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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)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED 30 JUNE 2023

The board of directors (the “**Board**”) of CANbridge Pharmaceuticals Inc. (the “**Company**”) is pleased to announce the unaudited condensed consolidated results of the Company and its subsidiaries (the “**Group**”, “**we**”, “**our**” or “**us**”) for the six months ended 30 June 2023 (the “**Reporting Period**”), together with comparative figures for the six months ended 30 June 2022 as follows.

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

***Hunterase® (CAN101)**, an enzyme replacement therapy (ERT) for the treatment of Mucopolysaccharidosis type II (MPS II), also known as Hunter syndrome. MPS II has been included in the “First National List of Rare Diseases” in China since May 2018.*

- Launched in May 2021 in mainland China as the first and only ERT for MPS II. Identification of new patients accelerates, with 739 identified as of 30 June 2023.
- Expanded commercial insurance programs (Huiminbao) to 109 cities, covering a population of 586 million in China.

***Livmarli® (CAN108 maralixibat oral solution)**, an oral, minimally absorbed reversible inhibitor of the ileal bile acid transporter (IBAT) that is under development to treat rare cholestatic liver diseases. CANbridge has the exclusive rights to develop, commercialize, and under certain conditions, manufacture Livmarli in Greater China.*

- On 29 May 2023, the National Medical Products Administration of China (NMPA) granted marketing approval of Livmarli, making Livmarli the first and only approved product in China to be marketed for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.

- CANbridge plans to launch Livmarli nationwide in China in January 2024 and is planning to negotiate with the *China National Reimbursement Drug List (NRDL)* in the second half of 2023.
- Completed enrollment of the Phase 2 study of Livmarli in biliary atresia (BA) in China. This clinical trial in BA is being conducted by Mirum Pharmaceuticals, Inc. (“**Mirum**”) and supported by CANbridge under the license agreement with Mirum. Topline data from this trial is expected in the second half of 2023.
- Anticipate new drug application (NDA) approval for Livmarli’s use in ALGS patients aged 1 year and older in Taiwan and Hong Kong by the end of 2023.
- We plan to submit NDA for Livmarli’s use in Progressive familial intrahepatic cholestasis (PFIC) patients in the second half of 2023.

***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.*

- Reported positive preliminary top-line data 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.
- Based on the positive results from the Phase 1b study, CANbridge will begin enrolling a registrational clinical trial in PNH in China that will commence in the second half of 2023 with potential data in the second half of 2024.

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

- An independent data monitoring committee completed an interim analysis and review of the ongoing Phase 2 study of CAN008 being conducted in China in patients with newly diagnosed GBM and recommended the study continue without any changes to the current trial design.

CAN103, an 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.

- Completed Part A of the ongoing Phase 1/2 clinical trial in China and initiated Part B in the first quarter of 2023, which will serve as a potential registrational trial.
- CAN103 is the first clinical stage ERT being developed for GD in China.

Gene Therapy, an 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. Fabry disease and spinal muscular atrophy (SMA) have been included in the “First National List of Rare Diseases” since May 2018.

- Announced the appointment of Jason West, Ph.D., to the position of Vice President, Head of Gene Therapy Research. Dr. West possesses expertise in areas such as gene therapy development, platform innovation, and clinical candidate development.
- Presented preclinical data at the 2023 American Society of Gene and Cell Therapy (ASGCT) Annual Meeting. Data shared at ASGCT highlights the potential of this novel, second-generation scAAV that expresses a codon optimized co-hSMN1 from 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, scAAV-CMVen/CB-hSMN1, which is similar to the U.S. Food and Drug Administration (FDA)-approved gene therapy vector for SMA.

FINANCIAL HIGHLIGHTS

- Our revenue increased by RMB8.4 million or 24.2%, from RMB34.7 million for the six months ended 30 June 2022 to RMB43.1 million for the six months ended 30 June 2023, which was mainly attributable to the increase of sales from Hunterase® and Livmarli®.
- Our research and development (“**R&D**”) expenses decreased by approximately RMB15.3 million or 9.7%, from RMB158.3 million for the six months ended 30 June 2022 to RMB143.0 million for the six months ended 30 June 2023, which was primarily attributable to the decrease in upfront and milestone payments made to our licensing partners, the decrease in technical service fees and partially offset by the increase in depreciation and amortization costs.
- Loss for the Reporting Period decreased by approximately RMB30.8 million or 12.4%, from RMB249.0 million for the six months ended 30 June 2022 to RMB218.2 million for the six months ended 30 June 2023, which was primarily attributable to the increase of our revenue and the decreases of selling and distribution expenses, R&D expenses and administrative expenses.
- The adjusted loss for the period decreased by RMB24.5 million or 10.7%, from RMB228.9 million for the six months ended 30 June 2022, to RMB204.4 million for the six months ended 30 June 2023. The adjusted loss for the period is arrived at by adjusting the IFRS loss for the Reporting Period of RMB218.2 million (for the six months ended 30 June 2022: RMB249.0 million) through excluding the effect of share-based payment expenses. Please refer to the section headed “Non-IFRS Measures” of this announcement for details.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the six months ended 30 June 2023

