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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, 2023

The board (the "Board") of directors (the "Director(s)") of CANbridge Pharmaceuticals Inc. (the "Company" or "CANbridge") 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, 2023 (the "Reporting Period"), together with comparative figures for the year ended December 31, 2022 as follows. These consolidated financial statements of the Group for the Reporting Period have been reviewed by the audit committee of the Board (the "Audit Committee") and audited by the Company's auditors, Ernst & Young.

In this announcement, "CANbridge", "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® (idursulfase beta, formerly known as CAN101), an enzyme replacement therapy (ERT) for the treatment of Mucopolysaccharidosis type II (MPS II), also known as Hunter syndrome. MPS II is number 73 in the "First National List of Rare Diseases" in China published in May 2018.

- Launched in May 2021 as the first and only ERT for MPS II in mainland China. The identification of new patients accelerated, with 757 identified as of December 31, 2023.
- Implemented commercial insurance programs (Huiminbao) in 103 cities, covering a population of 500 million in China.

Livmarli[®] (maralixibat oral solution, formerly known as CAN108), an oral, minimally absorbed, reversible inhibitor of the ileal bile acid transporter (IBAT) that is under development to treat rare cholestatic liver diseases including Alagille syndrome (ALGS) and progressive familial intrahepatic cholestasis (PFIC). CANbridge has the exclusive rights to develop, commercialize, and under certain conditions, manufacture Livmarli[®] in Greater China. ALGS is number 5 in the "Second National List of Rare Diseases" in China published in September 2023.

• In 2023, CANbridge received multiple marketing approvals for Livmarli® in mainland China, Hong Kong, and Taiwan. These approvals make Livmarli® the first and only approved product marketed for the treatment of cholestatic pruritus in patients with ALGS in these regions.

CAN106 (omoprubart), a novel, long-acting monoclonal antibody for the treatment of complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria (PNH), myasthenia gravis (MG) and other diseases that may benefit from treatment with an anti-C5 antibody. PNH is number 88 in the "First National List of Rare Diseases" in China published in May 2018.

- Reported positive preliminary top-line data on June 25, 2023 from the ongoing Phase 1b study of CAN106 being conducted in PNH patients in China. Results suggest complete blockade of complement function at safe and well-tolerated doses. The data also show a dose-dependent reduction of lactate dehydrogenase (LDH) and increased hemoglobin levels, demonstrating clinically meaningful hemolysis inhibition.
- Complement-mediated diseases amenable to treatment with an anti-C5 antibody remain an area of broad interest, demonstrating potential for CAN106 in multiple indications beyond PNH.

CANOO8, a glycosylated CD95-Fc fusion protein being developed for the treatment of glioblastoma multiforme (GBM). GBM is number 38 in the "Second National List of Rare Diseases" in China published in September 2023.

- An independent data monitoring committee performed an interim analysis of the ongoing Phase 2 study of CAN008 being conducted in China in patients with newly diagnosed GBM and recommended that the study continue without any changes to the current trial design.
- Data from the Phase 2 study of CAN008 is anticipated in the first half of 2024. Depending on the outcome of this trial, the Company may plan to seek accelerated regulatory response in Greater China.

CAN103, an ERT for the treatment of Gaucher Disease (GD). GD is number 31 in the "First National List of Rare Diseases" in China published in May 2018.

- CAN103 is the first clinical stage ERT being developed for GD in China.
- On October 16, 2023, CANbridge announced that the core part of the ongoing CAN103 Phase 2 trial in treatment-naïve patients aged 12 and above with Gaucher disease Types I and III reached full enrollment. The randomized, double-blind and dose-comparison Phase 2 study is designed to evaluate the efficacy, safety and pharmacokinetics of CAN103 in newly treated GD patients over 9 months, and is followed by a long-term extension period. This trial will serve as a potential registrational trial for CAN103.
- We expect to submit New Drug Application (NDA) in the second half of 2024.

Gene Therapy, a CANbridge-developed area of excellence, is a therapeutic modality that includes adeno-associated virus (AAV) as a gene delivery vehicle due to its potential to be a one-time, durable treatment for many genetic diseases. Fabry disease and spinal muscular atrophy (SMA) are number 27 and number 110, respectively, in the "First National List of Rare Diseases" in China published in May 2018.

- Presented preclinical data in May 2023 on CAN203 at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting. Data shared at the ASGCT highlights the potential of this novel, second-generation vector that expresses a codon-optimized hSMN1 transgene expressed under the control of an endogenous hSMN1 promoter, to treat SMA. The data demonstrated that low-dose intracerebroventricular delivery of the gene therapy was able to achieve superior potency, efficacy and safety in mice with SMA, compared to the benchmark vector, which is similar to the U.S. Food and Drug Administration (FDA)-approved gene therapy vector for SMA.
- Presented preclinical data in October 2023 on CAN201, a potential gene therapy for the treatment of patients with Fabry disease, at the European Society of Gene and Cell Therapy (ESGCT) 30th Annual Congress. CAN201 utilizes a novel AAV vector (sL65) that specifically targets the liver to produce the enzyme, α-galactosidase A (α-GAL), that is deficient in patients with Fabry disease. In preclinical studies involving Fabry mice and a PXB mouse model containing a humanized liver, CAN201 showed a dose-dependent increase in α-GAL enzyme levels across various tissues with a corresponding reduction in disease-causing Gb3 lipid levels. The gene therapy was well tolerated with no significant adverse effects observed in Fabry mice.
- In February 2024, our pioneering work, in collaboration with the Horae Gene Therapy Center at the UMass Chan Medical School, on developing a novel AAV-based gene therapy for SMA was published in the prestigious EMBO Molecular Medicine journal, accompanied by a commentary highlighting its scientific significance. Compared to the benchmark vector with an identical design to the vector used in the FDA-approved gene therapy for treating SMA that drove high, ubiquitous tissue expression of SMN, this second-generation vector restored SMN expression close to physiological levels in the central nervous system and major systemic organs of a severe SMA mouse model. Remarkably, it demonstrated superior safety without liver toxicity seen with the benchmark vector and markedly improved therapeutic efficacy over the benchmark vector. Compared to the benchmark vector, it prolonged longer survival, more efficiently rescued motor function and neuromuscular junction integrity, more effectively rescued heart and respiratory function and reduced peripheral tissue disease manifestations. This body of work is the basis of our CAN203 gene therapy program.

