

Appendix 4E

Neuren Pharmaceuticals Limited ARBN 111 496 130

Preliminary final report Financial year ended 31 December 2022

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 2022 together with comparative results for the year ended 31 December 2021.

All amounts shown are in Australian dollars unless otherwise stated.

2. Results for announcement to the market

	31 Dec 2022 \$'000	31 Dec 2021 \$'000	% Change
2.1 Revenue from ordinary activities	14,553	-	100%
2.2 Profit/(loss) from ordinary activities after tax attributable to members	184	(7,794)	102%
2.3 Net profit/(loss) for the period attributable to members	184	(7,794)	102%
2.4 Dividends	N/A	N/A	N/A

The Group's profit after tax was \$0.2 million compared with a loss after tax of \$7.8 million in 2021. Revenue of \$14.6 million was received under the licence agreement with Acadia (2021: nil) and foreign exchange gains were \$1.2 million (2021: \$0.4 million). These were offset by an increase of \$3.2 million in research and development costs, due to an increase in expenditures in 2022 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 \$1.5 million, mainly due to share-based payments and employee benefits expense, reflecting some expansion for the NNZ-2591 program. In addition, a loss of \$0.7 million on the fair value of the outstanding forward contracts to sell Australian dollars and buy US dollars was recognised at 31 December 2022.

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 2022 \$	31 December 2021 \$
Net tangible assets per security	\$0.33	\$0.31 ¹

10. Changes in Control Over Entities

Not applicable.

11. Associates and Joint Venture Entities

Not applicable.

12. Significant Information

Refer to attached Financial Statements.

¹ 31 December 2021 Net Tangible Assets per Security has been updated to exclude Treasury Shares

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 December 2021 Neuren's partner for trofinetide in North America, Acadia Pharmaceuticals (Nasdaq: ACAD), announced positive top-line results from the pivotal, Phase 3 Lavender™ study evaluating the efficacy and safety of trofinetide in 187 girls and young women aged 5-20 years with Rett syndrome. The trofinetide program has Orphan Drug, Fast Track and Rare Pediatric Disease designations from the US Food and Drug Administration (FDA). In September 2022 the FDA accepted for review the New Drug Application (NDA) for trofinetide to treat Rett syndrome in adults and pediatric patients two years of age or older, that was submitted in July by Acadia. The FDA granted a Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) action date of 12 March 2023. The FDA also informed Acadia that they were not planning to hold an Advisory Committee meeting. Upon FDA approval of a NDA with Rare Pediatric Disease designation, the sponsor may be eligible to receive a Priority Review Voucher, which can be used to obtain FDA review of a NDA for another product in an expedited period of six months. The voucher may also be sold for use by another company.

Under the terms of the licence agreement with Acadia, the development and commercialisation of trofinetide in North America is fully funded by Acadia and Neuren may receive potential milestone payments of up to US\$455 million, plus tiered escalating double-digit percentage royalties on net sales of trofinetide in North America, plus one third of the market value of a Rare Pediatric Disease Priority Review Voucher if awarded by the FDA upon approval of a NDA for trofinetide. Acceptance of the NDA for review by the FDA earned Neuren a milestone payment of US\$10 million from Acadia, which Neuren received in October 2022.

In 2023, if the NDA is approved by the FDA, Neuren expects to receive revenue a milestone payment of US\$40 million contingent on the first commercial sale of trofinetide in the United States and US\$33 million as Neuren's estimated one third share of the market value of a Priority Review Voucher, contingent on the FDA issuing a Prior Review Voucher upon approval of the NDA and sale of the voucher. Neuren is also eligible to receive royalties on net sales of trofinetide in North America, plus potential sales-related milestone payments of up to US\$350 million.

¹ 31 December 2021 Net Tangible Assets per Security has been updated to exclude Treasury Shares

Under the terms of the licence agreement with Acadia, Neuren retained all rights to trofinetide outside North America and has a fully paid-up, irrevocable licence for use in those countries to all data generated by Acadia. Neuren has received strong interest for potential commercial partnerships and discussions are continuing.