| | | Six months ended 30 June | |
|--|-------|--------------------------------|--------------------------------|
| | Notes | 2023 (Unaudited) RMB'000 | 2022 (Unaudited) RMB'000 |
| Revenue | 4 | 43,051 | 34,728 |
| Cost of sales | | <u>(16,374)</u> | <u>(12,561)</u> |
| Gross profit | | 26,677 | 22,167 |
| Other income and gains | | 8,529 | 6,445 |
| Selling and distribution expenses | | (38,334) | (42,626) |
| Administrative expenses | | (48,187) | (55,625) |
| Research and development expenses | | (142,975) | (158,260) |
| Other expenses | | (19,412) | (18,631) |
| Finance costs | | <u>(4,459)</u> | <u>(2,482)</u> |
| LOSS BEFORE TAX | 5 | (218,161) | (249,012) |
| Income tax expense | 6 | <u>-</u> | <u>-</u> |
| LOSS FOR THE PERIOD | | <u>(218,161)</u> | <u>(249,012)</u> |
| Attributable to: | | | |
| Owners of the parent | | <u>(218,161)</u> | <u>(249,012)</u> |
| LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (EXPRESSED IN RMB PER SHARE) | | | |
| – Basic and diluted | 8 | <u>(0.51)</u> | <u>(0.59)</u> |

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the six months ended 30 June 2023

| | Six months ended 30 June | |
|--|--------------------------|-------------------------|
| | 2023 | 2022 |
| | (Unaudited) | (Unaudited) |
| | RMB'000 | RMB'000 |
| LOSS FOR THE PERIOD | <u>(218,161)</u> | <u>(249,012)</u> |
| OTHER COMPREHENSIVE INCOME | | |
| Other comprehensive income that may be reclassified to profit or loss in subsequent periods: | | |
| Exchange differences on translation of foreign operations | <u>(60,656)</u> | <u>(61,002)</u> |
| Net other comprehensive income that may be reclassified to profit or loss in subsequent periods | <u>(60,656)</u> | <u>(61,002)</u> |
| Other comprehensive income that will not be reclassified to profit or loss in subsequent periods: | | |
| Exchange differences on translation of the Company | <u>79,932</u> | <u>103,350</u> |
| Net other comprehensive income that will not be reclassified to profit or loss in subsequent periods | <u>79,932</u> | <u>103,350</u> |
| OTHER COMPREHENSIVE INCOME FOR THE PERIOD, NET OF TAX | <u>19,276</u> | <u>42,348</u> |
| TOTAL COMPREHENSIVE INCOME FOR THE PERIOD | <u>(198,885)</u> | <u>(206,664)</u> |
| Attributable to: | | |
| Owners of the parent | <u>(198,885)</u> | <u>(206,664)</u> |

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

30 June 2023

| | <i>Notes</i> | 30 June 2023 (Unaudited) RMB'000 | 31 December 2022 (Audited) RMB'000 |
|--|--------------|---|---|
| NON-CURRENT ASSETS | | | |
| Property, plant and equipment | | 14,447 | 15,003 |
| Right-of-use assets | | 127,232 | 129,714 |
| Intangible assets | | 83,385 | 49,011 |
| Other non-current assets | | 1,730 | 3,157 |
| | | <hr/> | <hr/> |
| Total non-current assets | | 226,794 | 196,885 |
| CURRENT ASSETS | | | |
| Inventories | | 19,883 | 9,824 |
| Trade receivables | 9 | 26,387 | 19,054 |
| Prepayments, other receivables and other assets | | 12,425 | 13,175 |
| Cash and bank balances | 10 | 283,558 | 463,107 |
| | | <hr/> | <hr/> |
| Total current assets | | 342,253 | 505,160 |
| CURRENT LIABILITIES | | | |
| Trade payables | 11 | 172,234 | 107,540 |
| Other payables and accruals | | 121,557 | 130,670 |
| Interest-bearing bank and other borrowings | | 26,873 | 26,867 |
| Lease liabilities | | 9,811 | 13,028 |
| | | <hr/> | <hr/> |
| Total current liabilities | | 330,475 | 278,105 |
| NET CURRENT ASSETS | | <hr/> | <hr/> |
| | | 11,778 | 227,055 |
| TOTAL ASSETS LESS CURRENT LIABILITIES | | <hr/> | <hr/> |
| | | 238,572 | 423,940 |
| NON-CURRENT LIABILITIES | | | |
| Interest-bearing bank and other borrowings | | 7,875 | 10,779 |
| Lease liabilities | | 107,256 | 104,606 |
| | | <hr/> | <hr/> |
| Total non-current liabilities | | 115,131 | 115,385 |
| Net assets | | <hr/> | <hr/> |
| | | 123,441 | 308,555 |
| EQUITY | | | |
| Equity attributable to owners of the parent | | | |
| Share capital | 12 | 28 | 28 |
| Reserves | | 123,413 | 308,527 |
| | | <hr/> | <hr/> |
| Total equity | | 123,441 | 308,555 |
| | | <hr/> | <hr/> |