Organizational Updates:

- In May 2023, CANbridge announced the appointment of Dr. Jason West, Ph.D., to the position of Vice President and Head of Gene Therapy Research. Dr. West possesses expertise in areas such as gene therapy development, platform innovation, and clinical candidate development. Most recently, he was at Fractyl Health, Inc., as Senior Director and, previously, Gene Therapy Research Director, where he led in-vivo gene therapy research programs, helped to establish a gene therapy technology platform and pipeline and identify novel AAV capsid delivery procedures. Before then, Dr. West was Senior Scientist and group leader in the Hematology/Advanced Editing Research Department at CRISPR Therapeutics AG, where he applied CRISPR technologies for DNA repair. At CRISPR, Dr. West also identified and established academic and industry partnerships and supported pre-clinical gene editing studies.
- With effect from November 23, 2023, Dr. Derek Paul Di Rocco resigned as a non-executive Director and ceased to be a member of the nomination and corporate governance committee of the Board.

FINANCIAL HIGHLIGHTS

- Our revenue increased by RMB23.9 million or 30.3%, from RMB79.0 million for the year ended December 31, 2022 to RMB102.9 million for the year ended December 31, 2023, which was mainly attributable to the increase of sales from Hunterase® and Livmarli®.
- Our research and development ("R&D") expenses decreased by RMB54.0 million or 17.4%, from RMB311.2 million for the year ended December 31, 2022 to RMB257.2 million for the year ended December 31, 2023, which was primarily attributable to the decrease in upfront and milestone payments made to our licensing partners, the decrease in testing and clinical trial expenses, the decrease in the R&D employee costs and partially offset by the increase of depreciation and amortization costs.
- Loss for the year decreased by RMB104.7 million or 21.7% from RMB483.5 million for the year ended December 31, 2022 to RMB378.8 million for the year ended December 31, 2023, which was primarily attributable to the increase of our revenue and the decreases of R&D expenses and administrative expenses.
- The adjusted loss for the year decreased by RMB97.8 million, or 21.4%, from RMB456.7 million for the year ended December 31, 2022, to RMB358.9 million for the year ended December 31, 2023. The adjusted loss for the year was arrived at by adjusting the International Financial Reporting Standards ("IFRS") loss for the year of RMB378.8 million (2022: RMB483.5 million) through excluding the effect of share-based payment 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 2023

	Notes	2023 RMB'000	2022 RMB'000
REVENUE	4	102,871	78,972
Cost of sales		(38,707)	(30,078)
Gross profit		64,164	48,894
Other income and gains Selling and distribution expenses Administrative expenses Research and development expenses Finance costs Other expenses	4	12,659 (83,671) (89,830) (257,210) (8,948) (16,001)	12,883 (86,782) (108,907) (311,174) (6,863) (31,526)
LOSS BEFORE TAX		(378,837)	(483,475)
Income tax expense	5		
LOSS FOR THE YEAR		(378,837)	(483,475)
Attributable to: Owners of the parent		(378,837)	(483,475)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (EXPRESSED IN RMB PER SHARE) – Basic and diluted	7	(0.89)	(1.14)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2023

	2023 RMB'000	2022 RMB'000
LOSS FOR THE YEAR	(378,837)	(483,475)
OTHER COMPREHENSIVE INCOME Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange difference: Exchange differences on translation of foreign operations	(25,749)	(109,485)
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods	(25,749)	(109,485)
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:		
Exchange difference: Exchange differences on translation of the Company	36,250	181,268
Net other comprehensive income that will not be reclassified to profit or loss in subsequent periods	36,250	181,268
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	10,501	71,783
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	(368,336)	(411,692)
Attributable to: Owners of the parent	(368,336)	(411,692)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2023

N	Totes	31 December 2023 <i>RMB'000</i>	31 December 2022 <i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		9,180	15,003
Right-of-use assets		99,827	129,714
Intangible assets		76,491	49,011
Other non-current assets			3,157
Total non-current assets		185,498	196,885
CURRENT ASSETS			
Inventories		8,783	9,824
Trade receivables	8	31,228	19,054
Prepayments, other receivables and other assets		10,847	13,175
Cash and bank balances		137,491	463,107
		188,349	505,160
Non-current assets classified as held for sale		21,515	
Total current assets		209,864	505,160
CURRENT LIABILITIES			
Trade payables	9	198,054	107,540
Other payables and accruals		81,162	130,670
Interest-bearing bank and other borrowings		23,690	26,867
Lease liabilities		11,034	13,028
		313,940	278,105
Advances received for disposal of non-current assets		14.005	
classified as held for sale		14,005	
Total current liabilities		327,945	278,105
NET CURRENT (LIABILITIES)/ASSETS		(118,081)	227,055
TOTAL ASSETS LESS CURRENT LIABILITIES		67,417	423,940

	31 December 2023 <i>RMB'000</i>	31 December 2022 <i>RMB'000</i>
NON-CURRENT LIABILITIES		
Interest-bearing bank and other borrowings	6,625	10,779
Lease liabilities	100,580	104,606
Total non-current liabilities	107,205	115,385
Net (liabilities)/assets	(39,788)	308,555
EQUITY		
Equity attributable to owners of the parent		
Share capital	28	28
Treasury shares	_	_
Reserves	(39,816)	308,527
Total (deficit)/equity	(39,788)	308,555

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 December 10, 2021.

2 BASIS OF PREPARATION

These financial statements have been prepared in accordance with IFRS (which include all IFRS, 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. Non-current assets held for sale are stated at the lower of their carrying amounts and fair values less costs to sell. These financial statements are presented in Renminbi ("RMB") and all values are rounded to the nearest thousand except when otherwise indicated.

The financial statements have 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 next twelve months after December 31, 2023 notwithstanding that as at December 31, 2023, the Group had net liabilities of RMB39,788,000 and incurred a net loss of RMB378,837,000 during the year ended December 31, 2023.

In view of these circumstances, the directors of the Company have given careful consideration to the future liquidity and performance of the Group and its available sources of financing in assessing whether the Group will have sufficient financial resources to continue as a going concern. Certain measures have been taken to mitigate the liquidity pressure and to improve the Group's financial position which include, but not limited to, the following:

- (i) The Group is actively negotiating with external parties to obtain new sources of financing or strategic capital investments to finance the Group's working capital and improve the liquidity position;
- (ii) The Group will continue to take active measures to control selling and administrative costs and research and development costs, such as further reprioritisation of pipelines, containment of employee costs, subleasing of spare office to reduce rental costs etc.;
- (iii) The Group has obtained the approval of back-up facilities from certain banks and has subsequently drawn down RMB22 million as of the date of approval of these consolidated financial statements and the Company is also in the process of obtaining further draw-down of bank borrowings;
- (iv) The Group has been actively negotiating with banks for renewal and extension of existing bank borrowings that will become due during the next twelve months after December 31, 2023. The Group will also continue to actively negotiate with the suppliers to extend the repayment dates of the overdue payables; and
- (v) The Group will continue to actively negotiate with certain third parties to license out its products to streamline its operations further and improve liquidity position.