In July and August 2022, Neuren announced the commencement of Phase 2 clinical trials of its second drug candidate NNZ-2591 for Phelan-McDermid syndrome (PMS), Angelman syndrome (AS) and Pitt Hopkins syndrome (PTHS), after receiving in March 2022 approval from the FDA for Investigational New Drug (IND) applications to conduct the trials. In December 2022, Neuren submitted an IND application to the FDA for approval to proceed with a Phase 2 trial in Prader-Willi syndrome (PWS) and received approval from the FDA in January 2023. NNZ-2591 has received Orphan Drug designation from the FDA in all four syndromes.

The open label Phase 2 trials are each enrolling up to 20 children to examine safety, tolerability, pharmacokinetics and efficacy over 13 weeks of treatment with NNZ-2591. In December 2022, Neuren announced that the first subject had completed treatment in the AS trial and in the PMS trial. A series of top-line results announcements from the trials are anticipated, commencing with Phelan-McDermid syndrome in H2 2023. In order to accelerate the overall development plan, in parallel with conducting the Phase 2 trials, Neuren is executing additional development work required 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 2022 was \$0.2 million compared with a loss of \$7.8 million in 2021. Revenue of \$14.6 million was received under the licence agreement with Acadia (2021: nil) and foreign exchange gains were \$1.2 million (2021: \$0.4 million). These were offset by an increase of \$3.2 million in research and development costs, due to higher expenditures in 2022 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 \$1.5 million, mainly due to share-based payments and higher employee benefits expense, reflecting some expansion for the NNZ-2591 program. In addition, a loss of \$0.7 million on the fair value of outstanding forward contracts to sell Australian dollars and buy US dollars was recognised at 31 December 2022. Prudent control of expenditure continues to be an important principle in the Group's operations and financing.

Cash reserves at 31 December 2022 were \$40.2 million (2021: \$36.8 million). Net cash received from operating activities was \$3.6 million, compared with net cash used in operating activities of \$10.0 million in 2021. The increase of \$13.6 million was due to the receipt of the first milestone payment from Acadia of \$15.9 million (2021: nil), offset by higher payments for employees and directors of \$2.8 million (2021: \$1.8 million) and a lower receipt under the R&D Tax Incentive program of \$1.4 million (2021: \$2.5 million). Net cash from financing activities for 31 December 2022 was nil, compared with \$22.2 million in 2021, which was received for the issue of new ordinary shares in a share placement and share purchase plan.

14.1 Earnings per security

	31 December 2022 \$	31 December 2021 \$
Basic earnings/(loss) per share	\$0.001	(\$0.066)
Diluted earnings/(loss) per share	\$0.001	(\$0.066)

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 2022.

Neuren Pharmaceuticals Limited

Financial Report for the year ended 31 December 2022

Neuren Pharmaceuticals Limited

Consolidated Statement of Comprehensive Income

for the year ended 31 December 2022

	Note	2022 \$'000	2021 \$'000
Revenue from contracts with customers	4	14,553	-
Other income	4	2,480	3,636
Total income		17,033	3,636
Research and development costs		(12,712)	(9,516)
Corporate and administrative costs		(3,437)	(1,914)
Loss on financial derivatives measured at fair value through profit or loss		(700)	-
Profit/(loss) before income tax		184	(7,794)
Income tax	6	-	-
Profit/(loss) after income tax		184	(7,794)
Other comprehensive income, net of tax			
Amounts which may be subsequently reclassified to profit or loss:			
Exchange differences on translation of foreign operations		2	(4)
Total comprehensive income/(loss) for the year		186	(7,798)
Profit/(loss) after tax attributable to Equity holders of the Company:			
		184	(7,794)
Total comprehensive income/(loss) attributable to Equity holders of the Company:			
		186	(7,798)
Basic earnings/(loss) per share	7	\$0.001	(\$0.066)
Diluted earnings/(loss) per share	7	\$0.001	(\$0.066)