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

30 June 2023

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 period, 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.

2.1 BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended 30 June 2023 has been prepared in accordance with IAS 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group’s annual consolidated financial statements for the year ended 31 December 2022.

The interim condensed consolidated 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 coming twelve months notwithstanding that as at 30 June 2023, the Group had accumulated losses of RMB3,628,766,000 and net assets of RMB123,441,000. In the opinion of the directors of the Company, the Group will have the necessary liquid fund to finance its working capital and capital expenditure requirements for the next twelve months after 30 June 2023. This is due to the following considerations:

- (a) The Group had cash and bank balances of RMB283,558,000 and net current assets of RMB11,778,000 as at 30 June 2023; and
- (b) The Group has performed a cash flow 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.

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group’s annual consolidated financial statements for the year ended 31 December 2022, except for the adoption of the following new and revised International Financial Reporting Standards (“**IFRSs**”) for the first time for the current period’s financial information.

| | |
|---|---|
| IFRS 17 | <i>Insurance Contracts</i> |
| Amendments to IFRS 17 | <i>Insurance Contracts</i> |
| Amendment to IFRS 17 | <i>Initial Application of IFRS 17 and IFRS 9 – Comparative Information</i> |
| Amendments to IAS 1 and IFRS Practice Statement 2 | <i>Disclosure of Accounting Policies</i> |
| Amendments to IAS 8 | <i>Definition of Accounting Estimates</i> |
| Amendments to IAS 12 | <i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i> |
| Amendments to IAS 12 | <i>International Tax Reform – Pillar Two Model Rules</i> |

The nature and 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 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has applied the amendments since 1 January 2023. The amendments did not have any impact on the Group's interim condensed consolidated financial information but are expected to affect the accounting policy disclosures in the Group's annual consolidated 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. The Group has applied the amendments to changes in accounting policies and changes in accounting estimates that occur on or after 1 January 2023. Since the Group's policy of determining accounting estimates aligns with the amendments, the amendments did not have any impact on the financial position or performance of the Group.
- (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. The Group has applied the amendments on temporary differences related to leases as at 1 January 2022, with any cumulative effect recognised as an adjustment to the balance of retained profits or other component of equity as appropriate at that date. In addition, the Group has applied the amendments prospectively to transactions other than leases that occurred on or after 1 January 2022, if any.

Prior to the initial application of these amendments, the Group applied the initial recognition exception and did not recognise a deferred tax asset and a deferred tax liability for temporary differences for transactions related to leases. Upon initial application of these amendments, the Group recognised (i) a deferred tax asset for all deductible temporary differences associated with lease liabilities (provided that sufficient taxable profit is available), and (ii) a deferred tax liability for all taxable temporary differences associated with right-of-use assets as at 1 January 2022.

The adoption of amendments to IAS 12 did not have any impact on the interim condensed consolidated financial statements.

- (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. Entities are required to disclose the information relating to their exposure to Pillar Two income taxes in annual periods beginning on or after 1 January 2023, but are not required to disclose such information for any interim periods ending on or before 31 December 2023. 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.

3. OPERATING SEGMENT INFORMATION

For management purpose, the Group has only one reportable operating segment, which is the development, production, marketing and sale of medical products.

Geographical information

(a) Revenue from external customers

| | For the six months ended 30 June | |
|-------------------------|----------------------------------|--------------------------------|
| | 2023 RMB'000 (Unaudited) | 2022 RMB'000 (Unaudited) |
| Mainland China | 19,659 | 11,690 |
| Other countries/regions | 23,392 | 23,038 |
| | <u>43,051</u> | <u>34,728</u> |

(b) Non-current assets

| | 30 June 2023 | 31 December 2022 |
|-------------------------|------------------------|----------------------|
| | RMB'000 (Unaudited) | RMB'000 (Audited) |
| Mainland China | 28,616 | 31,710 |
| Other countries/regions | 198,178 | 165,175 |
| | <u>226,794</u> | <u>196,885</u> |

The non-current asset information above is based on the locations of the assets.