The board of directors have reviewed the Group's cash flow projections prepared by management, which cover a period of twelve months from December 31, 2023. They are of the opinion that, taking into account the above-mentioned plans and measures, the Group will have sufficient working capital to finance its operations and to meet its financial obligations as and when they fall due within twelve months from December 31, 2023. Accordingly, the directors are satisfied that it is appropriate to prepare the consolidated financial statements on a going concern basis.

Notwithstanding the above, significant uncertainties exist as to whether the Group is able to achieve its plans and measures as described above. Whether the Group will be able to continue as a going concern would depend upon the following:

- (i) The successful obtaining of financing or strategic capital investments in the Group;
- (ii) The successful and timely implementation of the plans to control costs and reduce expenditures;
- (iii) The successful obtaining of continuous support from the banks for provision of new bank loans under the approved back-up facilities and renewal and extension of existing bank borrowings;
- (iv) The successful negotiation with the suppliers to extend the repayment dates of overdue payables; and
- (v) The successful signing of binding agreement with third parties to license out certain of its products or pipelines.

Should the Group be unable to achieve the above-mentioned plans and measures and operate as a going concern, adjustments would have to be made to write down the carrying values of the Group's assets to their recoverable amounts, to provide for any further liabilities which might arise, and to reclassify non-current assets and non-current liabilities as current assets and current liabilities, respectively. The effects of these adjustments have not been reflected in these consolidated financial statements.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries (collectively referred to as the "Group") for the year ended December 31, 2023. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

Generally, there is a presumption that a majority of voting rights results in control. When the Company has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group's voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises the related assets (including goodwill), liabilities, any non-controlling interest and the exchange fluctuation reserve; and recognises the fair value of any investment retained and any resulting surplus or deficit in profit or loss. The Group's share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits or accumulated losses, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

3 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

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

IFRS 17 Amendments to IAS 1 and IFRS Practice Statement 2 Amendments to IAS 8 Amendments to IAS 12

Amendments to IAS 12

Insurance Contracts
Disclosure of Accounting Policies
Definition of Accounting Estimates
Deferred Tax related to Assets and Liabilities arising from a
Single Transaction

International Tax Reform - Pillar Two Model Rules

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

- (a) Amendments to IAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 *Making Materiality Judgements* provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The amendments did not have any impact on the measurement, recognition or presentation of any items in the Group's financial statements.
- (b) Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. Since the Group's approach and policy align with the amendments, the amendments had no impact on the Group's financial statements.
- (c) Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions.

Upon the application of the amendments, the Group has determined the temporary differences arising from right-of-use assets and lease liabilities separately. However, they did not have any material impact on the overall deferred tax balances presented in the consolidated statement of financial position as the related deferred tax balances qualified for offsetting under IAS 12.

(d) Amendments to IAS 12 International Tax Reform – Pillar Two Model Rules introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. The Group has applied the amendments retrospectively. Since the Group did not fall within the scope of the Pillar Two model rules, the amendments did not have any impact to the Group.

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2023 RMB'000	2022 RMB'000
Revenue from contracts with customers	102,871	78,972
(a) Disaggregated revenue information		
	2023 RMB'000	2022 RMB'000
Type of goods Sale of medical products	102,871	78,972
Timing of revenue recognition Goods transferred at a point in time	102,871	78,972

(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.

	2023 RMB'000	2022 RMB'000
Other income		
Bank interest income	10,977	3,893
Government grants*	1,433	8,454
Total other income	12,410	12,347
Gains		
Gain on disposal of right-of-use assets for early termination of leases	238	435
Others	11 _	101
Total gains	249	536
Total other income and gains	12,659	12,883

^{*} Government grants have been received from the PRC 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% (2022: 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 (2022: HK\$2,000,000) of assessable profits of this subsidiary are taxed at 8.25% (2022: 8.25%) and the remaining assessable profits are taxed at 16.5% (2022: 16.5%).

Taiwan

The subsidiary incorporated in Taiwan is subject to income tax at a rate of 20% (2022: 20%) on the estimated assessable profits arising in Taiwan during the year.

Chinese Mainland

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), the subsidiaries which operate in Chinese Mainland are subject to CIT at a rate of 25% (2022: 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% (2022: 21%) during the year.

Pursuant to the PRC Corporate Income Tax Law, a 10% withholding tax is levied on dividends declared to foreign investors from the foreign investment enterprises established in Chinese Mainland. The requirement became effective on January 1, 2008 and applies to earnings after December 31, 2007. A lower withholding tax rate may be applied if there is a tax treaty between the PRC and the jurisdiction of the foreign investors.

A reconciliation of the tax expense applicable to loss before tax at the statutory tax rate for the jurisdiction where the operations of the Group are substantially based to the tax expense at the effective tax rate is as follows:

	2023	2022
	RMB'000	RMB'000
Loss before tax	(378,837)	(483,475)
Tax at the statutory tax rate of 25% (2022: 25%)	(94,709)	(120,869)
Effect of tax rate differences in other jurisdictions	18,199	20,180
Expenses not deductible for tax	6,894	7,056
Additional deductible allowance for qualified research and development costs	(5,420)	(8,677)
Tax losses utilised from previous periods	(3,638)	(950)
Tax losses and deductible temporary differences not recognised	78,674	103,260
_		
Tax charge at the Group's effective rate	_	_

6. DIVIDENDS

No dividends have been declared and paid by the Company for the year ended December 31, 2023 (2022: 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 424,378,752 (2022: 424,210,824) in issue during the year.

No adjustment has been made to the basic loss per share amounts presented for the year ended December 31, 2023 (2022: 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:

8.

	2023 RMB'000	2022 RMB'000
Loss		
Loss attributable to owners of the parent, used in the basic loss per share calculation	(378,837)	(483,475)
	Number 2023	of shares
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	424,378,752	424,210,824
TRADE RECEIVABLES		
	2023 RMB'000	2022 RMB'000
Trade receivables Impairment	31,228	19,054
Net carrying amount	31,228	19,054

The Group's trading terms with its customers are mainly on credit. The credit period is generally 30 to 90 days. The Group seeks to maintain strict control over its outstanding receivables and has a credit control department to minimise credit risk. Overdue balances are reviewed regularly by senior management. In view of the aforementioned and the fact that the Group's trade receivables relate to certain major customers, there is a significant concentration of credit risk. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

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

	2023	2022
	RMB'000	RMB'000
Within 3 months	31,228	19,054

9. TRADE PAYABLES

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

	2023 RMB'000	2022 RMB'000
Within 6 months Over 6 months	80,753 117,301	63,645 43,895
Total	198,054	107,540

The trade payables are non-interest-bearing and are normally settled in less than six months or based on the specific agreement with certain suppliers.