The notes on pages 6 to 20 form part of these consolidated financial statements

Neuren Pharmaceuticals Limited

Consolidated Statement of Financial Position

as at 31 December 2022

	Note	2022 \$'000	2021 \$'000
ASSETS			
Current Assets:			
Cash and cash equivalents	8	40,180	36,783
Trade and other receivables	9	3,066	3,261
Total current assets		43,246	40,044
Non-current assets:			
Property, plant and equipment		21	12
Total non-current assets		21	12
TOTAL ASSETS		43,267	40,056
LIABILITIES AND EQUITY			
Current liabilities:			
Trade and other payables	10	978	803
Derivative liabilities	11	700	-
Total current liabilities		1,678	803
Total liabilities		1,678	803
EQUITY			
Share capital	12	167,740	167,578
Share option reserve		3,222	1,234
Currency translation reserve		(10,680)	(10,682)
Accumulated deficit		(118,693)	(118,877)
Total equity attributable to equity holders		41,589	39,253
TOTAL LIABILITIES AND EQUITY		43,267	40,056

The notes on pages 6 to 20 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 23 February 2023.



Patrick Davies
Non-Executive Chair



Dr Trevor Scott
Director

Neuren Pharmaceuticals Limited

Consolidated Statement of Changes in Equity

for the year ended 31 December 2022

	Share Capital	Share Option Reserve	Currency Translation Reserve	Accumulated Deficit	Total Equity
	\$'000	\$'000	\$'000	\$'000	\$'000
Equity as at 1 January 2021	145,567	394	(10,678)	(111,083)	24,200
Shares issued in capital raising	20,000	-	-	-	20,000
Shares issued in share purchase plan	3,281	-	-	-	3,281
Share issue costs	(1,270)	-	-	-	(1,270)
Share based payments	-	840	-	-	840
Transactions with owners	22,011	840	-	-	22,851
Loss after income tax	-	-	-	(7,794)	(7,794)
Other comprehensive loss	-	-	(4)	-	(4)
Total Comprehensive income for the year	-	-	(4)	(7,794)	(7,798)
Equity as at 31 December 2021	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 owners	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

The notes on pages 6 to 20 form part of these consolidated financial statements

Neuren Pharmaceuticals Limited

Consolidated Statement of Cash Flows

for the year ended 31 December 2022

	2022	2021
Note	\$'000	\$'000
Cash flows from operating activities:		
Receipts from licence agreement	15,921	-
Receipts from Australian R&D Tax Incentive	1,393	2,521
Interest received	188	54
GST refunded	252	372
Payments for employees and directors	(2,814)	(1,756)
Payments to other suppliers	(11,341)	(11,161)
Net cash flow received from/(used in) operating activities	3,599	(9,970)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(19)	(10)
Net cash used in investing activities	(19)	(10)
Cash flows from financing activities:		
Proceeds from the issue of shares	12	23,281
Payment of share issue expenses	(2)	(1,106)
Net cash flow received from/(used in) financing activities	(2)	22,175
Net increase in cash	3,578	12,195
Effect of exchange rate changes on cash balances	(181)	400
Cash and cash equivalents at the beginning of the year	36,783	24,188
Cash and cash equivalents at the end of the year	40,180	36,783
Reconciliation with loss after income tax:		
Profit/(loss) after income tax	184	(7,794)
<i>Non-cash items requiring adjustment:</i>		
Depreciation of property, plant and equipment	10	8
Loan funded share payments expense	1,988	840
Foreign exchange loss/(gain)	184	(404)
Loss on financial assets	700	-
<i>Changes in working capital:</i>		
Trade and other receivables	194	(2,506)
Trade and other payables	339	(114)
Net cash received from/(used in) operating activities	3,599	(9,970)

The notes on pages 6 to 20 form part of these consolidated financial statements

Neuren Pharmaceuticals Limited

Neuren Pharmaceuticals Limited Notes to the Consolidated Financial Statements

for the year ended 31 December 2022

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 23 February 2023.

Material Uncertainties

- The Group's research and development activities involve inherent risks. These risks include, among others: dependence on, and 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; 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 is contingent on future events and will be intermittent until product sales commence. 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 significant accounting policies

These general-purpose consolidated financial statements of the Group are for the year ended 31 December 2022 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 2022 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 18.