4. REVENUE

An analysis of revenue is as follows:

| | For the six months ended 30 June | |
|--|---|--------------------|
| | 2023 | 2022 |
| | RMB'000 | RMB'000 |
| | (Unaudited) | (Unaudited) |
| <i>Revenue from contracts with customers</i> | 43,051 | 34,728 |
| Disaggregated revenue information for revenue from contracts with customers | | |
| Types of goods or services | | |
| Sale of medical products | 43,051 | 34,728 |
| Timing of revenue recognition | | |
| Goods transferred at a point in time | 43,051 | 34,728 |

5. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging:

| | For the six months ended 30 June | |
|---|---|--------------------|
| | 2023 | 2022 |
| | RMB'000 | RMB'000 |
| | (Unaudited) | (Unaudited) |
| Cost of inventories sold | 16,374 | 12,561 |
| Research and development costs (excluding related employee benefit expenses, depreciation and amortisation) | 105,977 | 124,755 |
| Depreciation of property, plant and equipment | 1,704 | 1,085 |
| Depreciation of right-of-use assets | 8,451 | 4,686 |
| Amortisation of intangible assets | 3,529 | 3,335 |
| Lease payments not included in the measurement of lease liabilities | 352 | 354 |
| Auditor's remuneration | 1,500 | 2,000 |
| Employee benefit expenses (including directors' and chief executive's remuneration): | | |
| Wages, salaries and welfare | 59,670 | 62,715 |
| Pension scheme contributions | 2,491 | 4,423 |
| Staff welfare expenses | 2,747 | 4,812 |
| Share-based payment expenses | 13,525 | 19,111 |
| | 78,433 | 91,061 |
| Foreign exchange difference, net | 16,772 | 16,915 |

6. INCOME TAX EXPENSE

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% on the estimated assessable profits arising in Hong Kong during the period, except for one subsidiary of the Group which is a qualifying entity under the two-tiered profits tax rates regime. The first HK\$2,000,000 of assessable profits of this subsidiary are taxed at 8.25% and the remaining assessable profits are taxed at 16.5%.

Taiwan

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

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% 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% during the period.

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 Mainland China. The requirement became effective on 1 January 2008 and applies to earnings after 31 December 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.

7. DIVIDENDS

No dividends have been declared and paid by the Company for the six months ended 30 June 2023 (six months ended 30 June 2022: Nil).

8. 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 period attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares of 424,306,307 in issue during the six months ended 30 June 2023 (six months ended 30 June 2022: 424,191,920).

The calculation of the diluted loss per share amounts is based on the loss for the period attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the period, as used in the basic loss per share calculation, and the weighted average number of ordinary shares assumed to have been issued at no consideration on the deemed exercise or conversion of all dilutive potential ordinary shares into ordinary shares.

No adjustment has been made to the basic loss per share amounts presented for the six months ended 30 June 2023 (six months ended 30 June 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 loss per share are based on:

| | For the six months ended 30 June | |
|--|---|--------------------|
| | 2023 | 2022 |
| | RMB'000 | RMB'000 |
| | (Unaudited) | (Unaudited) |
| <u>Loss</u> | | |
| Loss attributable to ordinary equity holders of the parent used in the basic loss per share calculation: | (218,161) | (249,012) |
| | 424,306,307 | 424,191,920 |
| | 26,387 | 19,054 |

9. 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:

| | 30 June 2023 | 31 December 2022 |
|-----------------|---------------------|-------------------------|
| | RMB'000 | RMB'000 |
| | (Unaudited) | (Audited) |
| Within 3 months | 26,387 | 19,054 |

The Group has applied the simplified approach to provide for expected credit losses (“ECLs”) prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the ageing. Because there was no history of default of trade receivables, the Company assessed that the expected loss rate of trade receivables of the Group was very low. The Company also assessed that there was no significant change in the ECL rates during the period, mainly because there was no change of historical default rates of trade receivables and there were no significant changes in the economic conditions and performance and behaviour of the customers, based on which the ECL rates were determined. The directors of the Company are of the opinion that the ECL in respect of the balances of trade receivables is minimal.

No loss allowance for impairment of trade receivables is provided as at 30 June 2023 (31 December 2022: Nil).

10. CASH AND BANK BALANCES

| | 30 June 2023 <i>RMB'000</i> (Unaudited) | 31 December 2022 <i>RMB'000</i> (Audited) |
|---------------------------|--|---|
| Cash and bank balances | <u>283,558</u> | <u>463,107</u> |
| Less: | | |
| Pledged deposits* | <u>(12,398)</u> | <u>(11,950)</u> |
| Cash and cash equivalents | <u>271,160</u> | <u>451,157</u> |

* This represented pledged deposits in commercial banks held as collateral for issuance of letters of credit. None of these deposits are either past due or impaired.

