# **Appendix 4E**

# Neuren Pharmaceuticals Limited ARBN 111 496 130

# Preliminary final report Financial year ended 31 December 2023

The following information is given to the ASX under listing rule 4.3A:

## 1. Reporting Period

Neuren Pharmaceuticals Limited ARBN 111 496 130 presents the following consolidated information for the year ended 31 December 2023 together with comparative results for the year ended 31 December 2022.

All amounts shown are in Australian dollars unless otherwise stated.

## 2. Results for announcement to the market

		31 Dec 2023 \$'000	31 Dec 2022 \$'000	% Change
2.1	Revenue from ordinary activities	231,925	14,553	1494%
2.2	Profit from ordinary activities after tax attributable to members	157,081	184	85270%
2.3	Net profit for the period attributable to members	157,081	184	85270%
2.4	Dividends	N/A	N/A	N/A

Profit after tax for the year ended 31 December 2023 was A\$157.1 million (2022: A\$0.2 million). Revenue of A\$231.9 million was received under the licence agreement with Acadia Pharmaceuticals (2022: A\$14.6 million). This includes A\$59.4 million for the first commercial sale milestone, an upfront of A\$145.7 million under the expanded global licence agreement with Acadia and A\$26.8 million from quarterly royalty income. Other income includes interest income of A\$5.7 million (2022: A\$0.4 million) and foreign exchange gains of A\$2.4 million (2022: A\$1.2 million).

There was an increase of A\$14.1 million in research and development costs, due to higher expenditures in 2023 for the NNZ-2591 Phase 2 clinical trials and the foundational work to prepare for Phase 3 development of NNZ-2591 across multiple indications. There was also an increase in corporate and administrative costs of A\$2.5 million, mainly due to higher employee benefits and share-based payments expense. In addition, a loss of A\$2.2 million on the fair value of outstanding forward contracts to sell Australian dollars and buy US dollars was recognised at 31 December 2023 (2022: A\$0.7 million).

The net income tax expense recognised for the year ended 31 December 2023 was A\$48.1 million (2022: nil). After utilising Australian carried forward tax losses and the expectation of

offsetting the 5% withholding tax paid to the US Internal Revenue Service in relation to the milestone payments, Neuren has recognised a current tax liability of A\$37.1 million.

## 3. Income Statement

Refer to attached Financial Statements.

#### 4. Balance Sheet

Refer to attached Financial Statements.

#### 5. Statement of Cash Flows

Refer to attached Financial Statements.

#### 6. Statement of Changes in Equity

Refer to attached Financial Statements.

#### 7. Dividends

No dividends were paid in the financial year. The directors do not recommend the payment of any dividends with respect to the financial year.

#### 8. Dividend or Distribution Reinvestment Plan

Not applicable.

#### 9. Net Tangible Assets per Security

	31 December 2023 \$	31 December 2022 \$
Net tangible assets per security	\$1.61	\$0.33

#### 10. Changes in Control Over Entities

Not applicable.

#### 11. Associates and Joint Venture Entities

Not applicable.

#### 12. Significant Information

Refer to attached Financial Statements.

#### **13.** Accounting Standards

The Financial Statements have been prepared in accordance with and comply with generally accepted accounting practice in New Zealand (GAAP), New Zealand equivalents to International Financial Reporting Standards (NZ IFRS) which comply with International Financial Reporting Standards, the requirements of the Financial Markets Conduct Act 2013, and other applicable Financial Reporting Standards as appropriate for profit-oriented entities that fall into Tier 1 as determined by the New Zealand Accounting Standards Board.

#### 14. Commentary on the Results

Neuren is developing two new drug therapies to treat multiple neurodevelopmental disorders that emerge in early childhood. There are no, or limited, approved therapies currently available for these seriously debilitating disorders.

In April 2023, Neuren's partner Acadia Pharmaceuticals (NASDAQ: ACAD) launched DAYBUE<sup>™</sup> (trofinetide) in the United States as the first approved treatment for Rett syndrome. Net sales grew to US\$87.1 million in Q4 2023, which was the second full quarter of sales. Net sales for 2023 since April were US\$177 million, delivering royalties of A\$27 million to Neuren.

Acadia has provided guidance for net sales in 2024 of US\$370-420 million. Assuming this guidance is met and an exchange rate of 0.65, Neuren anticipates royalties of A\$61-70 million as well as A\$77 million from the first sales milestone payment which is due for the first calendar year in which net sales exceed US\$250 million.

Adoption of DAYBUE in the diagnosed Rett syndrome population has been faster than expected and caregivers and physicians have continued to report meaningful improvements in patients. Approximately 860 patients are currently on DAYBUE, with the high demand well supported by access from Medicaid and private health insurance payors. In the United States there are approximately 5,000 diagnosed Rett syndrome patients and prevalence studies suggest the total number of patients may be 6,000 to 9,000.

Under the terms of the licence agreement with Acadia, Neuren is eligible to receive ongoing quarterly royalties on net sales of trofinetide in North America, plus milestone payments of up to US\$350 million on achievement of a series of four thresholds of total annual net sales, plus one third of the market value of the Rare Pediatric Disease Priority Review Voucher that

<sup>&</sup>lt;sup>1</sup> 31 December 2021 Net Tangible Assets per Security has been updated to exclude Treasury Shares

was awarded to Acadia by the FDA, contingent on Acadia selling or using the voucher. Neuren estimates the value of its one third share as US\$33 million.

In July 2023, Neuren and Acadia expanded their partnership for trofinetide from North America to worldwide. Neuren received US\$100 million up-front and is eligible to receive milestone payments and royalties related to development and commercialization of trofinetide outside North America.

Acadia is now advancing in key markets outside the United States. For Canada, which is included in the economics for North America detailed above, Acadia anticipates a New Drug Submission (NDS) filing in Q1 2024 and potential approval around year-end 2024.

For Europe, Acadia is engaging with the European Medicines Agency (EMA) in Q1 2024, with a potential Marketing Authorisation Application filing in H1 2025. For Japan, Acadia is engaging the regulatory agency (PMDA) in 2024.

Neuren is developing NNZ-2591 for four serious neurodevelopmental disorders that emerge in early childhood and have no or limited approved treatment options. Phase 2 clinical trials are currently ongoing in children with each of Pitt Hopkins, Angelman and Prader-Willi syndromes. In Q4 2023 enrolment was completed in the Pitt Hopkins and Angelman syndrome trials. Top-line results are on track for Pitt Hopkins in Q2 2024 and for Angelman in Q3 2024.

In December 2023, Neuren announced positive top-line results from the Phase 2 clinical trial of NNZ-2591 in children with Phelan-McDermid syndrome (PMS). Significant improvement was observed by both clinicians and caregivers from treatment, across multiple efficacy measures. Improvements were consistently seen across many of the core PMS characteristics. NNZ-2591 was well tolerated and demonstrated a good safety profile.

PMS has severe quality of life impacts for those living with the syndrome, as well as parents and siblings. There are no approved treatments for PMS despite its severely debilitating impact.

The results for the global efficacy measures rated by both clinicians and caregivers showed a level of improvement typically considered clinically meaningful. 16 out of 18 children showed improvement measured by the Clinical Global Impression of Improvement (CGI-I), an assessment by the clinician of the child's overall status compared with baseline. The mean CGI-I score was 2.4. 10 children received a score of either 1 ("very much improved") or 2 ("much improved"). 15 out of 18 children showed improvement measured by the Caregiver Overall Impression of Change (CIC), an assessment by the caregiver of the child's overall status compared with baseline. The mean CIC score was 2.7. Seven children received a score of either 1 ("very much improved") or 2 ("much improved").