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 \$0.2 million for the year ending 31 December 2022 and had positive operating cash flows of \$3.6 million for the year ended 31 December 2022. The Group had net assets as at 31 December 2022 of \$41.6 million, including cash balances and receivables of \$43.2 million.

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.

Neuren Pharmaceuticals Limited

Impact of COVID-19 on our business

On March 11, 2020 the World Health Organization declared a pandemic resulting from the disease known as COVID-19 caused by a novel strain of coronavirus, SARS-CoV-2. In an effort to contain COVID-19 or slow its spread, state or federal governments around the world have enacted various measures, including orders to close businesses not deemed “essential”, isolate residents to their homes or places of residence, and practice social distancing when engaging in essential activities. In certain jurisdictions, such orders have been lifted, although subsequent trends in COVID-19 infections have led to the reinstatement of such orders in various jurisdictions.

To date there has been no financial impact of COVID-19 on the Group. It is possible that clinical trials or other research and development activities for NNZ-2591 could be impacted in the future by COVID-19 restrictions or risks. The Group is continuing to monitor the situation and may take further actions affecting its business operations as are deemed necessary.

Changes in accounting policies

There are no changes in accounting policies for the year ended 31 December 2022.

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.

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(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 any eventual 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 – Licences of intellectual property can 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.

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

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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) Impairment of non-financial assets

Assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment. All non-financial assets are tested for impairment if an indicator of impairment exists. The carrying amount of a long-lived asset is considered impaired when the recoverable amount from such asset is less than its carrying value. In that event, a loss is recognised in the Statement of Comprehensive Income based on the amount by which the carrying amount of the asset or the cash-generating unit to which the asset belongs exceeds the recoverable amount, being the higher of its fair value less costs of disposal and its value in use.

(h) 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.

(i) 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.

(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) Property, plant and equipment

Property, plant and equipment are stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the Statement of Comprehensive Income during the financial period in which they are incurred.

Depreciation is determined principally using the straight-line method to allocate their cost, net of their residual values, over their estimated useful lives.

(l) 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.

Neuren Pharmaceuticals Limited

(m) 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.

(n) 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 corporation 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 and trade receivables fall into this category of financial instruments.

Trade and other payables

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

Subsequently, financial liabilities are measured at amortised cost using the effective interest method.

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Derivative financial instruments

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 Group has a single reportable segment and internal management reporting systems present financial information as a single segment. The segment derives its revenue and incurs expenses through the development of pharmaceutical products. Grant income arises from the Australian R&D Tax Incentive and revenue from licence agreements is derived from the United States. The Board of the Company has been identified as the chief operating decision maker. The Board assesses the financial performance and position of the group and makes strategic decisions.

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:

	2022	2021
	\$'000	\$'000
Revenue from contracts with customers		
Licences of intellectual property - at a point in time	14,553	-
All revenue from licences of intellectual property is from the United States.		
Other income		
Interest income	391	41
Australian R&D tax incentive	864	3,197
Net foreign currency gains	1,225	398
Total other income	2,480	3,636

The net foreign currency gain of \$1.2 million includes a \$1.4 million gain on the milestone revenue from Acadia, offset by a loss on the translation for reporting purposes of the Group's US dollar cash balances into Australian dollars.

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5. Expenses

	2022 \$'000	2021 \$'000
Profit/(loss) before income tax includes the following expenses:		
Depreciation – property, plant and equipment		
Computer equipment	10	8
Total depreciation	10	8
Remuneration of auditors		
Audit and review of financial statements (Grant Thornton NZ)	70	66
Total remuneration of auditors	70	66
Employee benefits expense		
Short-term benefits	1,607	1,093
Post-employment benefits	153	91
Other employee benefits	34	26
Share based payments	868	611
Total employee benefits expenses	2,662	1,821
Directors' compensation		
Short-term benefits	732	498
Post-employment benefits	38	23
Share based payments	126	229
Total Directors' compensation	896	750
Other		
Consultants - share based payments	994	-

In the comparative figures, Jon Pilcher is included in Employee benefits until 14 June 2021, when he was appointed Managing Director. His remuneration post 14 June 2021 is included in Director's compensation.