11. 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:

| | 30 June 2023 <i>RMB'000</i> (Unaudited) | 31 December 2022 <i>RMB'000</i> (Audited) |
|-----------------|--|---|
| Within 6 months | 112,647 | 63,645 |
| Over 6 months | <u>59,587</u> | <u>43,895</u> |
| | <u>172,234</u> | <u>107,540</u> |

12. SHARE CAPITAL

| | 30 June 2023 <i>RMB'000</i> (Unaudited) | 31 December 2022 <i>RMB'000</i> (Audited) |
|---|--|---|
| Issued and fully paid: | | |
| 424,392,920 (31 December 2022: 424,291,920) ordinary shares | <u>28</u> | <u>28</u> |

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 30 June 2023, we have a comprehensive pipeline of 14 drug assets targeting prevalent rare disease and rare oncology indications that have unmet needs and significant market potential. These include four marketed products, three 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 further prioritized and optimized 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 118 employees of which 17 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 30 June 2023. 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 enrich our pipeline through business partnerships and collaborations with academic institutions, as well as with in-house R&D.

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, ALGS, PFIC and BA. We received marketing approval for Hunterase® (CAN101) for MPS II in mainland China in September 2020. We obtained the IND approval from the NMPA for a CAN106 study in PNH in July 2021; a 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 multiple dose ascending trial in PNH patients in China was reported in June 2023. Results showed promising efficacy and safety and dose-dependent reduction of LDH and increased hemoglobin levels that demonstrate clinically meaningful hemolysis inhibition and anemia improvement. In addition, the NDA of Livmarli® for ALGS was accepted and granted priority review by NMPA in January 2022 and received marketing approval in China in May 2023. The first patient was dosed in Livmarli Phase 2 trial in BA in China in July 2022 and the clinical trial completed enrolment in May 2023. Furthermore, the first patient was dosed in CAN103 Phase 1 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 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 30 June 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 have 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, increasing the chances of success in R&D. Sales efforts for rare disease drugs can be more targeted due to limited specialized hospitals treating these patients. Favorable regulatory environments, like the Orphan Drug Act in the United States, help 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 (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 the 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 USD1.3 billion in 2020, lower than the U.S. and Europe. However, with a high prevalence 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 great opportunities for pharmaceutical companies. Leading companies like Sanofi, AstraZeneca, and Roche have already launched products in China and other developing countries, recognizing the 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 environment, including allowing for the submission of clinical data from global trials, and is moving towards a more favorable reimbursement policy. In 2018, China published the National List of Rare Diseases, which included 121 rare conditions. Presently, China is working on a second edition of the list to encompass more rare diseases.

Gene therapies are emerging as a promising solution 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 diseases and offer curative potential. Recent advancements in genetic engineering and viral vector development have led to approved gene therapy products, such as Zolgensma® for SMA developed by Novartis, validating their potential for rare diseases.

On 9 May 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 the first new pediatric drugs 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.

Our Comprehensive and Diversified Pipeline

As of 30 June 2023, CANbridge holds global rights to 8 out of 14 assets, spanning biologics, small molecules, and gene therapy. These target most prevalent rare diseases and oncology indications, with proven mechanisms and market potential.

| | Candidate | Mechanism | Discovery | IND-enabling | Ph 1 | Ph 2/3 | NDA | Marketed | Dev Strategy | Partner | Commercial Rights |
|--------------|-------------------------------|---------------------------|---|--------------|------|--------|-----|----------|--------------------|--|--------------------------|
| Rare Onc. | CAN008 (Asunerecept) | CD95-Fe fusion protein | Glioblastoma Multifforme | | | | | | | apogenix | Greater China |
| | Hunterase® (Idursulfase beta) | ERT IDS | Hunter Syndrome (Mucopolysaccharidosis Type II) | | | | | | In China for China | GCPharma | Greater China |
| Rare Disease | Livmaril® (CAN 108) | IBAT inhibitor | Alagille Syndrome | | | | | | | mirum | Greater China |
| | CAN 106 | Anti-C5 mAb | Paroxysmal Nocturnal Hemoglobinuria | | | | | | | WuXi Biologics / Privus | Global |
| | CAN 103 | ERT GBA | Gaucher Disease | | | | | | | WuXi Biologics / Privus | Global |
| | CAN 107 | Anti-FGF23 mAb | XLH | | | | | | | WuXi Biologics / Privus | Global |
| | CAN 104 | ERT GLA | Fabry Disease | | | | | | | WuXi Biologics / Privus | Global |
| | CAN 105 | Anti-Factor IXa/X bsAb | Hemophilia A | | | | | | | WuXi Biologics / Privus | Greater China |
| | CAN 201 | AAV sL65 GLA | Fabry Disease | | | | | | | AstraZeneca / LogiBio | Global |
| | CAN 202 | AAV sL65 G4A | Pompe Disease | | | | | | | AstraZeneca / LogiBio | Global |
| | CAN 203 | AAV SMN1 | SMA | | | | | | | UMass Chan Medical School UW Medicine / Scripta | Global |
| | Undisclosed | AAV | DMD | | | | | | | UMass Chan Medical School UW Medicine / Scripta | Global |
| Other Onc. | Caphosol™ | Calcium phosphate rinse | Oral Mucositis | | | | | | | EDSA Pharma | China |
| | Nerlynx® (Neratinib) | Tyrosine kinase inhibitor | HER2+ Breast Cancer | | | | | | | Pierre Fabre | Hong Kong, Taiwan, Macau |