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

Founded in 2012, CANbridge is 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, 2023, we have a comprehensive pipeline of 14 drug assets targeting prevalent rare diseases and rare oncology indications that have high unmet needs and significant market potential. The robust pipelines include four marketed products and three drug candidates at the late clinical stage. Given the challenging macro environment, including volatile capital markets and limited biotech funding, CANbridge has further prioritized the key programs with significant development and regulatory milestones occurring 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. As of December 31, 2023, we have streamlined the workforce to 100 full-time employees, of which 13 have a Ph.D. and/ or M.D. degree, and more than 70% of our employees have prior experience working at multinational biopharmaceutical companies. 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 (U.S.), 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 prioritize and optimize our pipeline through out-licensing, partnerships and collaborations with academic institutions, as well as with in-house R&D.

In the rare disease area, we have seven biologic and small molecule product candidates. 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 ALGS and PFIC.. We received marketing approval for Hunterase® (CAN101) for the treatment of MPS II in mainland China in September 2020. We received marketing approval for Livmarli® for the treatment of ALGS from the National Medical Products Administration of China ("NMPA") in May 2023, from the Pharmacy & Poisons Board of Hong Kong in September 2023, and from Taiwan's TFDA in October 2023. We obtained the Investigational New Drug (IND) approval from NMPA for a CAN106 study in PNH in July 2021; positive top-line CAN106 Phase 1 data for the single ascending dose study in Singapore was reported in February 2022; and a positive preliminary CAN106 Phase 1b data for a multiple ascending dose study in PNH patients in China was reported in June 2023. Results showed promising efficacy and safety with a dose-dependent reduction of LDH levels and an increase in hemoglobin levels that demonstrate clinically meaningful hemolysis inhibition and improvement in transfusion-dependent anemia. Furthermore, the first patient was dosed in a Phase 1 trial of CAN103 in Gaucher disease in China in July 2022, and the first patient was dosed in a Phase 2 trial of Gaucher disease in China in January 2023. Enrollment for both trials has been completed.

In the rare oncology area, we are developing CAN008 for the treatment of 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 a Phase 2 clinical trial of CAN008 as a first-line treatment, 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 therapy. Gene therapy provides a potentially one-time, durable treatment for rare genetic diseases with limited treatment options. As of December 31, 2023, 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 exercised our option to secure the exclusive global rights to develop, manufacture and commercialize a novel second-generation gene therapy to treat SMA from UMass Chan Medical School. In addition, we are internally developing an 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 focuses on developing medicines for diseases affecting a small number of people. Rare diseases have unique characteristics that create an efficient market for therapeutic development. Most rare diseases are caused by genetic mutations that lead to a better understanding of the disease, increasing the chance of successful R&D. Sales efforts for rare disease drugs are more targeted due to the limited number of specialists and tertiary care hospitals treating these patients. A favorable regulatory environment, like the Orphan Drug Act and expedited approval pathways in the United States, helps to accelerate the development and commercialization of rare disease drugs.

The global rare disease drug market has grown rapidly since the enactment of the Orphan Drug Act in the United States in 1983. From USD109.0 billion in 2016, it reached USD135.1 billion in 2020 (at a CAGR of 5.5%). It is projected to reach USD383.3 billion by 2030, growing at a CAGR of 11.0% from 2020 to 2030. Rising awareness and healthcare expenditure have increased the demand for special treatments, positively impacting market growth. The U.S. and Europe are the largest rare disease 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, significantly lower than in the U.S. and Europe. However, with a similar prevalence rate of rare diseases, the patient pool in China is potentially over four times greater than in the U.S. According to Frost & Sullivan, the rare disease drug market in China is expected to reach USD25.9 billion by 2030, at a CAGR of 34.5%, offering attractive commercial opportunities for pharmaceutical companies. Leading companies like Sanofi, AstraZeneca, and Roche have already launched products in China and other developing countries, recognizing their market potential. CANbridge is uniquely positioned to address the medical needs of global rare disease patients efficiently.

The rare disease industry in China is expected to benefit from various regulatory initiatives. China has simplified the rare disease treatment application process, streamlined the regulatory approval pathway by allowing the submission of clinical data from global trials, and is moving towards a more favorable reimbursement policy. In 2018, China released the *First National List of Rare Diseases*, encompassing 121 rare conditions. In 2023, the second edition of the list was unveiled, incorporating 86 additional rare diseases. With this latest update, China's rare disease catalog now encompasses a total of 207 rare conditions across both editions.

Gene therapy is emerging as a promising therapeutic approach for rare diseases, with approximately 80% of rare diseases being genetic disorders, according to Frost & Sullivan. These therapies can address the root cause of the disease and offer curative potential. Recent advancements in genetic engineering and viral vector development have led to several approved gene therapy products, such as Zolgensma® for SMA developed by Novartis and Elevidys® for Duchenne muscular dystrophy (DMD) developed by Sarepta Therapeutics, Inc., validating their potential as a durable treatment for 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 draft proposes a market exclusivity period of up to 12 months for a first new pediatric drug and a market exclusivity period of up to seven years for new drugs addressing rare diseases, which provides the drug marketing license holders with continuous supply during this period.

Based on the two batches of national rare disease catalogs and the 2023 National Medical Insurance Drug Catalog, China has launched 165 rare disease drugs for 92 rare diseases, with 112 of them included in medical insurance, involving 64 rare diseases. From 2018 to 2022, 27 rare disease drugs (excluding new indications) were launched domestically, of which only 4 drugs were introduced or replicated by domestic companies. In 2023, a total of 45 rare disease drugs were approved for marketing domestically (excluding type 4 rare disease drugs for chemical drugs), of which 18 products were developed by Chinese companies, involving 13 rare diseases.¹

The "Guiding Catalog for Industrial Structure Adjustment (2024 Edition)" released by the National Development and Reform Commission (NDRC) officially came into effect on February 1, 2024. Rare disease drugs, biocatalysts, and gene therapy drugs are included in the encouraged category of industries.

