

Appendix 4E

Neuren Pharmaceuticals Limited ARBN 111 496 130

Preliminary final report Financial year ended 31 December 2021

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 2021 together with comparative results for the year ended 31 December 2020.

All amounts shown are in Australian dollars unless otherwise stated.

2. Results for announcement to the market

	31 Dec 2021 \$'000	31 Dec 2020 \$'000	% Change
2.1 Revenue from ordinary activities	3,636	964	277%
2.2 Loss after tax attributable to equity holders	(7,794)	(9,193)	15%
2.3 Loss attributable to equity holders	(7,794)	(9,193)	15%
2.4 Dividends	N/A	N/A	N/A

The loss after tax was \$7.8 million compared with \$9.2 million in 2020. This was mainly due to grant revenue of \$3.2 million (2020: \$0.7 million) from the R&D Tax Incentive following AusIndustry's approval of an Advance and Overseas finding for the development of NNZ-2591 as a novel therapy for neurodevelopmental disorders. Research and development costs were \$1.7 million higher, due to an increase in expenditures in 2021 for the NNZ-2591 non-clinical studies, Phase 1 trial, Phase 2 trials and manufacture of the required drug for the Phase 2 trials. Cash reserves at 31 December 2021 were \$36.8 million (2020: \$24.2 million). Financing provided cash of \$22.2 million, received for the issue of new ordinary shares at \$2.05 per share in the capital raise and share purchase plan.

During the year significant progress was made in both the development of trofinetide for Rett syndrome and the development of NNZ-2591 for Phelan-McDermid syndrome, Angelman syndrome, Pitt Hopkins and Prader-Willi syndromes.

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.

Neuren successfully completed a Phase 1 clinical trial of NNZ-2591 and a program of non-clinical safety studies, as well as manufacture to supply Phase 2 trials. Neuren has submitted updated protocols and Investigational New Drug (IND) Applications to the US Food and Drug Administration for review and clearance to commence Phase 2 trials in each of Phelan McDermid, Angelman and Pitt Hopkins syndromes.

Neuren added Prader-Willi syndrome to the NNZ-2591 development pipeline, following positive results in the *Mage12*-null mouse model of Prader-Willi syndrome. Neuren is planning to commence a Phase 2 clinical trial in Prader-Willi syndrome in mid-2022.

A more detailed discussion of the activities undertaken in the financial year is set out in the Directors' Report contained in the attached Financial Statements.

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 2021	31 December 2020
	\$	\$
Net tangible assets per security	\$0.33	\$0.24

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

Refer to attached Financial Statements.

15. Audit Status

This report is based upon the attached audited financial statements for the year ended 31 December 2021.

Neuren Pharmaceuticals Limited

Financial Report and Directors' Report for the year ended 31 December 2021

Directors' Report

Principal Activities

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

Review of Operations

Neuren is developing two new drug therapies to treat multiple neurodevelopmental disorders that emerge in early childhood and are characterized by impaired connection and signalling between brain cells. No approved therapies are currently available for these seriously debilitating disorders. Neuren's potential therapies utilize synthetic analogs of neurotrophic peptides that occur naturally in the brain.

During the year ended 31 December 2021, significant progress was made in both the development of trofinetide for Rett syndrome and the development of NNZ-2591 for Phelan-McDermid syndrome, Angelman syndrome, Pitt Hopkins syndrome and Prader-Willi syndrome.

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 12-week placebo-controlled study demonstrated a statistically significant improvement over placebo for both co-primary endpoints. On the Rett Syndrome Behaviour Questionnaire (RSBQ), change from baseline to week 12 was -5.1 vs. -1.7 ($p=0.0175$; effect size=0.37). The Clinical Global Impression-Improvement (CGI-I) score at week 12 was 3.5 vs. 3.8 ($p=0.0030$; effect size=0.47). The RSBQ is a caregiver assessment of the core symptoms of Rett syndrome and the CGI-I is a global physician assessment of worsening or improving of Rett syndrome. Additionally, trofinetide demonstrated a statistically significant separation over placebo on the key secondary endpoint, the Communication and Symbolic Behavior Scales Developmental Profile™ Infant-Toddler Checklist-Social composite score (CSBS-DP-IT-Social) change from baseline to week 12 was -0.1 vs. -1.1 ($p=0.0064$; effect size=0.43).