The overall aim of these first clinical trials in patients is to expedite the generation of data that will inform the design of subsequent registration trials. In order to accelerate the overall development plan, in parallel with conducting the Phase 2 trials Neuren has been executing the additional development work required to be ready for Phase 3 development. This includes non-clinical toxicity studies to support longer clinical trials and commercial use of the product as well as optimisation of the drug product and drug substance manufacturing arrangements.

Profit after tax for the year ended 31 December 2023 was A\$157.1 million (2022: A\$0.2 million). Revenue of A\$231.9 million was received under the licence agreement with Acadia (2022: A\$14.6 million). This includes A\$59.4 million for the first commercial sale milestone, an upfront of A\$145.7 million under the expanded global licence agreement with Acadia and A\$26.8 million from quarterly royalty income. Other income includes interest income of A\$5.7 million (2022: A\$0.4 million) and foreign exchange gains of A\$2.4 million (2022: A\$1.2 million).

There was an increase of A\$14.1 million in research and development costs, due to higher expenditures in 2023 for the NNZ-2591 Phase 2 clinical trials and the foundational work to prepare for Phase 3 development of NNZ-2591 across multiple indications. There was also an increase in corporate and administrative costs of A\$2.5 million, mainly due to higher employee benefits and share-based payments expense. In addition, a loss of A\$2.2 million on the fair value of outstanding forward contracts to sell Australian dollars and buy US dollars was recognised at 31 December 2023 (2022: A\$0.7 million).

The net income tax expense recognised for the year ended 31 December 2023 was A\$48.1 million (2022: nil). After utilising Australian carried forward tax losses and the expectation of offsetting the 5% withholding tax paid to the US Internal Revenue Service in relation to the milestone payments, Neuren has recognised a current tax liability of A\$37.1 million.

Total cash and short-term investments at 31 December 2023 were A\$228.5 million (2022: A\$40.2 million). Net cash received from operating activities was A\$184.9 million (2022: A\$3.6 million). The increase of \$181.3 million was primarily due to the receipt of \$221.0 million (2022: A\$15.9 million) from Acadia for the first commercial sale milestone payment of US\$40 million, the up-front payment of US\$100 million under the expanded global licence agreement for trofinetide and receipt of quarterly royalty payments. This was offset by higher payments to other suppliers of A\$24.6 million (2022: A\$11.3 million) due to higher expenditures for the NNZ-2591 Phase 2 clinical trials and the foundational work to prepare for Phase 3 development of NNZ-2591 across multiple indications. Withholding tax of A\$11.8 million was paid to the US Internal Revenue Service by Acadia on Neuren's behalf. This will be offset against Neuren's Australian tax liability. Net cash from financing activities for 31 December 2023 was A\$3.6 million (2022: nil), comprising proceeds received on conversion of loan funded shares and exercise of share options.

Following the receipt of the first commercial sale milestone, up-front payment under the expanded global licence agreement for trofinetide and quarterly royalty payments, Neuren is holding more funds than are required to meet currently forecast short-term cash commitments. As a result, Neuren has classified A\$211.4 million of short-term deposits as Short-term Investments.

## 14.1 Earnings per security

	31 December 2023 \$	31 December 2022 \$
Basic earnings per share	\$1.236	\$0.001
Diluted earnings per share	\$1.201	\$0.001

# **14.2** Returns to shareholders including distributions and buy backs Not applicable.

#### 15. Audit Status

This report is based upon the attached audited financial statements for the year ended 31 December 2023.

Financial Report for the year ended 31 December 2023

# **Consolidated Statement of Comprehensive Income**

for the year ended 31 December 2023

	Note	2023 \$'000	2022 \$'000
Revenue from contracts with customers	4	231,925	14,553
Other income	4	8,138	2,480
Total income	-	240,063	17,033
Research and development costs		(26,751)	(12,712)
Corporate and administrative costs		(5,946)	(3,437)
Loss on financial derivatives measured at fair value through profit or loss		(2,226)	(700)
Profit before income tax		205,140	184
Income tax	6	(48,059)	-
Profit after income tax		157,081	184
Amounts which may be subsequently reclassified to profit or loss: Exchange differences on translation of foreign operations		(10)	2
Total comprehensive income for the year		157,071	186
Profit after tax attributable to Equity holders of the Company:		157,081	184
Total comprehensive income attributable to Equity holders		157,071	186
of the Company:		107,071	100
Basic earnings per share	7	\$1.236	\$0.001
Diluted earnings per share	7	\$1.201	\$0.001

The notes on pages 6 to 21 form part of these consolidated financial statements

# **Consolidated Statement of Financial Position**

as at 31 December 2023

		2023	2022
	Note	\$'000	\$'000
ASSETS			
Current Assets:			
Cash and cash equivalents	8	17,094	40,180
Short-term investments	9	211,445	-
Trade and other receivables	10	18,617	3,066
Total current assets	_	247,156	43,246
Non-current assets:			
Property, plant and equipment		43	21
Deferred taxasset	6	771	-
Total non-current assets		814	21
TOTAL ASSETS		247,970	43,267
LIABILITIES AND EQUITY			
Current liabilities:			
Trade and other payables	11	3,418	978
Derivative liabilities	12	2,226	700
Income tax payable	6	37,119	-
Total current liabilities		42,763	1,678
Total liabilities		42,763	1,678
EQUITY			
Share capital	13	173,127	167,740
Share option reserve	13	4,382	3,222
Currency translation reserve		(10,690)	(10,680)
Accumulated surplus/(deficit)		38,388	(118,693)
Total equity attributable to equity holders		205,207	41,589
TOTAL LIABILITIES AND EQUITY		247,970	43,267

The notes on pages 6 to 21 form part of these consolidated financial statements

For and on behalf of the Board of Directors who authorised the issue of these consolidated financial statements on 29 February 2024.

Patrick Davies Non-Executive Chair

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Joe Basile Director

# Consolidated Statement of Changes in Equity for the year ended 31 December 2023

	Share Capital	Share Option Reserve	Currency Translation Reserve	Accumulated Surplus/ (Deficit)	Total Equity
	\$'000	\$'000	\$'000	\$'000	\$'000
Equity as at 1 January 2022	167,578	1,234	(10,682)	(118,877)	39,253
Reversal of share issue costs	162	-	-	-	162
Share based payments	-	1,988	-	-	1,988
Transactions with ow ners	162	1,988	-	-	2,150
Profit after income tax	-	-	-	184	184
Other comprehensive income	-	-	2	-	2
Total Comprehensive income for the year	-	-	2	184	186
Equity as at 31 December 2022	167,740	3,222	(10,680)	(118,693)	41,589
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Share issue costs	(18)	-	-	-	(18)
Loan funded shares converted	1,104	-	-	-	1,104
Transfer on conversion of loan funded shares	420	(420)	-	-	-
Share options exercised	2,533	-	-	-	2,533
Transfer on exercise of options	1,348	(1,348)	-	-	-
Share based payments	-	2,928	-	-	2,928
Transactions with ow ners	5,387	1,160	-	-	6,547
Profit after income tax	-	-	-	157,081	157,081
Other comprehensive loss	-	-	(10)	-	(10)
Total Comprehensive income for the year	-	-	(10)	157,081	157,071
Equity as at 31 December 2023	173,127	4,382	(10,690)	38,388	205,207