 Clinical trials performed by license partner
 Biologic
 Small Molecule
 Gene Therapy
 Medical Device

BUSINESS REVIEW

The Company was listed on the Stock Exchange on 10 December 2021. Since then and up to 30 June 2023, 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).
- CANbridge 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.
- CANbridge commercially launched Hunterase® (CAN101) in China in May 2021 in a non-reimbursed market. Patient identification has accelerated since launch, with 739 patients identified as of 30 June 2023. We have expanded Huiminbao to 109 cities, covering a population of 586 million in China.
- The Company continues 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 IBAT and is under development to treat rare cholestatic liver diseases, including ALGS (approved by FDA), PFIC and BA. 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 open-label extension in children (aged 1-18 years) conducted for ALGS by 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 sNDA (Supplemental New Drug Application) for Livmarli for the treatment of cholestatic pruritus in patients two months of age and older with PFIC. Mirum received 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 of Livmarli for three indications: ALGS, PFIC and BA in Greater China.
- On 29 May 2023, the NMPA approved Livmarli making Livmarli the first and only approved product in China to be marketed for the treatment of cholestatic pruritus in patients with ALGS 1 year of age and older. Prior to the formal approval by the NMPA, Livmarli had 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. CANbridge plans to launch Livmarli nationwide in China in January 2024 and is planning to negotiate with the NRDL in the second half of 2023.
- In addition to treating ALGS, Livmarli is also being developed for the treatment of other cholestatic liver diseases, including PFIC and BA, and has been granted Orphan Drug designation by the FDA. Under the license agreement with CANbridge, Mirum, in May 2023, announced that the China region of the global Phase 2 EMBARK¹ study of Livmarli in BA has been fully enrolled, with nearly twice the expected number of patients. There are currently no pharmacological agents approved for the treatment of patients with biliary atresia. Topline data from the EMBARK trial is expected in the second half of 2023.
- We anticipate to receive NDA approval for Livmarli's use in ALGS patients aged 1 year and older in Taiwan and Hong Kong by the end of 2023.
- Mirum's net product sales of Livmarli for the first half of 2023 amounted to USD61.6 million, while its net product sales of Livmarli in 2022 totalled USD75.1 million.

CAN106

- CAN106 is a novel long-acting monoclonal antibody directed against C5 complement being developed for the treatment of complement-mediated diseases, including PNH, other complement mediated diseases that are targeted by approved anti-C5 antibodies and other new potential indications. Based on pre-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 and potentially with reduced dosing frequency versus the current standard of care.
- 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 ("**Privus**") in 2019 and 2020, respectively.

1: 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.

- 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, 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 with free C5 levels rapidly reduced within 24 hours in a dose-dependent manner, with all subjects in Cohort 3 maintaining values below 0.5 ug/mL, a 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. CANbridge plans to advance CAN106 to a pivotal trial in PNH in China, where there are no approved long-acting PNH treatments. Based on the positive results from the Phase 1 study, CANbridge will begin enrolling a registrational clinical trial in PNH in China that will commence in the second half of 2023 with potential data in the second half of 2024.
- The Company presented Phase 1a 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 14th International Conference on Complement Therapeutics during June 17 to 22 in Rhodes, Greece. Presentations highlighted positive top-line Phase 1a 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.
- CAN106 has received Orphan Drug Designation from the FDA for the treatment of 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 (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 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. 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 at 12 months and was selected as the Phase 2 dose. 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.

- In June 2023, CANbridge announced an independent data monitoring committee completed an interim analysis and review of the ongoing Phase 2 study of CAN008 being conducted in China in patients with newly diagnosed GBM. Based on the review, the committee has recommended the study to continue without any changes to the current trial design. The Phase 2 double-blinded 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 progression-free survival (PFS), and the secondary endpoint is overall survival (OS). CANbridge plans to report data from the Phase 2 clinical trial in the first half of 2024.
- 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 and is currently conducting a CAN008 Phase 2 trial in GBM in China.
- Based on the data and NMPA approval, we anticipate commercializing CAN008 within the next 3 years.