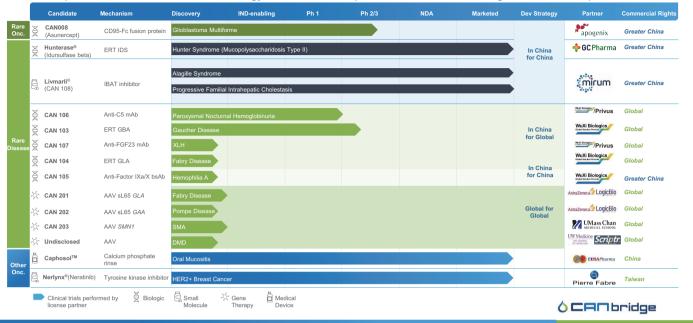
In March 2024, Premier Li Qiang, on behalf of the State Council, delivered the "Government Work Report" at the Second Session of the Fourteenth National People's Congress. Article ten of the report proposes "strengthening research, diagnosis, treatment services, and medication guarantee for rare diseases."

Beijing Disease Challenge Public Welfare Foundation and Frost & Sullivan jointly released "2024 China Rare Disease Industry Trends Observation Report".

PIPELINE

Our Comprehensive and Diversified Pipeline

CANbridge holds global rights to 8 out of 14 assets, spanning biologics, small molecules, and gene therapy, targeting most prevalent rare diseases and oncology indications, with proven mechanisms and significant market potential



BUSINESS REVIEW

The Company was listed on The Stock Exchange of Hong Kong Limited (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® (IDURSULFASE BETA, FORMERLY KNOWN AS 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®.

- CANbridge received the marketing approval from the NMPA for Hunterase® in September 2020 as the first and the only treatment for MPS II in China. Hunterase® is currently marketed in over 10 countries worldwide by GC Pharma. In a head-to-head Phase 1/2 study, Hunterase® demonstrated favorable efficacy as compared to Elaprase®, a drug commonly used to treat Hunter syndrome globally. In a Phase III clinical trial in Chinese MPS II patients, Hunterase® demonstrated favorable efficacy compared to placebo over a period of up to two years with no specific safety concerns.
- CANbridge commercially launched Hunterase® in China in May 2021 in a non-reimbursed market. Patient identification has accelerated since launch, with 757 patients identified as of December 31, 2023. As of December 31, 2023, we have implemented commercial insurance programs (Huiminbao) in 103 cities, covering a population of 500 million in China.
- The Company continues to strengthen integrated commercialization team and with the ability to commercialize multiple rare disease products.

LIVMARLI® (MARALIXIBAT ORAL SOLUTION, FORMERLY KNOWN AS CAN108)

- Livmarli® is an oral, minimally-absorbed, reversible IBAT inhibitor and is under development to treat rare cholestatic liver diseases, including ALGS (approved by FDA) and PFIC. Livmarli® possesses an extensive safety dataset, having been evaluated in more than 1,700 human subjects. Livmarli® has been studied in a number of completed and ongoing clinical trials in ALGS and PFIC with over 200 children treated and some on study for over seven years. A Phase 2b placebo-controlled randomized withdrawal period clinical trial with an 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 a Phase 3 study of Livmarli® in PFIC, 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 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 the combined genetic subtypes.
- CANbridge and Mirum have an exclusive license agreement for the development, commercialization and manufacturing, under certain conditions, of Livmarli® in Greater China.
- In 2023, CANbridge received multiple marketing approvals for Livmarli® in mainland China, Hong Kong, and Taiwan. The broad marketing approvals make Livmarli® the first and only approved product marketed for the treatment of cholestatic pruritus in patients with ALGS in these regions.
- Mirum received FDA approval for Livmarli® for ALGS in September 2021 and EU marketing approval in December 2022. Mirum also received FDA approval for Livmarli® for PFIC in March 2024.

CAN106 (OMOPRUBART)

- CAN106 is a novel, long-acting, monoclonal antibody directed against C5 complement that is being developed for the treatment of complement-mediated diseases, including PNH and MG among other approved and new potential indications. Based on clinical 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 with a convenient four-week dosing frequency.
- CANbridge obtained global rights to develop, manufacture and commercialize CAN106 in PNH, as well as for other complement-mediated diseases that involve activation of the C5 protein, from WuXi Biologics Ireland Limited and Privus Biologics, LLC in 2019 and 2020, respectively.
- CAN106 has received Orphan Drug Designation from the FDA for the treatment of MG, an autoimmune neuromuscular disease that causes muscle weakness. 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.
- In June 2023, CANbridge announced positive preliminary results from the ongoing Phase 1b study of CAN106 being conducted in China for PNH. The trial is being conducted under the direction of principal investigator, Dr. Bing Han, MD, PhD, Chief Physician and Professor in the Department of Hematology at Peking Union Medical College Hospital in Beijing, China. CAN106 showed dose-proportional exposure and rapid, dose-dependent reductions in free C5 levels within 24 hours, with all subjects in Cohort 3 maintaining values below 0.5 ug/mL, a historical threshold for complete C5 inhibition. CAN106 was safe and well-tolerated at all doses, and all drug-related adverse events were mild or moderate and transient, and none led to discontinuation from the study. There were no drug-related serious adverse events, and no cases of anaphylaxis or meningococcal infection. Currently, CAN106 is the only domestically-developed treatment for PNH that is actively being developed.
- Complement-mediated diseases amenable to treatment with an anti-C5 antibody remain an area of broad interest, demonstrating potential for CAN106 in multiple indications beyond PNH.

CAN008 (ASUNERCEPT)

- 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 between CD95L and CD95 on T cells, thereby preventing apoptosis and restoring immune function.
- CAN008 has been granted FDA Orphan Drug Designation and Orphan Medicinal Product Designation by the European Medicines Agency (EMA) for GBM. It has also been accepted into the EMA's PRIME (Priority Medicines) program, which provides support to medicines that could address unmet medical needs. In China, CAN008 has been classified as a Class 1 New Drug by the National Medical Products Administration. CANbridge holds the rights to develop and commercialize CAN008 for any indication in Greater China.
- 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. We 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 (PFS) at 12 months and was selected as the recommended Phase 2 dose. A Phase 2 pivotal trial conducted by Apogenix in patients with relapsed GBM showed statistically significant and clinically meaningful improvements of more than 50% in 4-month to 6-month PFS and quality of life as well as a positive trend in overall survival.
- In June 2023, an independent data monitoring committee reviewed the interim analysis of the ongoing Phase 2 study of CAN008 being conducted in China in patients with newly diagnosed GBM and recommended that the study continue without any changes to the current trial design. The Phase 2 double-blind study enrolled 119 subjects who were randomized 2:1 to receive intravenous CAN008 400 mg or placebo, in addition to standard-of-care chemoradiotherapy. All subjects underwent surgical excision of the GBM tumor prior to study treatment. The primary endpoint is PFS, and the secondary endpoint is overall survival (OS). Results from the Phase 2 study of CAN008 are anticipated in the first half of 2024. Depending on the outcome of this trial, the Company may plan to seek accelerated regulatory response in Greater China.