The notes on pages 6 to 21 form part of these consolidated financial statements

# **Consolidated Statement of Cash Flows**

for the year ended 31 December 2023

Note2023 \$'0002022 \$'000Cash flows from operating activities: Receipts from licence agreement221,00415,921Withholding tax paid(11,840)-Receipts from Australian R&D Tax Incentive8821,393Interest received4,360188GST refunded272252Payments for employees and directors(5,161)(2,814)Payments to other suppliers(24,592)(11,341)Net cash flow received from operating activities184,9253,599Cash flows from investing activities(211,445)-Purchase of property, plant and equipment(40)(19)Transfer of funds to short-term investments(211,445)-Net cash flow received from/jused tivities(211,445)-Proceeds from the issue of shares133,637-Payment of share issue expenses(18)(2)Net (ash flow received from/jused in) financing activities(145)(181)Cash and cash equivalents at the beginning of the year17,09440,180Cash and cash equivalents at the end of the year17,09440,180Profit after income tax157,081184Non-cash items requiring adjustment:2,9281,988Poreigi exchange loss136184Loss on financial assets1,526700Changes in working capital:1710Trade and other receivables2,440339Current and deferred taxes36,348-Net cash recei	for the year ended 31 December 2023			
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Payment of share issue expenses(18)(2)Net cash flow received from/(used in) financing activities3,619(2)Net (decrease)/increase in cash(22,941)3,578Effect of exchange rate changes on cash balances(145)(181)Cash and cash equivalents at the beginning of the year40,18036,783Cash and cash equivalents at the end of the year17,09440,180Reconciliation with profit after income tax:157,081184Non-cash items requiring adjustment:1710Depreciation of property, plant and equipment1710Share based payments expense2,9281,988Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital:(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-	Cash flows from financing activities:	-		<u> </u>
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Effect of exchange rate changes on cash balances(145)(181)Cash and cash equivalents at the beginning of the year40,18036,783Cash and cash equivalents at the end of the year17,09440,180Reconciliation with profit after income tax:157,081184Profit after income tax157,081184Non-cash items requiring adjustment:1710Depreciation of property, plant and equipment1710Share based payments expense2,9281,988Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital:(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-	activities	-	3,019	(2)
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Cash and cash equivalents at the end of the year17,09440,180Reconciliation with profit after income tax: Profit after income taxProfit after income tax157,081184Non-cash items requiring adjustment: Depreciation of property, plant and equipment1710Share based payments expense2,9281,988Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital: Trade and other receivables(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-	Effect of exchange rate changes on cash balances		(145)	(181)
Reconciliation with profit after income tax:Profit after income tax157,081Profit after income tax157,081Non-cash items requiring adjustment:Depreciation of property, plant and equipment17Depreciation of property, plant and equipment17Share based payments expense2,9281,988Foreign exchange loss136Loss on financial assets1,526700Changes in working capital:Trade and other receivables(15,551)1942,440Current and deferred taxes36,348	Cash and cash equivalents at the beginning of the year		40,180	36,783
Profit after income tax157,081184Non-cash items requiring adjustment:110Depreciation of property, plant and equipment1710Share based payments expense2,9281,988Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital:11Trade and other receivables(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-	Cash and cash equivalents at the end of the year	=	17,094	40,180
Profit after income tax157,081184Non-cash items requiring adjustment:110Depreciation of property, plant and equipment1710Share based payments expense2,9281,988Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital:11Trade and other receivables(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-	Reconciliation with profit after income tax:			
Non-cash items requiring adjustment:Depreciation of property, plant and equipment1710Share based payments expense2,9281,988Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital:710194Trade and other receivables2,440339Current and deferred taxes36,348-	-		157,081	184
Share based payments expense2,9281,988Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital:Trade and other receivables(15,551)Trade and other payables2,440339Current and deferred taxes36,348-	Non-cash items requiring adjustment:		,	
Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital:Trade and other receivables(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-	Depreciation of property, plant and equipment		17	10
Foreign exchange loss136184Loss on financial assets1,526700Changes in working capital:Trade and other receivables(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-	Share based payments expense		2,928	1,988
Changes in working capital:Trade and other receivables(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-			136	184
Trade and other receivables(15,551)194Trade and other payables2,440339Current and deferred taxes36,348-	Loss on financial assets		1,526	700
Trade and other payables2,440339Current and deferred taxes36,348-	Changes in working capital:			
Current and deferred taxes 36,348 -	Trade and other receivables		(15,551)	194
	Trade and other payables			339
Net cash received from operating activities         184,925         3,599		-		-
	Net cash received from operating activities	=	184,925	3,599

The notes on pages 6 to 21 form part of these consolidated financial statements

# Notes to the Consolidated Financial Statements

#### for the year ended 31 December 2023

#### 1. Nature of business

Neuren Pharmaceuticals Limited (Neuren or the Company, and its subsidiaries, or the Group) is a publicly listed biopharmaceutical company developing drugs for neurological disorders.

The Company is a limited liability company incorporated in New Zealand. The address of its registered office in New Zealand is at the offices of Lowndes Jordan, Level 15 HSBC Tower, 188 Quay Street, Auckland 1141. Neuren ordinary shares are listed on the Australian Securities Exchange (ASX code: NEU).

These consolidated financial statements have been approved for issue by the Board of Directors on 29 February 2024.

#### **Material Uncertainties**

- The Group's licensing and research and development activities involve inherent risks. These risks include, among others: dependence on the sales made by licensees, the Group's ability to retain key personnel; the Group's ability to protect its intellectual property and prevent other companies from using the technology; part of the Group's business is based on novel and yet to be proven technology; the Group's ability to sufficiently complete the clinical trials process; and technological developments by the Group's competitors could render its products obsolete.
- The Group's revenue from licence agreements includes quarterly royalty income contingent on the amount of ongoing sales, whilst other milestone payments are contingent on future sales and events and will be intermittent. The business plan therefore may require expenditure in excess of revenue and in the future the Group may need to raise further financing through other public or private equity financings, collaborations or other arrangements with corporate sources, or other sources of financing to fund operations. There can be no assurance that such additional financing, if available, can be obtained on terms reasonable to the Group.

#### 2. Summary of material accounting policies

These general-purpose consolidated financial statements of the Group are for the year ended 31 December 2023 and have been prepared in accordance with and comply with generally accepted accounting practice in New Zealand (GAAP), New Zealand equivalents to International Financial Reporting Standards (NZ IFRS) issued by the New Zealand Accounting Standards Board which comply with International Financial Reporting Standards, the requirements of the Financial Markets Conduct Act 2013, and other applicable Financial Reporting Standards as appropriate for profit-oriented entities that fall into Tier 1 as determined by the New Zealand External Reporting Board.

#### (a) Basis of preparation

#### Entities Reporting

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of the Group as at 31 December 2023 and the results of all subsidiaries for the year then ended. Neuren Pharmaceuticals Limited and its subsidiaries, which are designated as profit-oriented entities for financial reporting purposes, together are referred to in these financial statements as the Group.

#### Statutory Base

Neuren is registered under the New Zealand Companies Act 1993. Neuren is also registered as a foreign company under the Australian Corporations Act 2001.

#### Historical cost convention

These consolidated financial statements have been prepared under the historical cost convention as modified by certain policies below. Amounts are expressed in Australian Dollars and are rounded to the nearest thousand, except for earnings per share.

#### Critical accounting estimates

The preparation of financial statements requires the use of certain critical accounting estimates. It also requires the Group to exercise its judgement in the process of applying the Group's accounting policies. Actual results may differ from those estimates. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements are disclosed in note 19.

#### Going concern basis

The directors monitor the Group's cash position and initiatives to ensure that adequate funding continues to be available for the Group to meet its business objectives. The Group recorded a profit after tax of \$157.0 million for the year ending 31 December 2023 and had positive operating cash flows of \$184.9 million for the year ended 31 December 2023. The Group had cash of \$17.1 million and short-term investments (term deposits) of \$211.5 million at 31 December 2023.