6. Income tax

	2022 \$'000	2021 \$'000
Income tax expense		
Current tax expense	-	-
Deferred tax expense	-	-
	-	-
Numerical reconciliation of income tax to prima facie tax receivable:		
Profit / (Loss) before income tax	184	(7,794)
Tax at applicable rates 25.0% (2021: 26.0%)	46	(2,026)
Non-taxable Australian R&D tax incentive income	(216)	(831)
Non-deductible expenses for R&D incentive	497	1,973
Non-deductible share option expenses	497	218
Non-deductible loss in fair value of derivative	175	-
Other non-assessable income	(68)	-
Utilisation of previously unrecognised tax losses	(946)	-
Deductible temporary differences and tax losses for which no deferred tax asset was recognised	15	666
Income tax expense	-	-

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Unrecognised deferred tax asset

Deferred tax is recognised on the basis there is probable realisation through future profits. The future income tax benefit of tax losses and other deferred tax assets in relation to temporary timing differences, have therefore not been recognised at 31 December 2022.

	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	-	-	-
2021			
Patents	(208)	(9)	(217)
Capital raising costs	(234)	(169)	(403)
Employee benefits	(55)	(21)	(76)
Other temporary differences	(4)	(6)	(10)
	(501)	(205)	(706)
Deferred tax not recognised	501	205	706
Net deferred tax asset	-	-	-

	2022	2021
	\$'000	\$'000
Gross tax losses for which no deferred tax asset has been recognised (a)	106,115	110,750

(a) Of these gross tax losses, \$62.6 million (2021: \$63.3 million) relates to New Zealand tax losses, which are unlikely to be utilised unless future taxable income is generated in New Zealand. The movement is due to the New Zealand tax losses being translated at the closing foreign exchange rate at each reporting date.

There are no franking credits available for use as at 31 December 2022 (2021: 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.

	2022	2021
Earnings/(loss) after income tax attributable to equity holders (basic) - (\$'000)	184	(7,794)
Weighted average shares outstanding (basic) - (No.)	125,965,676	117,770,052
Basic earnings/(loss) per share	\$0.001	(\$0.066)
Earnings/(loss) after income tax attributable to equity holders (diluted) - (\$'000)	184	(7,794)
Weighted average shares outstanding (diluted) - (No.)	128,908,995	118,524,002
Diluted earnings/(loss) per share	\$0.001	(\$0.066)

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8. Cash and cash equivalents

	2022	2021
	\$'000	\$'000
Cash	2,304	6,912
Demand and short-term deposits	37,876	29,871
	<u>40,180</u>	<u>36,783</u>

9. Trade and other receivables

	2022	2021
	\$'000	\$'000
Trade receivables	-	7
Other receivables	17	21
Interest receivables	207	3
Prepayments	1,977	1,837
Australian R&D tax incentive	865	1,393
	<u>3,066</u>	<u>3,261</u>

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 (2021: nil).

10. Trade and other payables

	2022	2021
	\$'000	\$'000
Trade payables	258	245
Accruals	267	209
Employee benefits	453	349
	<u>978</u>	<u>803</u>

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.

11. Derivatives

	2022	2021
	\$'000	\$'000
<i>Current derivative liabilities</i>		
Forward exchange contracts	<u>700</u>	<u>-</u>

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12. Share capital

	2022	2021	2022	2021
	Shares	Shares	\$'000	\$'000
Issued Share Capital				
Ordinary shares on issue at beginning of year	128,965,676	117,608,108	167,578	145,567
Shares issued in private placement	-	9,756,098	-	20,000
Share issued in Share Purchase Plan	-	1,601,470	-	3,281
Share issue expenses - issue costs	-	-	162	(1,270)
	<u>128,965,676</u>	<u>128,965,676</u>	<u>167,740</u>	<u>167,578</u>

At 31 December 2022 125,965,676 ordinary shares are quoted on the ASX, and 3,000,000 unquoted ordinary shares (31 December 2021: 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 2022 \$2.0 million (31 December 2021: \$0.8 million) was recognised in share-based 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 2022 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.