CAN103

- CAN103, a recombinant, human glucocerebrosidase (acid β -glucosidase), an ERT for the treatment of GD. CANbridge maintains global proprietary rights to develop and commercialize the product.
- 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 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 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.
- The multi-center Phase 1/2 clinical trial consists of four parts: The Company has almost completed Part A and already initiated dosing in Part B in the first quarter of 2023.
- CAN103 is the first ERT for Gaucher disease in the clinical development stage trial in China.

GENE THERAPY

- In May 2023, CANbridge announced the appointment of Jason West, Ph.D., to the position of Vice President, 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.
- The Company, in collaboration with the Horae Gene Therapy Center at the UMass Chan Medical School, presented preclinical data 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 scAAV vector that expresses a codon optimized co-hSMN1 from 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, scAAV-CMVen/CB-hSMN1, which is identical in design to the FDA-approved gene therapy vector for SMA.
- 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 co-hSMN1 from an endogenous hSMN1 promoter, for the treatment of SMA.
- In the second half of 2022, the Company amended its previous agreement with LogicBio[®] Therapeutics (now a wholly-owned subsidiary of Alexion, AstraZeneca Rare Disease) and completed the full technology transfer of two gene therapy products under development for the treatment of Fabry and Pompe diseases, and the proprietary manufacturing process.
- CANbridge has also built a fully operational in-house gene therapy R&D laboratory at their Burlington, MA U.S. site.

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 cost-efficiency and quality control of our drug products and/or candidates. In an effort to advance our gene therapy pipelines, we are enhancing our in-house process development platform and anticipate entering into a CDMO partnership to enable the further development of our gene therapy products.

Commercialization

With our late-stage drug candidates entering the commercialization stage, 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 late-stage drug candidates, that can be quickly expanded in line with our business growth, comprising four major functions, including marketing and sales, medical affairs and patient advocacy assistance and market access, 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.

SUBSEQUENT EVENTS AFTER THE REPORTING PERIOD

Save as disclosed in this announcement, as of the date of this announcement, the Company has no subsequent events affecting the Group which occurred since the end of the Reporting Period.

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 RMB8.4 million from RMB34.7 million for the six months ended 30 June 2022 to RMB43.1 million for the six months ended 30 June 2023, which was primarily attributable to the increase of sales from Hunterase® and Livmarli®.

Cost of Sales

Our cost of sales increased by RMB3.8 million from RMB12.6 million for the six months ended 30 June 2022 to RMB16.4 million for the six months ended 30 June 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 RMB4.5 million from RMB22.2 million for the six months ended 30 June 2022 to RMB26.7 million for the six months ended 30 June 2023. Our gross profit margin for the six months ended 30 June 2023 was 62.0% (for the six months ended 30 June 2022: 63.8%).

Other Income and Gains

Our other income and gains increased by RMB2.1 million from RMB6.4 million for the six months ended 30 June 2022 to RMB8.5 million for the six months ended 30 June 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 for the six months ended 30 June 2023.

Selling and Distribution Expenses

Our selling and distribution expenses decreased by RMB4.3 million from RMB42.6 million for the six months ended 30 June 2022 to RMB38.3 million for the six months ended 30 June 2023, which was primarily due to the decrease in employee costs as a result of the increased effectiveness in sales activities during the six months ended 30 June 2023.

Administrative Expenses

Our administrative expenses decreased by RMB7.4 million from RMB55.6 million for the six months ended 30 June 2022 to RMB48.2 million for the six months ended 30 June 2023. Such decrease was primarily attributable to the decrease in the administrative employee costs, office expenses and professional service fees, partially offset by the increase in depreciation and amortization costs.

Research and Development Expenses

Our research and development expenses decreased by RMB15.3 million from RMB158.3 million for the six months ended 30 June 2022 to RMB143.0 million for the six months ended 30 June 2023. Such decrease was primarily attributable to the decrease in upfront and milestone payments made to our licensing partners, the decrease in technical service fees and partially offset by the increase in depreciation and amortization costs.

| | Six months ended 30 June | |
|--|--------------------------|----------------|
| | 2023 | 2022 |
| | <i>RMB'000</i> | <i>RMB'000</i> |
| Research and development expenses | | |
| Staff costs | 30,248 | 30,567 |
| Testing and clinical trial expenses | 100,042 | 100,493 |
| License fees | – | 12,981 |
| Depreciation and amortization | 6,750 | 1,200 |
| Other expenses | 5,935 | 13,019 |
| | <hr/> | <hr/> |
| Total | 142,975 | 158,260 |
| | <hr/> <hr/> | <hr/> <hr/> |