CAN103

- CAN103, a recombinant, human glucocerebrosidase (acid β-glucosidase), an ERT for the treatment of GD. CANbridge holds global proprietary rights to develop and commercialize the product.
- CAN103 is the first ERT for Gaucher disease in the clinical development stage trial in China.
- The first patient was dosed in the CAN103 Phase 1/2 trial, which is being developed for the treatment of patients with GD Types I and III in China. Bing Han MD, Ph.D., 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. GD, a lysosomal storage disorder, is caused by a genetic enzyme deficiency leading to the accumulation of a cellular sphingolipid called glucocerebroside in macrophages residing in liver, spleen, and bone marrow, resulting in hepatosplenomegaly, anemia, thrombocytopenia, and skeletal disease (infarction, osteoporosis, and pain). In GD Type III, glucocerebroside also accumulates in the central nervous system, causing chronic neurodegeneration and premature death. CAN103 is an ERT under development by CANbridge, as part of its rare disease partnership with WuXi Biologics (Cayman) Inc. (stock code: 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.
- In October 2023, the Company announced that the core part of the ongoing CAN103 Phase 2 trial, in treatment-naïve patients aged 12 or above with GD Types I and III, completed enrollment. The randomized, double-blind, dose comparison Phase 2 study is designed to evaluate the efficacy, safety and pharmacokinetics of CAN103 in newly treated GD patients over 9 months, followed by a long-term extension period. This trial will serve as a potential registrational trial for CAN103.
- We expect to submit NDA in the second half of 2024.

GENE THERAPY

- CANbridge has a fully operational in-house gene therapy R&D laboratory at their Burlington, MA U.S. site.
- The Company announced a license from the UMass Chan Medical School for the global development and commercialization rights to a novel second-generation scAAV gene therapy, expressing hSMN1 under the control of an endogenous hSMN1 promoter, for the treatment of SMA.

- The Company, in collaboration with the Horae Gene Therapy Center at the UMass Chan Medical School, presented preclinical data in May 2023 on CAN203 at the 2023 ASGCT Annual Meeting. These data support continued development of this second-generation vector as a potential best-in-class gene therapy for SMA. This next-generation gene therapy leverages advances in the gene therapy field that have occurred since the first gene therapy for SMA was developed over a decade ago. Data shared at ASGCT highlights the potential of this novel, second-generation vector that expresses a codon-optimized hSMN1 transgene under the control of an endogenous hSMN1 promoter, to treat SMA. The data demonstrated that low-dose intracerebroventricular delivery of the gene therapy was able to achieve superior potency, efficacy and safety in mice with SMA, compared to the benchmark vector, which is similar in design to the FDA-approved gene therapy vector for SMA.
- Presented preclinical data in October 2023 on CAN201, a potential gene therapy for the treatment of patients with Fabry disease, at the ESGCT 30th Annual Congress. CAN201 utilizes a liver-targeting AAV capsid sL65 to produce in the liver the key enzyme, α-GAL, that is deficient in patients with Fabry disease. In preclinical studies involving Fabry mice and a PXB mouse model containing a humanized liver, CAN201 showed a dose-dependent increase in α-GAL enzyme levels across various tissues with a corresponding reduction in disease-causing Gb3 lipid levels. The gene therapy was well tolerated with no significant adverse effects observed in Fabry mice.
- In February 2024, our pioneering work, in collaboration with the Horae Gene Therapy Center at the UMass Chan Medical School, on developing a novel AAV-based gene therapy for SMA was published in the prestigious EMBO Molecular Medicine journal, accompanied by a commentary highlighting its scientific significance. Compared to the benchmark vector with an identical design to the vector used in the FDA-approved gene therapy for treating SMA that drove high, ubiquitous tissue expression of SMN, this second-generation vector restored SMN expression close to physiological levels in the central nervous system and major systemic organs of a severe SMA mouse model. Remarkably, it demonstrated superior safety without liver toxicity seen with the benchmark vector and markedly improved therapeutic efficacy over the benchmark vector. Compared to the benchmark vector, it prolonged longer survival, more efficiently rescued motor function and neuromuscular junction integrity, more effectively rescued heart and respiratory function and reduced peripheral tissue disease manifestations. This body of work is the basis of our CAN203 gene therapy program.

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

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 costefficiency and quality control of our drug products and/or candidates. In an effort to advance our gene therapy pipelines, we are exploring manufacturing strategy for gene therapy that can help us to achieve high quality and capital efficiency anticipate to use CDMO to enable the further development of our gene therapy products.

Commercialization

With multiple products currently approved for marketing in multiple geographies, we have established our key operation hubs in both Beijing and Shanghai, with offices in other locations in Greater China. We have set up a commercialization team dedicated to our approved products and 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 assistance and market access, with the mission to execute medical engagement plans for key opinion leader (KOL) development, promote community awareness and explore industry insights for better drug development and marketing strategy.

The management continues to monitor the market to develop the most cost-effective strategy for commercializing these upcoming pipeline products.

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").

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 RMB23.9 million or 30.3%, from RMB79.0 million for the year ended December 31, 2022 to RMB102.9 million for the year ended December 31, 2023, which was mainly attributable to the increase of sales from Hunterase® and Livmarli®.

Cost of Sales

Our cost of sales increased by RMB8.6 million from RMB30.1 million for the year ended December 31, 2022 to RMB38.7 million for the year ended December 31, 2023, which was primarily attributable to the increase in costs incurred as a result of the increased sales of commercialized products.

Gross Profit and Gross Profit Margin

Our gross profit increased by RMB15.3 million from RMB48.9 million for the year ended December 31, 2022 to RMB64.2 million for the year ended December 31, 2023. Our gross profit margin for the year ended December 31, 2023 was 62.4% (2022: 61.9%).

Other Income and Gains

Our other income and gains decreased by RMB0.2 million from RMB12.9 million for the year ended December 31, 2022 to RMB12.7 million for the year ended December 31, 2023, which was primarily attributable to the increase of the bank interest income which was partially offset by the decrease of subsidies received from local government during the year.