The trofinetide program has Orphan Drug, Fast Track and Rare Pediatric Disease designations from the US Food and Drug Administration (FDA). Acadia plans to submit a New Drug Application (NDA) to the US Food and Drug Administration (FDA) around mid-year 2022. A NDA with Orphan Drug Designation is eligible for Priority Review in 6 months, compared with the standard review period of 10 months, which means potential for approval in the first quarter of 2023. 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. In February 2022, a voucher was sold for US\$110 million.

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.

Neuren expects to receive revenue over 2022 and 2023 for Rett syndrome in the US alone of A\$115 million plus double-digit percentage royalties on net sales. The expected revenue in addition to royalties comprises:

- A milestone payment in 2022 of US\$10 million (A\$14 million at assumed exchange rate of 0.72) following acceptance of the NDA for review by the FDA;
- A milestone payment in 2023 of US\$40 million (A\$55 million), following the first commercial sale of trofinetide in the United States; and
- US\$33 million (A\$46 million) in 2023 as Neuren's estimated one third share of the market value of a Priority Review Voucher.

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 to all data for use in those countries. There is urgent unmet need for a treatment for Rett syndrome around the world. Neuren has received strong interest for potential commercial partnerships and the number of interested parties has increased significantly since the Phase 3 results were announced. Discussions are now in progress under a process to secure the best outcome for shareholders and for patients.

Neuren is also preparing for Phase 2 clinical trials of its second drug candidate NNZ-2591 for Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome. Based on its mechanism of action and positive results in animal models, NNZ-2591 has received Orphan Drug designation in both the United States and the European Union for each of these disorders.

In February 2021, Neuren announced completion of a Phase 1 clinical trial in Australia, in which twice daily oral dosing of NNZ-2591 for seven days was safe and well tolerated in healthy volunteers at doses expected to be within the effective therapeutic range. An extensive range of non-clinical toxicology and manufacturing studies have also been completed. In September 2021, Neuren submitted to the FDA three Investigational New Drug (IND) applications for review and clearance to start Phase 2 trials in each of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome. Following feedback from the FDA, Neuren was required to add additional clinical assessments to each trial protocol to enhance safety monitoring during these first trials in pediatric patients. Neuren worked with expert clinical

advisors to address all the detailed feedback that was received from the FDA and has recently submitted all three protocols for FDA review. The programs are supervised by the FDA Office of Neuroscience, with Phelan-McDermid and Pitt Hopkins reviewed by the Division of Neurology 1 and Angelman reviewed by the Division of Psychiatry.

A fourth disorder, Prader-Willi syndrome was added to the NNZ-2591 development pipeline in February 2021, when Neuren announced positive results in the *Mage12*-null mouse model of Prader-Willi syndrome, in which treatment with NNZ-2591 for 6 weeks normalized fat mass, insulin levels, IGF-1 levels and all behavioural defects. The FDA granted Orphan Drug designation to NNZ-2591 for the treatment of Prader-Willi syndrome in September 2021. Neuren is planning to commence a Phase 2 clinical trial in Prader-Willi syndrome in mid-2022.

The consolidated financial statements are presented on pages 6 to 22. All amounts in the consolidated Financial Statements are shown in Australian dollars unless otherwise stated.

The Group's loss after tax attributable to equity holders of the Company for the year ended 31 December 2021 was \$7.8 million compared with the Group's loss after tax of \$9.2 million in 2020. This was mainly due to the R&D Tax incentive income of \$3.2 million (2020: \$0.7 million) following AusIndustry's approval of an Advance and Overseas finding for the development of NNZ-2591 as a novel therapy for neurodevelopmental disorders. Research and development costs were \$1.7 million higher, due to an increase in expenditures in 2021 for the NNZ-2591 non-clinical studies, Phase 1 trial, Phase 2 trials and manufacture of the required drug for the Phase 2 trials. In addition, foreign exchange gains were \$0.4 million compared with foreign exchange losses of \$0.6 million in 2020. This is due to an increase in the carrying value in AUD of USD cash held to eliminate exchange risk for USD expenditure, as a result of the strengthening of the USD against the AUD. Prudent control of expenditure continues to be an important principle in the Group's operations and financing.