It is the considered view of the Directors that the Group will have access to adequate resources to meet its ongoing obligations for at least a period of 12 months from the date of signing these financial statements. On this basis, the Directors have assessed it is appropriate to adopt the going concern basis in preparing its consolidated financial statements. The consolidated financial statements do not include any adjustments that would result if the Group was unable to continue as a going concern.

#### Changes in accounting policies

There are no changes in accounting policies for the year ended 31 December 2023.

#### Standards, interpretations and amendments to published standards that are not yet effective

At the date of authorisation of these consolidated financial statements, several new, but not yet effective, Standards and amendments to existing Standards, and Interpretations have been published by the IASB. None of these Standards or amendments to existing Standards have been adopted early by the Group. Management anticipates that all relevant pronouncements will be adopted for the first period beginning on or after the effective date of the pronouncement. New Standards, amendments and Interpretations not adopted in the current year have not been disclosed as they are not expected to have a material impact on the Group's consolidated financial statements.

#### (b) Principles of Consolidation

#### Subsidiaries

Subsidiaries are all entities (including structured entities) over which the group has control. The group controls an entity when the group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the group. They are deconsolidated from the date that control ceases.

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. When necessary, amounts reported by subsidiaries have been adjusted to conform with the group's accounting policies.

#### (c) Foreign Currency Translation

#### (i) Functional and Presentation Currency

The functional currency of the Company and the presentation currency of the Group is Australian Dollars.

#### (ii) Transactions and Balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the Statement of Comprehensive Income, except when deferred in equity as qualifying net investment hedges.

#### (iii) Foreign Operations

The results and financial position of foreign entities (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each Statement of Financial Position presented are translated at the closing rate at the date of that statement of financial position;
- revenue and expenses for each Statement of Comprehensive Income are translated at average exchange rates; and
- all resulting exchange differences are recognised as a separate component of equity.

Exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other currency instruments designated as hedges of such investments, are taken to a separate component of equity.

Goodwill and fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the closing rate.

#### (d) Revenue

NZ IFRS 15 establishes a five-step model to account for revenue arising from contracts with customers and requires that revenue be recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer. The five-step process is as follows:

- identify the contract(s) with a customer;
- identify the performance obligations in the contract(s);
- determine the transaction price;
- allocate the transaction price to the performance obligations in the contract(s); and
- recognise revenue when (or as) the performance obligations are satisfied.

#### Licence revenue

Licence revenues in connection with licensing of the Group's intellectual property to customers are recognised as a right to use the entity's intellectual property as it exists at the point in time at which the licence is granted. This is because the contracts for the licence of intellectual property are distinct and do not require, nor does the customer reasonably expect, that the Group will undertake further activities that significantly affect the intellectual property to which the customer has rights.

Although the Group is entitled to sales-based royalties from sales of goods and services to third parties using the intellectual property transferred, these royalty arrangements do not of themselves indicate that the customer would reasonably expect the Group to undertake such activities, and no such activities are undertaken or contracted in practice. Accordingly, the promise to provide rights to the Group's intellectual property is accounted for as a performance obligation satisfied at a point in time.

The following consideration is received in exchange for licences of intellectual property:

(i) Up-front payments - These are fixed amounts and are recognised at the point in time when the Group transfers the intellectual property to the customer.

(ii) Milestone payments – This is variable consideration that is contingent on the customer reaching certain clinical, regulatory or commercial targets in relation to the intellectual property licenced. Variable consideration is estimated using the most likely amount method, variable consideration is constrained such that amounts are only recognised when it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur when the uncertainty associated with the variable consideration (that is, the customer meeting the conditions) is subsequently resolved. Milestone payments that are not in control of the Group, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received.

(iii) Sales-based royalties – Licenses of intellectual property include royalties, which are variable consideration that are based on the sale of products that are produced using the intellectual property. The specific exception to the general requirements of estimating variable consideration for sales or usage-based royalties promised in a licence of intellectual property is applied. The exception requires such revenue to be recognised at the later of when (a) subsequent sales or usage occurs and (b) the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated is satisfied (or partially satisfied).

#### Grants

Grant income is recognised in profit or loss within the Statement of Comprehensive Income over the periods in which the related costs for which the grants are intended to compensate are recognised as expenses and when there is reasonable assurance that the grant will be received and all attached conditions will be complied with.

#### Research and development tax incentives

Other income from the Australian government Research and Development tax incentive (RDTI) program is recognised when there is reasonable assurance that the tax incentive will be received and all attached conditions will be complied with. The research and development activities and expenditure are assessed to determine eligibility under the RDTI program. When Group revenue exceeds the threshold of aggregated turnover of \$20 million or more, a non-refundable tax offset can be claimed. This is recognised as a reduction in current tax liability.

#### Interest income

Interest income is recognised as it is earned using the effective interest method.

#### (e) Research and development

Research costs include direct and directly attributable overhead expenses for drug discovery, research and pre-clinical and clinical trials. Research costs are expensed as incurred.

#### (f) Income tax

The income tax expense or benefit for the period is the tax payable on the period's taxable income or loss using tax rates enacted or substantively enacted at the reporting date, adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and unused tax losses.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to apply when the assets are realised or liabilities are settled, based on those tax rates which are enacted or substantively enacted at the reporting date. The relevant tax rates are applied to the cumulative amounts of deductible and taxable temporary differences to measure the deferred tax asset or liability. An exception is made for certain temporary differences arising from the initial recognition of an asset or a liability in a transaction, other than a business combination, that at the time of the transaction did not affect either accounting profit or taxable profit or loss.

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if it is probable that the temporary differences will reverse in the foreseeable future and future taxable amounts will be available to utilise those temporary differences and losses.

Current and deferred tax balances attributable to amounts recognised directly in equity are also recognised directly in equity.

#### (g) Goods and services tax (GST)

The financial statements have been prepared so that all components are presented exclusive of GST. All items in the statement of financial position are presented net of GST, with the exception of receivables and payables, which include GST invoiced.

#### (h) Cash and cash equivalents

Cash and cash equivalents comprises cash and demand deposits held with established financial institutions and highly liquid investments, which have maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value. Cash and cash equivalents are held to meet currently forecast short-term cash commitments.

#### (i) Short-term investments

Short-term investments comprise short-term deposits, which have maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value. When the Group is holding more short-term deposits than are required to meet currently forecast short-term cash commitments, these are held as short-term investments.

#### (j) Trade and other receivables

The Group makes use of a simplified approach in accounting for trade and other receivables and records the loss allowance as lifetime expected credit losses. These are the expected shortfalls in contractual cash flows, considering the potential for default at any point during the life of the financial instrument. In calculating, the Group assesses trade receivables on an individual basis, and uses its historical experience, external indicators and forward-looking information to calculate the expected credit losses.

#### (k) Employee benefits

#### Wages and salaries, annual leave, long service leave and superannuation

Liabilities for wages and salaries, bonuses, annual leave, long service leave and superannuation expected to be settled within 12 months of the reporting date are recognised in accrued liabilities in respect of employees' services up to the reporting date and are measured at the amounts expected to be paid when the liabilities are settled. Liabilities for non-accumulating personal leave are recognised when the leave is taken and measured at the rates paid or payable.

Contributions are made by the Group to employee superannuation funds and are charged as expenses when the obligation to pay them arises.