Selling and Distribution Expenses

Our selling and distribution expenses decreased by RMB3.1 million from RMB86.8 million for the year ended December 31, 2022 to RMB83.7 million for the year ended December 31, 2023, which was primarily due to the decrease in employee costs as a result of the increased effectiveness in sales activities and partially offset by the increase of marketing and promotion expenses.

Administrative Expenses

Our administrative expenses decreased by RMB19.1 million from RMB108.9 million for the year ended December 31, 2022 to RMB89.8 million for the year ended December 31, 2023. Such decrease was primarily attributable to the decrease in the administrative employee costs and partially offset by the increase of office expenses.

Research and Development Expenses

Our research and development expenses decreased by RMB54.0 million from RMB311.2 million for the year ended December 31, 2022 to RMB257.2 million for the year ended December 31, 2023. Such decrease was primarily attributable to the decrease in upfront and milestone payments made to our licensing partners, the decrease in testing and clinical trial expenses, the decrease in the R&D employee costs and partially offset by the increase of depreciation and amortization costs.

	For the year ended		
	December 31,		
Research and development expenses	2023	2022	
	RMB'000	RMB'000	
Staff costs	47,261	54,244	
Testing and clinical trial expenses	169,034	174,305	
License fees	11,149	59,488	
Depreciation and amortization	12,777	7,342	
Other expenses	16,989	15,795	
Total	257,210	311,174	

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Finance Costs

Our finance costs increased from RMB6.9 million for the year ended December 31, 2022 to RMB8.9 million for the year ended December 31, 2023. Such increase was primarily due to 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. 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:

	For the year ended December 31,	
	2023	2022
	RMB'000	RMB'000
Loss for the year	(378,837)	(483,475)
Add: Share-based payment expenses	19,917	26,822
Adjusted loss for the year	(358,920)	(456,653)

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

Our cash and bank balances as of December 31, 2023 were RMB137.5 million, of which RMB48.3 million, RMB82.2 million, RMB1.5 million and RMB5.5 million, were denominated in RMB, USD, HKD and TWD, respectively. As compared to RMB463.1 million as of December 31, 2022, 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, 2023, 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. We closely monitor the uses of cash and cash equivalents to ensure that our financial resources have been used in the most cost-effective and efficient way. We also consider and endeavor to seek various funding sources depending on the Group's funding needs.

Bank Loans and Other Borrowings

Our bank loans and other borrowings as of December 31, 2023 were RMB30.3 million (December 31, 2022: RMB37.6 million), of which RMB23.7 million and RMB6.6 million, were denominated in RMB and USD, respectively and carried fixed nominal interest rates ranging from 3.35% to 4.00% per annum.

Current ratio

Current ratio (calculated by current assets divided by current liabilities) of the Group as of December 31, 2023 was 64.0% (December 31, 2022: 181.6%). The decrease in current ratio was primarily due to the decrease in cash and bank balances, and the increase in trade payables as of December 31, 2023.

Gearing ratio

The gearing ratio (calculated by total interest-bearing borrowings divided by total assets) of the Group as of December 31, 2023 was 7.7% (December 31, 2022: 5.4%).

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, 2023, we did not have any material contingent liabilities.

Capital Expenditure and Commitments

The Group's capital expenditures in the year ended December 31, 2023 were primarily related to the purchase of property, plant and equipment and intangible assets. In the year ended December 31, 2023, the Group incurred RMB38.7 million in relation to capital expenditures.

Charges on Group Assets

As of December 31, 2023, 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 (the "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, 2023, the Group pledged deposits of RMB12.6 million in commercial banks held as collateral for issuance of letters of credit for lease. Saved as disclosed above, as of 31 December 2023, the Group did not have other charges over its assets.

Significant Investment Held

As of December 31, 2023, the Group did not have any significant investments.

Material Acquisition and Disposal of Subsidiaries, Associates and Joint Ventures

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

DISCLOSEABLE TRANSACTION IN RELATION TO LAND RESUMPTION

On December 15, 2023, CANbridge (Suzhou) Bio-Pharma Co., Ltd.* (北海康成(蘇州) 生物製藥有限公司), a wholly-owned subsidiary of the Company ("CANbridge Suzhou"), entered into a land resumption agreement (the "Land Resumption Agreement") with Suzhou Industrial Park Land Reserve Center* (蘇州工業園區土地儲備中心) (the "Local Government") in respect of the resumption (the "Land Resumption") of the land use rights held by CANbridge Suzhou for a property situated west of Guangxian Street and north of Chuangyuan Road at the Suzhou Industrial Park (numbered 50888), Suzhou, China, with a total site area of approximately 51,014.9 square meters (the "Land"). Pursuant to the Land Resumption Agreement, CANbridge Suzhou shall surrender the land use rights of the Land to the Local Government for a total compensation of RMB28,010,000 payable by the Local Government to CANbridge Suzhou. The compensation was fully settled by February 2024.

Principle terms of the Land Resumption Agreement

The principal terms of the Land Resumption Agreement are set out below:

Date: December 15, 2023

Parties: (1) CANbridge Suzhou; and

(2) the Local Government.

Assets to be resumed: Pursuant to the Land Resumption Agreement, the Local Government agreed

to compensate CANbridge Suzhou an amount of RMB28,010,000 for

resuming the Land.

The Land is for industrial use and situated west of Guangxian Street and north of Chuangyuan Road at the Suzhou Industrial Park (numbered 50888), Suzhou, China, with a total site area of approximately 51,014.9 square meters and was vacant as of the date of the Land Resumption Agreement.

Total compensation and payment terms:

The compensation payable to CANbridge Suzhou for the Land Resumption is RMB28,010,000. The compensation was determined with reference to (i) the consideration that CANbridge Suzhou paid for the acquisition of the land use rights of the Land in June 2022; and (ii) costs and expenses incurred related to the preliminary construction planning and design of the Land.

In accordance with the Land Resumption Agreement, the compensation was fully settled by the Local Government via three instalments, with the last instalment fully settled in February 2024.

Information of the Parties to the Land Resumption Agreement

The Company is an investment holding company. The Group is principally engaged in the research, development and commercialization of biotech therapies targeting rare diseases in large underserved global markets.

CANbridge Suzhou is a wholly-owned subsidiary of the Company. The principal activities of CANbridge Suzhou are research, development and commercialization of medical products.

The Local Government is an institutional unit (事業單位) under the Suzhou Industrial Park Land and Resources Bureau of Land and Real Estate Board, Jiangsu Province, the PRC* (中華人民共和國江蘇省蘇州市工業園區國土房產局).

To the best knowledge, information and belief of the Directors, having made all reasonable enquires, as of the date of this announcement, both the Local Government and its ultimate beneficial owner are third parties independent of the Company and its connected persons (as defined under the Rules Governing the Listing of Securities on the Stock Exchange (the "Listing Rules")).