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:

	Loan Funded Shares	Weighted Average Exercise Price	Weighted Average Exercise Price
			Exercisable
Outstanding at 31 December 2021	3,000,000	\$1.84	-
Outstanding at 31 December 2022	3,000,000	\$1.84	1,200,000

The exercise price for 3.0 million Loan Funded Shares is \$1.84 per share.

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Options to acquire ordinary shares

During the year ended 31 December 2022, options to acquire 2,200,000 ordinary shares were issued to employees and consultants. Options to acquire ordinary shares 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.

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.

Details of the options to acquire ordinary shares issued during the year ended 31 December 2022, the estimated fair value and variable inputs into the valuation model are shown in the table below. The exercise price for the options to acquire ordinary shares is the 5-day weighted average price at which the shares were traded on the ASX in the 5 days preceding the issue of the options.

Number of shares under option	1,450,000	750,000
Issue date	3 February 2022	8 July 2022
Exercise price per share option	\$3.46	\$3.83
Share price on date of valuation	\$3.90	\$3.90
Fair value per share option	\$2.03	\$1.79
Estimated future volatility	77.58%	68.20%
Annual risk-free interest rate	1.40%	3.09%

Movements in the number of Share Options were as follows:

	Weighted Average		Weighted Average	
	Share Options	Exercise Price	Exercisable	Exercise Price
Outstanding at 31 December 2021	-	-	-	-
Issued	2,200,000	\$3.59	-	-
Outstanding at 31 December 2022	2,200,000	\$3.59	200,000	\$3.46

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13. 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.

14. Commitments and contingencies

(a) Legal claims

The Group had no significant legal matter contingencies as at 31 December 2022 or at 31 December 2021.

(b) Commitments

The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 31 December 2022 (2021: nil).

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. At 31 December 2021, the Group had commitments under product development contracts amounting to approximately \$6.1 million, comprising approximately US\$3.3 million, GBP 0.3 million and AU \$0.9 million.

(c) Contingent liabilities

The Group had no contingent liabilities at 31 December 2022 or at 31 December 2021.

15. 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:

	2022	2021
	\$'000	\$'000
Short-term benefits	1,682	1,340
Post-employment benefits	112	83
Other long-term benefits	34	26
Share based payment compensation	837	840
	<u>2,665</u>	<u>2,289</u>

(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.

16. Events after reporting date

As at the date of these consolidated financial statements authorised for issue, there are no events arising since 31 December 2022 that require disclosure.

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17. Financial instruments and risk management

(a) Categories of financial instruments

		At amortised cost		At fair value	Total
		Floating Interest Rate	Non-Interest Bearing	through profit or loss	
		\$'000	\$'000	Non-Interest Bearing	\$'000
				\$'000	
2022					
Financial assets					
Cash and cash equivalents	8	40,180	-	-	40,180
Trade and other receivables	9	-	207	-	207
Total financial assets		40,180	207	-	40,387
Financial liabilities					
Trade and other payables	10	-	525	-	525
Derivative financial instruments - forward exchange contracts	11	-	-	700	700
		-	525	700	1,225
2021					
Financial assets					
Cash and cash equivalents	8	36,783	-	-	36,783
Trade and other receivables	9	-	10	-	10
Total financial assets		36,783	10	-	36,793
Financial liabilities					
Trade and other payables	10	-	454	-	454
Total financial liabilities		-	454	-	454

At 31 December 2022, 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 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 2021, there were no forward contracts outstanding.

At 31 December 2022, there were two forward contracts to convert Australian dollars to US dollars outstanding. Adjustment of these financial instruments to fair value as measured at 31 December 2022 resulted in a loss of \$0.7 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 2022 is as follows:

	Buy USD	Sell AUD	Term	Weighted average exchange rate
	\$'000	\$'000		
Buy US dollar / sell AU dollar	7,873	12,323	3 months or less	0.6389

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During the year, the US dollar fluctuated against the Australian dollar. A net foreign exchange gain of \$1.2 million is included in results for the year ended 31 December 2022 (2021: \$0.4 million), this includes a \$1.4 million gain on the milestone revenue from Acadia, offset by a loss on the translation for reporting purposes of the Group's US dollar cash balances into Australian dollars.