#### Share-based payments

Neuren operates a loan funded share plan and share option plan. Both plans are accounted for as share options and the loan is not recognised as an asset. The fair value of the services received in exchange for the grant of the options or shares is recognised as an expense with a corresponding increase in the share option reserve over the vesting period. The total amount to be expensed over the vesting period is determined by reference to the fair value of the options or shares at grant date. At each reporting date, except for options that are subject to a market condition for vesting, the Company revises its estimates of the number of options that are expected to vest. It recognises the impact of these revisions, if any, in the Statement of Comprehensive Income, and a corresponding adjustment to equity over the remaining vesting period.

When options are exercised, the proceeds received net of any directly attributable transaction costs are credited to share capital.

#### (I) Share issue costs

Costs associated with the issue of new shares which are recognised in shareholders' equity are treated as a reduction of the amount collected per share.

#### (m) Financial instruments

#### Recognition and derecognition

Financial assets and financial liabilities are recognised when the Group becomes a party to the contractual provisions of the financial instrument.

Financial assets are derecognised when the contractual rights to the cash flows from the financial asset expire, or when the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risks and rewards of ownership.

When it has neither transferred nor retained substantially all of the risks and rewards of the asset, nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of its continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

A financial liability is derecognised when it is extinguished, i.e. the obligation is discharged, cancelled or expired.

#### Classification and initial measurement of financial assets

Except for those trade receivables that do not contain a significant financing component and are measured at the transaction price in accordance with NZ IFRS 15 'Revenue from contracts with customers', all financial assets are initially measured at fair value adjusted for transaction costs (where applicable).

Financial assets, other than those designated and effective as hedging instruments, are classified into the following categories:

amortised cost

• fair value through profit or loss (FVTPL)

• fair value through other comprehensive income (FVOCI).

In the periods presented the company does not have any financial assets categorised as FVTPL or FVOCI.

The classification is determined by both:

- the entity's business model for managing the financial asset
- the contractual cash flow characteristics of the financial asset.

All income and expenses relating to financial assets that are recognised in profit or loss are presented within finance cost or finance income, except for impairment of trade receivables which is presented within other expenses.

#### Subsequent measurement of financial assets

#### Financial assets at amortised cost

Financial assets are measured at amortised cost if the assets meet the following conditions (and are not designated as FVTPL):

• they are held within a business model whose objective is to hold the financial assets and collect its contractual cash flows

• the contractual terms of the financial assets give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding.

After initial recognition, these are measured at amortised cost using the effective interest method. Discounting is omitted where the effect of discounting is immaterial. The Group's cash and cash equivalents, short-term investments and trade receivables fall into this category of financial instruments.

#### Classification and measurement of financial liabilities

The Group's financial liabilities include trade and other payables and derivative financial liabilities. Financial liabilities are initially measured at fair value, and, where applicable, adjusted for transaction costs.

Subsequently, trade and other payables are measured at amortised cost using the effective interest method.

Derivative financial instruments are initially recognised at fair value on the date on which a derivative contract is entered into and subsequently remeasured at fair value. Derivatives are carried as financial assets when the fair value is positive and as financial liabilities when the fair value is negative. Gains or losses on derivative financial instruments are recognised in the profit or loss.

#### 3. Segment information

The segment reporting reflects the way information is reported internally to the chief operating decision maker. The Board of the Group has been identified as the chief operating decision maker. The Board assesses the financial performance and position of the group and makes strategic decisions. The Group has two reportable operating segments, commercial products and research and development.

Reportable segment	Principal activities
Commercial products	Milestone and royalty revenue from licence of intellectual property.
Research & development	Development of pharmaceutical products for the treatment of neurodevelopmental disorders.

	Commercial products		Research & Development		Corporate		Total	
	2023 \$'000	2022 \$'000	2023 \$'000	2022 \$'000	2023 \$'000	2022 \$'000	2023 \$'000	2022 \$'000
Revenue	231,925	14,553	-	-	-	-	231,925	14,553
Total segment revenue	231,925	14,553	-	-	-	-	231,925	14,553
Research and								
development costs	(66)	(453)	(26,685)	(12,259)	-	-	(26,751)	(12,712)
Interest income	-	-	-	-	5,687	391	5,687	391
Other income	-	-	-	-	2,451	2,089	2,451	2,089
Other expenses	-	-	-	-	(8,172)	(4,137)	(8,172)	(4,137)
Profit before income tax	231,858	14,100	(26,685)	(12,259)	(34)	(1,657)	205,140	184
ncome tax expense	_	-	_	-	(48,059)	-	(48,059)	-
Profit after income tax	231,858	14,100	(26,685)	(12,259)	(48,093)	(1,657)	157,081	184

All revenue from licences of intellectual property is from Acadia Pharmaceuticals Inc. (Acadia) and is from the United States.

Assets and liabilities are not allocated to segments and are therefore not reported.

#### 4. Revenue

Disaggregation of revenue from contracts with customers

The Group derives revenue from the sale and transfer of goods and services at a point in time under the following major business activities:

	2023	2022
	\$'000	\$'000
Revenue from contracts with customers		
Licences of intellectual property - up-front payments	145,711	-
Licences of intellectual property - milestone payments	59,434	14,553
Licences of intellectual property - royalty income	26,780	-
	231,925	14,553

All revenue from licences of intellectual property is from the United States. The revenue from licences of intellectual property was earned by Neuren on the first commercial sale of DAYBUE by Acadia in the United States, and on signing the expanded worldwide licence agreement with Acadia.

Neuren is eligible to receive quarterly royalty income, calculated as a percentage of net sales of DAYBUE in North America and is recognised in the period Acadia makes the sales of DAYBUE. Sales of DAYBUE commenced in April 2023. The royalty rate for annual sales of less than or equal to US\$250 million is 10%. The royalty rate then increases to 12% for annual net sales greater than US\$250 million but less than or equal to US\$500 million.

Other income		
Interest income	5,687	391
Australian R&D tax incentive	17	864
Net foreign currency gains	2,434	1,225
Total other income	8,138	2,480
5. Expenses		
	2023	2022
	\$'000	\$'000
Profit/(loss) before income tax includes the following expenses:		
Remuneration of auditors		
Audit of financial statements (Grant Thornton New Zealand Audit	70	50
Limited)	76	58
Review of financial statements (Grant Thornton New Zealand	00	10
Audit Limited)	23	12
Total remuneration of auditors	99	70
Employee benefits expense Short-term benefits	2,970	1,607
Post-employment benefits	2,970	1,007
Other employee benefits	39	34
Share based payments	1.388	868
Total employee benefits expenses	4,608	2,662
	.,	_,
Directors' compensation		
Short-term benefits	1,444	732
Post-employment benefits	43	38
Share based payments	289	126
Total Directors' compensation	1,777	896
Other		
Consultants - share based payments	1,251	994
	-,	551

6. Income tax

	2023	2022
	\$'000	\$'000
Income tax expense		
Current tax expense	48,102	-
Deferred tax benefit	(771)	-
Adjustment <sup>1</sup>	728	-
	48,059	-
Numerical reconciliation of income tax to prima facie tax receivable:		
Profit before income tax	205,140	184
Tax at applicable rates $30.0\% (2022: 25.0\%)^2$	61,542	46
Research and development incentives	(324)	281
Non-deductible share option expenses	879	497
Other non-deductible expenses/(non-assessable income)	99	122
Utilisation of previously unrecognised tax losses	(13,905)	(946)
Change in tax rates	(138)	-
Recognition of deferred tax asset for deductible temporary differences	(689)	-
Adjustment <sup>1</sup>	728	-
Difference in overseas tax rates	(133)	-
Income tax expense	48,059	-
Current tax		
Current tax liabilities		
Opening balance	-	-
Income tax	48,102	-
Witholding tax credits	(10,983)	-
	37,119	-

<sup>1</sup>The adjustment to tax expense relates to the utilisation of a foreign income tax offset rather than previously unrecognised tax losses in relation to the prior year income tax return.