Finance Costs

Our finance costs increased from RMB2.5 million for the six months ended 30 June 2022 to RMB4.5 million for the six months ended 30 June 2023. 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 period 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 period as loss for the period excluding the effect of share-based payment expenses. The term adjusted loss for the period 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 period during the periods indicated:

| | Six months ended 30 June | |
|------------------------------|---------------------------------|-------------------------|
| | 2023 | 2022 |
| | <i>RMB'000</i> | <i>RMB'000</i> |
| Loss for the period | (218,161) | (249,012) |
| Add: | | |
| Share-based payment expenses | 13,721 | 20,078 |
| Adjusted loss for the period | <u>(204,440)</u> | <u>(228,934)</u> |

Liquidity and Financial Resources

Our cash and bank balances as of 30 June 2023 were RMB283.6 million, of which RMB49.9 million, RMB220.7 million, RMB5.3 million and RMB7.7 million, were denominated in RMB, USD, HKD and TWD, respectively. As compared to RMB463.1 million as of 31 December 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 our R&D activities, 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 R&D, business operation and expansion plans. For the six months ended 30 June 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 30 November 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 30 June 2023 were RMB34.7 million (31 December 2022: RMB37.6 million), of which RMB14.4 million and RMB20.3 million, were denominated in RMB and USD, respectively and carried fixed nominal interest rates ranging from 4.0% to 4.2% per annum. Among all, approximately RMB26.8 million will be due within one year and approximately RMB7.9 million will be due in more than one year.

Current Ratio

Current ratio (calculated by current assets divided by current liabilities) of the Group as at 30 June 2023 was 103.6% (31 December 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 30 June 2023.

Gearing Ratio

The gearing ratio (calculated by total interest-bearing borrowings divided by total assets) of the Group as at 30 June 2023 was 6.1% (31 December 2022: 5.4%).

Foreign Currency Risk

We have transactional currency risk 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 30 June 2023, we did not have any material contingent liabilities.

Capital Expenditure and Commitments

The Group's capital expenditures during the six months ended 30 June 2023 were primarily related to the purchase of property, plant and equipment and intangible assets. During the six months ended 30 June 2023, the Group incurred RMB3.0 million in relation to capital expenditures as compared to RMB27.0 million during the six months ended 30 June 2022. The decrease in capital expenditures was primarily due to the acquisition of land use rights within the six months ended 30 June 2022, but there were no such acquisition during the Reporting Period.

Charges on Group Assets

As of 30 June 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 30 June 2023, the Group pledged deposits of RMB12.4 million in commercial banks held as collateral for issuance of letters of credit for lease.

Saved as disclosed above, as of 30 June 2023, the Group did not have other charges over its assets.

Significant Investment Held

As of 30 June 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.

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 adopted 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 Board is of the view that the Company has complied with all applicable code provisions of the CG Code during the Reporting Period, save for the deviation from the then code provision C.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 reviews 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 devised its own code of conduct for the trading of securities by its Directors and the relevant employees of the Group (who are likely to possess inside information about the securities of the Company due to their offices or employments in the Company or its subsidiaries) on terms that 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**”).

Having made specific enquiry by the Company, all Directors have confirmed that they have complied with the required standard set out in the Model Code throughout the Reporting Period. No incident of non-compliance of the Model Code by the relevant employees was noted by the Company for the Reporting Period.

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

Neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company’s listed securities during the Reporting Period.

Employee and Remuneration Policy

As at 30 June 2023, the Group had 118 employees (31 December 2022: 117 employees). 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 China and other 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 RMB78.4 million (2022: RMB91.1 million). Such decrease was primarily due to the decrease in share-based payment expenses and the decrease of our employee headcounts.

INTERIM DIVIDEND

The Board has resolved not to declare the payment of an interim dividend for the six months ended 30 June 2023 (six months ended 30 June 2022: nil).

AUDIT COMMITTEE AND REVIEW OF INTERIM RESULTS

The audit committee of the Board (the "**Audit Committee**") has three members comprising Mr. Peng Kuan Chan (chairperson), Mr. James Arthur Geraghty and Dr. Kan Chen, with its terms of reference in compliance with the Listing Rules.

The Audit Committee has considered and reviewed the unaudited interim results of the Group for the six months ended 30 June 2023 and the accounting principles and practices adopted by the Group, and has discussed with management on issues in relation to, among others, financial reporting. The Audit Committee is of the opinion that the unaudited interim results of the Group for the six months ended 30 June 2023 are in compliance with the relevant accounting standards, laws and regulations.

The consolidated financial statements of the Group for the Reporting Period have not been reviewed or audited by the Company's auditors.

PUBLICATION OF INTERIM RESULTS AND INTERIM 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 interim report of the Company containing all relevant information required under the Listing Rules will be published on the aforementioned websites and despatched to the shareholders of the Company in September 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, 30 August 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.