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

	2022 \$'000	2021 \$'000
Assets		
US dollars	2,104	6,905
Liabilities		
US dollars	803	38

An increase of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have increased the consolidated loss after income tax by \$1,238,107 (2021: \$624,255). A decrease of 10% in the rate of the US dollar against the Australian dollar as at the reporting date would have decreased the consolidated loss after income tax by \$1,514,242 (2021: \$762,978). 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 \$12,419 (2021: increase of \$2,109). 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 \$15,179 (2021: decrease of \$2,578).

Interest rate risk

The Group is exposed to changes in market interest rates as entities in the Group hold cash and cash equivalents. The effective interest rates on financial assets are as follows:

	2022 \$'000	2021 \$'000
Financial Assets		
Cash and cash equivalents		
Australian dollar cash deposits	38,076	29,885
Australian dollar interest rate	3.58%	0.17%
US dollar cash deposits	2,104	6,898
US dollar interest rate	-%	-%

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 loss after tax by approximately \$68,200 (2021: \$2,580). 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, 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 are held and transacted with National Australia Bank, 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 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 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.

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18. 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's research and development activities are eligible under the Australian R&D Tax Incentive. The Group has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. For the period to 31 December 2022 the Group has recorded other revenue of \$0.9 million (2021: \$3.2 million).

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.

Cash and cash equivalents include term deposits of \$37.9 million with 3-month or less maturities which are held to meet short-term cash commitments, rather than for investment or other purposes.

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

Grant Thornton New Zealand Audit Limited
 L4, Grant Thornton House
 152 Fanshawe Street
 PO Box 1961
 Auckland 1140
 T +64 (09) 308 2570
 www.grantthornton.co.nz

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 20 which comprise the consolidated statement of financial position as at 31 December 2022, and the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the financial position of the Group as at 31 December 2022 and of its financial performance and cash flows for the year then ended in accordance with the New Zealand equivalents to International Financial Reporting Standards ("NZ IFRS") issued by the New Zealand Accounting Standards Board.

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 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. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Why the audit matter is significant	How our audit addressed the key audit matter
<p>Share Based Payments</p> <p>During the year ended 31 December 2022, the Group issued share options to key employees and contractors, which have been accounted for as share based payments under IFRS 2: <i>Share-Based Payments</i>.</p> <p>Share-based payments are a complex accounting area including assumptions utilised in the fair value calculations</p>	<p>Our procedures in relation to management's valuation include:</p> <ul style="list-style-type: none"> Evaluating management's assessment of the valuation and recognition of the options. Obtaining an understanding of the key terms and conditions of the share options by reviewing the relevant agreements.

Why the audit matter is significant	How our audit addressed the key audit matter
<p>and judgements regarding the options issued during the year.</p> <p>The fair value was determined using the Grant-Date Method via a Black-Scholes Model as described in Note 12 in the financial statements.</p> <p>The valuation involved significant judgements and estimates from management, including the estimated future volatility of the share price, and an annual risk-free interest rate.</p> <p>We included the valuation of the share options as a key audit matter, due to the high estimation uncertainty within the assumptions and the impact these have on the fair value of the shares.</p>	<ul style="list-style-type: none"> Engaged auditor's valuation expert to assess reasonability of key assumptions and methodology used in the estimation of fair value of the share options. Recalculating the estimated fair value of the share options using the valuation methodology selected. Performed a sensitivity analysis on key inputs on the model and reviewed the impact on the fair value. Reviewing the adequacy of the Company's disclosures in respect of the accounting treatment of share-based payments in the financial statements, including significant judgments involved and the accounting policies adopted.

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 annual report. The annual report is expected to be made available to us after the date of this 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 report that fact.

Directors' responsibilities for the Consolidated Financial Statements

The Directors are responsible on behalf of the Group for the preparation and fair presentation of the consolidated financial statements in accordance with New Zealand equivalents to International Financial Reporting Standards issued by the New Zealand Accounting Standards Board, 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 Group 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: <https://www.xrb.govt.nz/assurance-standards/auditors-responsibilities/audit-report-1/>

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**Ryan Campbell**

Partner

Auckland**23 February 2023**