<sup>2</sup>The tax rate of the Group changed from the base rate of 25.0% to the full company tax rate of 30.0% effective 1 January 2023. Neuren is not a base rate entity for the year ended 31 December 2023 as its aggregated turnover for the year is greater than the aggregated turnover threshold of \$50 million.

#### **Deferred tax**

2023	Opening balance \$'000	Recognised in profit or loss \$'000	Closing balance \$'000
Patents	(183)	(14)	(197)
Capital raising costs	(276)	77	(199)
Employee benefits	(92)	(47)	(139)
Unrealised foreign exchange	(177)	(491)	(668)
Interest receivable	51	408	459
Other temporary differences	(14)	(13)	(27)
	(691)	(80)	(771)
Deferred tax not recognised	691	(691)	-
Net deferred tax asset	-	(771)	(771)

	Opening balance	Recognised in profit or loss	Closing balance
2022	\$'000	\$'000	\$'000
Patents	(217)	34	(183)
Capital raising costs	(403)	127	(276)
Employee benefits	(76)	(16)	(92)
Unrealised foreign exchange	-	(177)	(177)
Other temporary differences	(10)	47	37
	(706)	15	(691)
Deferred tax not recognised	706	(15)	691
Net deferred tax asset		-	-

		2023	2022
		\$'000	\$'000
Gross tax losses for which no deferred tax asset has been recognised	(a)	62,475	106,115

(a) Of these gross tax losses, \$62.5 million (2022: \$62.6 million) relate to New Zealand tax losses, which are unlikely to be utilised unless future taxable income is generated in New Zealand. The movement in New Zealand gross tax losses is due to the New Zealand tax losses being translated at the closing foreign exchange rate at each reporting date. All previously unrecognised Australian tax losses have been utilised for the year ended 31 December 2023.

There are no franking credits or imputation credits available for use as at 31 December 2023 (2022: nil).

#### 7. Earnings per share

Basic earnings per share is calculated by dividing the profit for the year attributable to the equity holders of the company by the weighted average number of ordinary shares on issue during the year excluding shares held as treasury stock.

Diluted earnings per share is calculated by dividing the profit attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

	2023	2022
Earnings after income tax attributable to equity holders (basic) - (\$'000)	157,081	184
Weighted average shares outstanding (basic) - (No.)	127,069,512	125,965,676
Basic earnings per share	\$1.236	\$0.001
= Earnings after income tax attributable to equity holders	157.081	184
(diluted) - (\$'000)	,	-
Weighted average shares outstanding (diluted) - (No.)	130,768,487	128,908,995
Diluted earnings per share	\$1.201	\$0.001
8. Cash and cash equivalents	0000	
	2023	2022
	\$'000	\$'000
Cash	17,094	2,304
Demand and short-term deposits	-	37,876

40,180

17,094

#### 9. Short-term investments

	2023	2022
	\$'000	\$'000
Short-term investments	211,445	-

Following the receipt of the first commercial sale milestone payment and the upfront payment for the expansion of the partnership with Acadia Pharmaceuticals for trofinetide to a worldwide exclusive licence, Neuren is holding more funds than are required to meet currently forecast short-term cash commitments. As a result, the Company has classified short-term deposits as short-term investments.

#### 10. Trade and other receivables

	2023	
	\$'000	\$'000
Royalty receivable	12,800	-
Other receivables	80	17
Interest receivables	1,532	207
Prepayments	4,205	1,977
Australian R&D tax incentive	-	865
	18,617	3,066

The Group has not recognised any amounts receivable in relation to the R&D tax incentive for the year ended 31 December 2023, as a result of revenue exceeding the threshold of \$20,000,000 in the financial year. As a result of exceeding this threshold, eligible R&D expenditure qualifies for a non-refundable tax offset and is recognised as a reduction in current tax liability.

In 2022 the R&D tax incentive receivable was determined based on a combination of eligible domestic and international expenditure of \$1,988,057 at a rate of 43.5 cents tax incentive rebate per eligible R&D dollar spent. This amount was received in cash during the financial year.

The Group applies the simplified model of recognising lifetime expected credit losses for all trade receivables as these items do not have a significant financing component.

In measuring the expected credit losses, the trade receivables have been assessed on an individual basis due to the limited number of receivables.

The expected loss rates are based on the payment profile of the individual receivable including historical experience, external indicators and forward-looking information to calculate the expected credit losses.

Trade receivables are written off (i.e. de-recognised) when there is no reasonable expectation of recovery. Failure to make payments within 180 days from the invoice date and failure to engage with the Group on alternative payment arrangements amongst others are considered indicators of no reasonable expectation of recovery. No credit losses have been determined for the current year (2022: nil).

#### 11. Trade and other payables

	2023	2022
	\$'000	\$'000
Trade payables	675	258
Accruals	2,174	267
Employee benefits	569	453
	3,418	978

Trade payables and accruals relate to operating expenses, primarily research and development expenses. Trade payables comprise amounts invoiced prior to the reporting date and accruals comprise the value of goods or services received but not invoiced at each reporting date.

#### 12. Derivatives

	2023	2022	
	\$'000	\$'000	
Current derivative liabilities			
Forward exchange contracts	2,226	700	

#### 13. Share capital

2023 Shares	2022 Sharos	2023 \$'000	2022 \$'000
Onares	Onares	<del>000</del>	<i>\</i>
128,965,676	128,965,676	167,740	167,578
-	-	1,524	-
700,000	-	3,881	-
-	-	(18)	162
129,665,676	128,965,676	173,127	167,740
	Shares 128,965,676 - 700,000 -	Shares         Shares           128,965,676         128,965,676           -         -           700,000         -           -         -	Shares         Shares         \$'000           128,965,676         128,965,676         167,740           -         -         1,524           700,000         -         3,881           -         -         (18)

At 31 December 2023 127,265,676 ordinary shares are quoted on the ASX, and 2,400,000 unquoted ordinary shares (31 December 2022: 3,000,000 ordinary shares) were held as treasury stock in respect of the Loan Funded Share Plan described below.

#### Ordinary shares

The ordinary shares have no par value and all ordinary shares are fully paid-up and rank equally as to dividends and liquidation, with one vote attached to each fully paid ordinary share.

#### Share based payments

During the year ended 31 December 2023 \$2.9 million (31 December 2022: \$2.0 million) was recognised in sharebased payments expense.

#### Loan funded shares

The Company has a Loan Funded Share Plan to support the achievement of the Company's business strategy by linking executive reward to improvements in the financial performance of the Company and aligning the interests of executives with shareholders. Under the Loan Funded Share Plan, loan funded shares may be offered to employees or consultants ("Participants"). The Company issues new ordinary shares, which are placed in a trust to hold the shares on behalf of the Participant. The trustee issues a limited-recourse, interest-free loan to the participant, which is equal to the number of shares multiplied by the issue price. A limited-recourse loan means that the repayment amount will be the lesser of the outstanding loan and the market value of the shares that are subject to the loan. The trustee continues to hold the shares on behalf of the Participant until all vesting conditions have been satisfied and the Participant chooses to settle the loan, at which point ownership of the shares is transferred from the trust to the Participant. Any dividends paid by the Company while the shares are held by the trust are applied as repayment of the loan at the after-tax value of the dividend. On request by the participant, the Company may dispose of, or buy back, vested shares and utilise the proceeds to settle the outstanding loan. The directors may apply vesting conditions to be satisfied before the shares can be transferred to the Participant. Before the loan can be given, the New Zealand Companies Act requires the Company to disclose to shareholders the provision of financial assistance to the Participant. The maximum loan term is 5 years.