Financial information of the Land

The following table sets forth the financial information attributable to the Land for the two years ended December 31, 2023 based on the Company's audited financial statements:

Year ended December 31,	
2023	2022
(Audited)	
RMB'000	
(648)	(324)

Profit/(loss) before and after taxation and extraordinary items

As recognised in the audited consolidated financial statements of the Company for the year ended December 31, 2023, the audited carrying value of the land use rights and relevant capital expenditures of the Land recorded as non-current assets classified as held for sale was approximately RMB21.5 million.

Given that the Land Resumption was completed in February 2024, the Company expects to recognize a gain of approximately RMB6.5 million in its financial statements for the year ending December 31, 2024 from the Land Resumption, being the difference between the compensation for the Land Resumption over the above-mentioned audited carrying value of the Land and other capital expenditures attributable to the Land. The actual gain in relation to the Land Resumption is subject to assessment and audit in respect of the Land Resumption. The net proceeds from the Land Resumption after deducting the relevant costs and expenses (before tax), being approximately RMB28,010,000, will mainly be utilised as working capital of the Group.

Reasons for and Benefits of the Land Resumption

CANbridge Suzhou acquired the land use rights of the Land from the Suzhou Industrial Park Planning and Construction Committee* (蘇州工業園區規劃建設委員會) for a consideration of RMB18,880,000 in June 2022. The Group had originally planned to construct its own research and development center and manufacturing site on the Land should the Group secure sufficient cash and resources to fund such construction. Given the recent market conditions and the Group's current liquidity position, the Group has not commenced the construction on the Land and, as of the date of the Land Resumption Agreement, the Land was vacant and was not used by the Group. The Company is of the view that the Land Resumption provided an opportunity to generate cash without any material adverse effect on the business and operation of the Group.

In addition, given that the Land Resumption was part of the Local Government's initiative to re-purpose the land use in the area, the Company was of the view that it had no choice but to surrender the Land and proceed with the Land Resumption.

The Board is of the view that (i) the Land Resumption does not have any material adverse effect on the Group's business operation; (ii) the terms of the Land Resumption Agreement are fair and reasonable; (iii) although the Land Resumption is not conducted in the ordinary and usual course of business of CANbridge Suzhou, the terms and conditions are on normal commercial terms or better, fair and reasonable; and (iv) the Land Resumption is in the interests of the Company and the Shareholders taken as a whole.

Listing Rules Implications

As the highest applicable percentage ratio calculated under Rule 14.07 of the Listing Rules in respect of the Land Resumption is more than 5% but less than 25%, the Land Resumption constitutes a discloseable transaction of the Company, and is therefore subject to the reporting and announcement requirements but exempt from the shareholders' approval requirement under Chapter 14 of the Listing Rules.

Delay in Publication of Announcement in respect of the Land Resumption under Rule 14.34 of the Listing Rules

The Company understands that it should have informed the Stock Exchange and published an announcement as soon as possible in accordance with Rule 14.34 of the Listing Rules as and when the obligations in relation to the Land Resumption arose (i.e., when the Land Resumption Agreement was entered into). The Company deeply regrets its delay in compliance with the Listing Rules but would like to stress that the delay in compliance of the Listing Rules was inadvertent. The Company also understands that it should have consulted and sought advice from its professional adviser on a timely basis where a notifiable transaction is contemplated.

In order to prevent the occurrence of similar incidents in the future, the Group has put in place the following remedial measures:

- (i) providing internal trainings on notifiable transaction(s) to all relevant personnel, including accounting staff and senior management, to reinforce and re-explain the relevant requirements of the Listing Rules;
- (ii) strengthening the implementation of the Company's internal controls system on transactions, including but not limited to strengthening the coordination and reporting arrangements for notifiable transaction(s) among various departments; and
- (iii) where there is any uncertainty arising from the interpretation or application of the Listing Rules, consulting professional advisers and the Stock Exchange (where necessary) in a timely manner prior to the entering into of such transaction(s).

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, 2023, 150,200 options were exercised, and 1,392,731 options were forfeited. As of December 31, 2023, the Company had 38,986,855 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 of 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.

During the Reporting Period, no RSUs were granted by the Company under the Post-IPO RSU Scheme.

During the year ended December 31, 2023, 752,250 RSUs were vested, and 285,000 RSUs were forfeited. As of December 31, 2023, the Company had 4,612,750 RSUs outstanding.

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 same class of the Company as of the date of approval of the Post-IPO Share Option Scheme.

During the Reporting Period, no share options were granted by the Company under the Post-IPO Share Option Scheme.

During the year ended December 31, 2023, no share options were exercised, and 1,318,000 share options were forfeited. As of December 31, 2023, the Company has 9,622,000 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 C1 to the Listing Rules as its own code of corporate governance.

The Board is of the view that the Company has complied with the principles and all applicable code provisions of the CG Code during the Reporting Period, save for the deviation from C.2.1 of the CG Code 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 C3 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, 2023.

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 of December 31, 2023, the Group had 100 employees (2022: 117). 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 (including pension plans, unemployment insurance, work-related injury insurance, medical insurance and maternity insurance) 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 periodically 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 RMB126.9 million (2022: RMB158.6 million).

FINAL DIVIDEND

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2023 (2022: 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, 2023 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.

EXTRACT OF THE AUDITOR'S REPORT

The following is the extract of the independent auditor's report on the Company's consolidated financial statements for the year ended December 31, 2023:

Opinion

In our opinion, the consolidated financial statements give a true and fair view of the consolidated financial position of the Group as of 31 December 2023, and of its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with IFRS issued by the IASB and have been properly prepared in compliance with the disclosure requirements of the Hong Kong Companies Ordinance.

Material uncertainty related to going concern

We draw attention to note 2.1 to the consolidated financial statements, which indicates that the Group incurred a net loss of RMB378,837,000 during the year ended 31 December 2023 and the Group had net liabilities of RMB39,788,000 as of 31 December 2023. These conditions, along with other matters as set forth in note 2.1 to the consolidated financial statements, indicate the existence of a material uncertainty which may cast significant doubt on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

The aforesaid "note 2.1 to the consolidated financial statements" in the extract from the Auditor's Report is disclosed as note 2 to this 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, 2023 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, 2023 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) and the website of the Stock Exchange (www.hkexnews.hk).

The 2023 annual report of the Company containing all relevant information required under the Listing Rules will be published on the aforementioned websites in April 2024.

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 28, 2024

As of 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 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.