The basic loss per share for 2021 was \$0.066 (2020: earnings of \$0.086 per share), based on a weighted average number of shares outstanding of 117,770,052 (2020: 107,057,317).

Cash reserves at 31 December 2021 were \$36.8 million (2020: \$24.2 million). Net cash used in operating activities was \$10.0 million (2020: \$8.1 million). The increase of \$1.9 million was mainly in payments to other suppliers, due to higher research and development expenditure of \$3.5 million, which was partially offset by the receipt of \$2.5 million under the R&D Tax Incentive program (2020: \$0.5 million). Financing provided cash of \$22.2 million, received for the issue of new ordinary shares in the capital raise and share purchase plan, compared with \$19.1 million in 2020.

In September 2021, the Group announced the successful completion of a capital raise of \$20 million. The Group issued 9,756,098 fully paid ordinary shares at an issue price of \$2.05 per share to institutional investors in Australia and overseas. In October, the Group announced the completion of its Share Purchase Plan (SPP), raising \$3.3m and issuing 1,601,470 new fully paid ordinary shares at \$2.05 per share. The funds will accelerate the development and increase the value of NNZ-2591 for four neurodevelopmental disorders, by enabling a Phase 2 clinical trial in Prader-Willi syndrome and the foundational work for Phase 3 development across Prader-Willi, Phelan-McDermid, Angelman and Pitt-Hopkins syndromes.

No dividends were paid in the year, or in the prior year and the Directors recommend none for the year.

Directors

Patrick Davies B EC, MBA (Non-Executive Chair)

Patrick joined the Neuren Board in July 2018. He has held executive management roles in the Australian and New Zealand healthcare industry for over twenty five years having performed successfully in senior roles across many industry sectors including pharmacy, primary care, pharmaceutical and consumer products. During his ten year period as Chief Executive Officer of EBOS Group Limited (and previously Symbion), the enterprise value of the group achieved compound annual growth in enterprise value of +20% (from circa \$450M to in excess of \$3.1B). He is a director on other corporate boards and provides strategic advice to a range of healthcare businesses and investors.

Jon Pilcher BSc (Hons), FCA (Managing Director)

Jon joined Neuren in August 2013 as CFO and was appointed CEO in May 2020. Jon was appointed to the Board as Managing Director in June 2021. He has played a central role in all aspects of Neuren's R&D, commercial and corporate activities. Before joining Neuren he was a member of the leadership team at Acrux (ASX: ACR) throughout a period that included Acrux's IPO and listing on the ASX, the development and FDA approval of three novel pharmaceutical products and a transforming licensing deal with Eli Lilly in 2010. He formerly spent seven years in a series of senior financial positions in the R&D and corporate functions of international pharmaceutical groups Medeva and Celltech, which are now part of UCB. Jon is a Chartered Accountant and holds a degree in Biotechnology from the University of Reading in the UK. He is a non-executive director of BTC Health (ASX:BTC).

Dr Trevor Scott, MNZM, LLD (Hon), BCom, FCA, FNZIM, DF Inst D (Non-Executive Director)

Trevor joined the Neuren Board in March 2002. He is the founder of T.D. Scott and Co., an accountancy and consulting firm, which he formed in 1988. He is an experienced advisor to companies across a variety of industries. Trevor serves on numerous corporate boards and is chairman of several.

Dianne Angus BSc (Hons), Master of Biotechnology, IPTA (Non-Executive Director)

Dianne joined the Neuren Board in July 2018. She has worked as a senior executive and non-executive director within the biotechnology, biopharmaceutical and agritech industries for over twenty-five years. She has created numerous

global industry partnerships which include Prana Biotechnology, Gerolymatos International, Florigene, Suntory & Monsanto to yield novel and competitive medical, pharmaceutical and agricultural products. Dianne has successfully forged strong partnerships with key medical opinion leaders to create innovative clinical research programs and driven the development path for novel neurological pre-clinical agents to late-stage clinical assets before the FDA and European regulators. With over fifteen years' experience in an ASX and NASDAQ listed company, she has expertise in business development, capital raising, investor relations, regulatory affairs and intellectual property, together with corporate governance and compliance capabilities. Dianne holds a Masters degree in biotechnology and is a registered patent attorney.