All loan funded shares under the plan during the year ended 31 December 2023 are subject to the following vesting conditions:

- i. 40% of the Loan Funded Shares shall vest on acceptance by the US Food and Drug Administration of the filing of a New Drug Application for Trofinetide; and
- ii. 40% of the Loan Funded Shares shall vest when the Company determines to progress NNZ-2591 to a Phase 2b or Phase 3 clinical trial following a positive Phase 2 clinical trial outcome, or executes a partnering transaction for NNZ-2591;
- iii. 20% of the Loan Funded Shares shall vest when the Company executes a partnering transaction for trofinetide outside North America, or submits a Marketing Authorisation Application for trofinetide in the European Union, the United Kingdom, or Japan.

Each of these vesting conditions shall be tested separately from the other vesting conditions. The first vesting condition (i) was met in September 2022 and the third vesting condition (iii) was met in July 2023.

The estimated fair value of the shares has been determined using the Black-Scholes valuation model. The significant inputs into the model were the share price on date of valuation, the estimated future volatility of the share price, a dividend yield of 0%, an expected life of 5 years, and an annual risk-free interest rate of 0.4%. The estimated future volatility of the share price was derived by analysing the historic volatility of the share price during the relevant period.

Movements in the number of Loan Funded Shares were as follows:

	2023 Number '000	2023 \$ WAEP <sup>1</sup>	2022 Number '000	2022 \$ WAEP <sup>1</sup>
Balance at 1 January	3,000	1.84	3,000	1.84
Granted during the year	-	-	-	-
Exercised during the year	(600)	1.84	-	-
Balance at 31 December	2,400	1.84	3,000	1.84
Vested and exercisable at 31 December	1,200	1.84	1,200	1.84

<sup>1</sup>WAEP – weighted average exercise price

#### Options to acquire ordinary shares

All options to acquire ordinary shares at 31 December 2023 vest subject to remaining an employee or consultant if and when the following non-market performance vesting conditions are met:

		950,000 share options	500,000 share options	750,000 share options
i.	on acceptance by the US Food and Drug Administration of the filing of a New Drug Application for trofinetide	-	40%	-
ii.	when the Company determines to progress NNZ-2591 to a Phase 2b or Phase 3 clinical trial following a positive Phase 2 clinical trial outcome, or executes a partnering transaction for NNZ-2591	60%	40%	60%
iii.	when the Company executes a partnering transaction for trofinetide outside North America, or submits a Marketing Authorisation Application for trofinetide in the European Union, the United Kingdom, or Japan	40%	20%	40%

Each of these vesting conditions shall be tested separately from the other vesting conditions. The first vesting condition (i) was met in September 2022 and the third vesting condition (iii) was met in July 2023.

The estimated fair value of the options to acquire ordinary shares has been determined using the Black-Scholes valuation model. The significant inputs into the model were the share price on date of valuation, the estimated future volatility of the share price, the risk-free interest rate, a dividend yield of 0% and an expected life of 2.75 years. The estimated future volatility of the share price was derived by analysing the historic volatility of the share price on a daily basis during the two years prior to the issue date, as this period is reflective of the anticipated volatility in the future.

Movements in the number of Share Options were as follows:

	2023 Number '000	2023 \$ WAEP <sup>1</sup>	2022 Number '000	2022 \$ WAEP <sup>1</sup>
Balance at 1 January	2,200	3.59	-	-
Granted during the year	-	-	2,200	3.59
Exercised during the year	(700)	3.62	-	
Balance at 31 December	1,500	3.57	2,200	3.59
Vested and exercisable at 31 December	280	3.46	200	3.46

<sup>1</sup>WAEP – weighted average exercise price

During the year ended 31 December 2023, no additional options to acquire ordinary shares were issued to employees and consultants.

#### 14. Subsidiaries

#### (a) Investment in subsidiaries

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiaries in accordance with the accounting policy described in note 2(b).

Name of entity	Date of incorporation	Principle activities	Interest held Domicile	
Neuren Pharmaceuticals Inc.	20-Aug-02	Development services	100%	USA
Neuren Pharmaceuticals (Australia) Pty Ltd	9-Nov-06	Dormant	100%	AUS
Neuren Trustee Limited	29-May-13	Holds loan funded shares	100%	NZ

All subsidiaries have a reporting date of 31 December.

#### 15. Commitments and contingencies

#### (a) Legal claims

The Group had no significant legal matter contingencies as at 31 December 2023 or at 31 December 2022.

#### (b) Commitments

The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 31 December 2023 (2022: nil).

At 31 December 2023, the Group had commitments under product development contracts amounting to approximately \$7.4 million, including approximately US\$4.4 million and AU\$0.4 million. At 31 December 2022, the Group had commitments under product development contracts amounting to approximately \$6.0 million, comprising approximately US\$3.9 million, GBP 0.1 million, EUR 0.1 million and AU \$0.2 million.

#### (c) Contingent liabilities

The Group had no contingent liabilities at 31 December 2023 or at 31 December 2022.

#### 16. Related party transactions

#### (a) Key Management Personnel

The Key Management Personnel of the Group (KMP) include the directors of the Company and employees who reporting directly to the Managing Director. Compensation for KMP was as follows:

	2023	2022
	\$'000	\$'000
Short-term benefits	3,266	1,682
Post-employment benefits	169	112
Other long-term benefits	74	34
Share based payment compensation	1,446	837
	4,955	2,665

#### (b) Subsidiaries

The ultimate parent company in the Group is Neuren Pharmaceuticals Limited ("Parent"). The Parent funds the activities of the subsidiaries throughout the year as needed. All amounts due between entities are payable on demand and bear no interest.

#### 17. Events after reporting date

As at the date of these consolidated financial statements authorised for issue, there are no events arising since 31 December 2023 that require disclosure.

#### 18. Financial instruments and risk management

#### (a) Categories of financial instruments

		At amortised cost		At fair value through profit or loss	
2023		Floating Interest Rate \$'000	Non-Interest Bearing \$'000	Non-Interest Bearing \$'000	Total \$'000
Financial assets	_				
Cash and cash equivalents	8	17,094	-	-	17,094
Short-term investments	9	211,445	-	-	211,445
Trade and other receivables	10	-	14,332	-	14,332
Total financial assets	=	228,539	14,332	-	242,871
Financial liabilities					
Trade and other payables	11	-	2,849	-	2,849
Derivative financial instruments - forw ard exchange contracts	12	-	-	2,226	2,226
C C	_	-	2,849	2,226	5,075
2022 Financial assets	=				
Cash and cash equivalents	8	40,180	_	_	40,180
Trade and other receivables	10	40,100	207	-	40,100
Total financial assets	=	40,180	207	-	40,387
Financial liabilities					
Trade and other payables	11	-	525	-	525
Derivative - financial liability	12	-	-	700	700
Total financial liabilities	-	-	525	700	1,225
	-				

At 31 December 2023, the carrying value of all financial instruments approximated their fair value.

#### (b) Risk management

The Group is subject to a number of financial risks which arise as a result of its activities.

#### Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: currency risk, interest rate risk and other price risk.

#### Currency risk

During the normal course of business the Group enters into contracts with overseas customers or suppliers or consultants that are denominated in foreign currency. As a result of these transactions there is exposure to fluctuations in foreign exchange rates. The Company also has a net investment in a foreign operation, whose net assets are exposed to foreign currency translation risk.

