Date.

The Board is of the view that the Company has complied the principles and all applicable code provisions of the CG Code during the Reporting Period, save for the deviation from the then code provision A.2.1 as disclosed below.

We have not separated the roles of the Chairman of the Board and the Chief Executive Officer. Dr. Xue has served as chairman of the board and general manager of CANbridge Life Sciences Ltd. since June 2012 and as Chairman of the Board, Director and Chief Executive Officer since the inception of our Company in January 2018. Dr. Xue is the founder of the Group and has extensive experience in the business operations and management of our Group. Our Board believes that, in view of his experience, personal profile and his roles in our Company, Dr. Xue is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our Chief Executive Officer. Our Board also believes that the combined role of Chairman of the Board and Chief Executive Officer can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Directors consider that the balance of power and authority will not be impaired due to this arrangement. In addition, all major decisions are made in consultation with members of the Board, including the relevant Board committees, and four independent non-executive Directors.

The Board will review the corporate governance structure and practices from time to time and shall make necessary arrangements when the Board considers appropriate.

## **Compliance with Model Code**

The Company has adopted a code of conduct regarding Directors' securities transactions on terms no less exacting than the required standard set out in the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules (the "Model Code"). Specific enquiries have been made to all the Directors and they have confirmed that they have complied with the Model Code during the year ended December 31, 2022.

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

During the Reporting Period, neither the Company nor any of its subsidiaries purchased, redeemed or sold any of the Company's listed securities.

## **Employee and Remuneration Policy**

As at December 31, 2022, the Group had 117 employees (2021: 183). The Group's employees' remuneration consists of salaries, bonuses, share-based incentive plans, an employees' provident fund, and social security contributions and other welfare payments. In accordance with applicable laws in relevant jurisdictions, we have made contributions to social security insurance funds and housing funds for the employees of the Group.

We conduct new staff training regularly to guide new employees and help them adapt to the new working environment. In addition, we provide on-line and in-person formal and comprehensive company-level and department-level training to our employees in addition to on-the-job training. We also encourage our employees to attend external seminars and workshops to enrich their technical knowledge and develop competencies and skills.

During the Reporting Period, the total staff costs (including Director's emoluments) were approximately RMB158.6 million (2021: RMB148.3 million).

## **FINAL DIVIDEND**

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2022 (2021: nil).

## **ANNUAL GENERAL MEETING AND CLOSURE OF REGISTER OF MEMBERS**

Further announcement(s) will be made by the Company in respect of the proposed date on which the forthcoming annual general meeting will be held and the period during which the register of members of the Company will be closed in order to ascertain shareholders' eligibility to attend and vote at the said meeting.

## **SCOPE OF WORK OF ERNST & YOUNG**

The financial information in respect of the announcement of the Group's results for the year ended December 31, 2022 have been agreed by the Group's auditors, Ernst & Young, to the amounts set out in the Group's draft consolidated financial statements for the year. The work performed by Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Ernst & Young on the results announcement.

## **AUDIT COMMITTEE REVIEW OF FINANCIAL STATEMENTS**

The Audit Committee has considered and reviewed the audited consolidated annual results of the Group for the year ended December 31, 2022 and the accounting principles and practices adopted by the Group, and has discussed with management on issues in relation to internal control, risk management and financial reporting. The Audit Committee is of the opinion that the audited consolidated annual results of the Group for the year ended December 31, 2022 are in compliance with the relevant accounting standards, laws and regulations.

## **PUBLICATION OF ANNUAL RESULTS AND ANNUAL REPORT**

This results announcement is published on the Company's website ([www.canbridgepharma.com](http://www.canbridgepharma.com)) and the website of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)).

The 2022 annual report of the Company containing all relevant information required under the Listing Rules will be published on the aforementioned websites and dispatched to the shareholders of the Company in April 2023.

By order of the Board  
**CANbridge Pharmaceuticals Inc.**  
北海康成製藥有限公司  
**Dr. James Qun Xue**  
*Chairman*

Hong Kong, March 30, 2023

*As at the date of this announcement, the Board of Directors of the Company comprises Dr. James Qun Xue as Chairman and executive Director, Dr. Kan Chen, Dr. Derek Paul Di Rocco and Mr. Edward Hu as non-executive Directors, and Dr. Richard James Gregory, Mr. James Arthur Geraghty, Mr. Peng Kuan Chan and Dr. Lan Hu as independent non-executive Directors.*