The principle currency risk faced by the business is the exchange rate between the Australian dollar and the US dollar. The Group holds cash denominated in US dollars and Australian dollars and has material revenue and expenditure in each of these currencies. Where possible, the Group matches foreign currency income and foreign currency expenditure as a natural hedge, holding foreign currency cash to facilitate this natural hedge. When foreign currency expenditure exceeds foreign currency revenue and foreign currency cash, the group purchases foreign currency to meet anticipated requirements under spot and forward contracts. The Group does not designate formal hedges.

At 31 December 2023, there were three forward contracts to convert Australian dollars to US dollars outstanding. Adjustment of these financial instruments to fair value as measured at 31 December 2023 resulted in a loss of \$2.2 million. This fair value measurement is categorised within Level 2 of the fair value hierarchy. A summary of the forward contracts outstanding at 31 December 2023 is as follows:

	Buy USD \$'000	Sell AUD \$'000	Term	Weighted average exchange rate
Buy US dollar / sell AU dollar	23,611	36,672	3 months or less	0.6439

During the year, the US dollar fluctuated against the Australian dollar. A net foreign exchange gain of \$2.4 million is included in results for the year ended 31 December 2023 (2022: \$1.2 million), this includes a \$1.9 million gain on the milestone revenue from Acadia (2022: \$1.4 million gain).

The carrying amounts of US dollar denominated financial assets and liabilities are as follows:

	2023	2022
	\$'000	\$'000
Assets		
US dollars	168,688	2,104
Liabilities		
US dollars	2,760	803

An increase of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have decreased the consolidated profit after income tax by \$18,418,196 (2022: \$1,238,107). A decrease of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have increased the consolidated profit after income tax by \$22,511,129 (2022: \$1,514,242). An increase of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have decreased equity by \$51,743 (2022: decrease of \$12,419). A decrease of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have increased equity by \$53,242 (2022: increase of \$15,179).

#### Interest rate risk

The Group is exposed to changes in market interest rates as entities in the Group hold cash and cash equivalents and short-term investments.

The effective interest rates on financial assets are as follows:

	2023	2022
Financial Assets	\$'000	\$'000
Cash and cash equivalents		
Australian dollar cash deposits	59,858	38,076
Australian dollar interest rate	4.79%	3.58%
US dollar cash deposits	168,688	2,104
US dollar interest rate	4.67%	-%

The Company and Group do not have any interest-bearing financial liabilities. Trade and other receivables and payables do not bear interest and are not interest rate sensitive.

A 5% change in average market interest rates would have changed reported profit after tax by approximately \$537,400 (2022: \$68,200). A 5% increase/decrease in the average market interest rates would have no impact on other components of equity.

#### Credit risk

The Group incurs credit risk from transactions with financial institutions. The total credit risk on cash and cash equivalents and short-term investments, which have been recognised in the statement of financial position, is the carrying amount. The Company and its subsidiaries do not retain any collateral or security to support transactions with financial institutions. Cash and cash equivalents and short-term are held and transacted with National Australia Bank, Commonwealth Bank, Westpac, Western Union and Primis bank.

#### Liquidity risk

The Group's financial liabilities, comprising trade and other payables and derivatives, are generally repayable within 1 - 3 months. The maturity and availability of financial assets, comprising cash and cash equivalents, short-term investments and trade and other receivables, are monitored and managed to ensure financial liabilities can be repaid when due.

#### Capital management

The Group monitors capital including share capital, retained earnings and reserves and the cash and cash equivalents and short-term investments presented in the consolidated statement of financial position. The Group has no debt. The key objective of the Group when managing its capital is to safeguard its ability to continue as a going concern, so that the Group can sustain the future development of the research and development activities being performed by the Group.

#### 19. Critical accounting estimates and assumptions

The Group makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing material adjustment to the carrying amounts of assets and liabilities within the next financial year are as discussed below.

The Group has assessed that all research and development expenditure to date does not meet the requirements for capitalisation as an intangible asset because it is not yet probable that the expected future economic benefits that are attributable to the asset will flow. The Group's current assessment is that future expenditure will not meet that requirement prior to the approval of a New Drug Application by the US Food and Drug Administration.

The Group is subject to income taxes in Australia because it is domiciled in that country. There are transactions and calculations undertaken during the ordinary course of business for which the ultimate tax determination may be uncertain. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred tax provisions in the period in which such determination is made.

The Group measures the fair value of loan funded shares and options to acquire ordinary shares with employees and consultants by reference to the fair value of the equity instruments at the date at which they are granted. The estimated fair value of the shares is determined using the Black-Scholes valuation model, taking into account the terms and conditions upon which the instruments were granted. Some judgements are made on the inputs into the valuation model, including the expected life and volatility.



# Independent Auditor's Report

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# To the Shareholders of Neuren Pharmaceuticals Limited

# Report on the Audit of the Consolidated Financial Statements

#### Opinion

We have audited the consolidated financial statements of Neuren Pharmaceuticals Limited (the "Company") and its subsidiaries (the "Group") on pages 2 to 21 which comprise the consolidated statement of financial position as at 31 December 2023, and the consolidated statement of comprehensive income, consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including material accounting policy information.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the financial position of the Group as at 31 December 2023 and of its financial performance and cash flows for the year then ended in accordance with New Zealand equivalents to International Financial Reporting Standards ("NZ IFRS") issued by the New Zealand Accounting Standards Board and International Financial Reporting Standards ("IFRS").

#### **Basis for Opinion**

We conducted our audit in accordance with International Standards on Auditing (New Zealand) ("ISAs (NZ)") issued by the New Zealand Auditing and Assurance Standards Board. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Consolidated Financial Statements* section of our report. We are independent of the Group in accordance with Professional and Ethical Standard 1 *International Code of Ethics for Assurance Practitioners (including International Independence Standards) (New Zealand*) issued by the New Zealand Auditing and Assurance Standards) (*New Zealand*) issued by the New Zealand Auditing and Assurance Standards Board and the International Ethics Standards Board for Accountants' *International Code of Ethics for Professional Accountants (including International Independence Standards)* ("IESBA Code"), and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Other than in our capacity as auditor we have no relationship with, or interests in, the Group.

#### **Key Audit Matters**

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements of the current year. We have determined that there are no key audit matters to communicate in our report.

#### Information Other than the Consolidated Financial Statements and Auditor's Report thereon

The Directors are responsible for the other information. The other information comprises the information included in the annual report but does not include the financial statements and our auditor's report thereon. The annual report is expected to be made available to us after the date of this auditor's report.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of audit opinion or assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements, or our knowledge obtained in the audit, or otherwise appears to be materially misstated.



When we read the annual report, if we conclude that there is a material misstatement therein, we are required to communicate the matter to those charged with governance.

#### Directors' responsibilities for the Consolidated Financial Statements

The Directors are responsible on behalf of the Company for the preparation and fair presentation of the consolidated financial statements in accordance with NZ IFRS, and for such internal control as the Directors determine is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the directors are responsible on behalf of the Company for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

#### Auditor's responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (NZ) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

A further description of the auditor's responsibilities for the audit of the consolidated financial statements is located on the External Reporting Board's website at: <u>https://www.xrb.govt.nz/assurance-standards/auditors-responsibilities/audit-report-1/</u>

#### Restriction on use of our report

This report is made solely to the Company's shareholders, as a body. Our audit work has been undertaken so that we might state to the Company's shareholders, as a body, those matters which we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's shareholders, as a body, for our audit work, for this report or for the opinion we have formed.

**Grant Thornton New Zealand Audit Limited** 

Frant Thornton

Ryan Campbell Partner Auckland 29<sup>th</sup> February 2024