Dr Jenny Harry BSc (Hons), PhD (Non-Executive Director)

Jenny joined the Neuren Board in 2018. She has 20 years' experience in executive management of companies in the biotechnology and biopharmaceutical sectors. Jenny is an accomplished CEO and Managing Director with experience in growing companies from start-up to commercialisation. She has served on the Boards of a number of listed and unlisted companies and is currently a Non-Executive Director of Aeris Environmental Limited (ASX:AEI) and on the Board's IP sub-committee of the Children's Medical Research Institute. Jenny is a graduate of the Harvard Business School General Manager Program and the Australian Institute of Company Directors.

Board and Committee Attendance

The table below shows the number of Board and Committee meetings each Director was eligible to attend and attended during the financial year ended 31 December 2021:

Director	Board		Audit and Risk		Remuneration	
	Held ⁽ⁱ⁾	Attended	Held ⁽ⁱ⁾	Attended	Held ⁽ⁱ⁾	Attended
Patrick Davies	11	11	2	2	1	1
Dr Trevor Scott	11	11	2	2	1	1
Dianne Angus	11	11	2	2	1	1
Dr Jenny Harry	11	11	2	2	1	1
Jonathan Pilcher ⁽ⁱⁱ⁾	7	7	-	-	-	-

(i) Number of meetings held during the time the Director was a member of the Board or Committee

(ii) Appointed to the Board on 14 June 2021.

Interests Register

The Company is required to maintain an interests register in which particulars of certain transactions and matters involving Directors must be recorded. Details of the entries in this register for each of the Directors during and since the end of 2021 are as follows:

Director	Ordinary Shares Purchased/(Sold)	Consideration Paid/(Received)	Date of Transaction
Jon Pilcher	19,039	\$25,000	15 Jun 2021
Jon Pilcher	7,317	\$15,000	08 Oct 2021
Patrick Davies	35,211	\$50,175	17 Feb 2021
Patrick Davies	14,634	\$30,000	08 Oct 2021
Dianne Angus	30,000	\$59,316	15/18 Oct 2021
Dr Jenny Harry	9,756	\$20,000	08 Oct 2021

Information used by Directors

During the year the Board received no notices from Directors of the Company requesting to use Company information received in their capacity as Directors, which would not otherwise have been available to them.

Indemnification and Insurance of Directors and Officers

Neuren has entered into a deed of indemnity, insurance and access with Directors and Officers, which provides that Directors and Officers generally will incur no monetary loss as a result of actions undertaken by them as Directors and Officers. The indemnity does not cover criminal liability or liability in respect of a breach of a director's duty to act in good faith and in what the director believes to be the best interests of the Company or a breach of any fiduciary duty owed to the Company or a subsidiary.

Donations

No donations were made by the Company or its subsidiary companies during the year (2020: \$nil).

Non-Executive Director Remuneration

Remuneration of Non-Executive Directors is shown in the table below:

	2021	2020
	\$	\$
Patrick Davies (appointed Chair May 2020)	120,000	95,000
Dr Trevor Scott	72,000	72,000
Dianne Angus	60,000	60,000
Dr Jenny Harry	66,000	60,000

Executive Director Remuneration

The Managing Director, Jon Pilcher, receives remuneration and other benefits in his executive role as Chief Executive Officer and, accordingly, does not receive a director fee. The table below shows the total remuneration for Jon Pilcher since his appointment to Managing Director on 14 June 2021.

	Fixed remuneration (including superannuation)	Share based payments	Total Remuneration
	\$	\$	\$
2021			
Jonathan Pilcher	203,125	229,123	432,248
2020			
Dr Richard Treagus (resigned May 2020)	146,000	-	146,000

Employee Remuneration

The number of employees, not being directors of the Company, who received remuneration and benefits in their capacity as employees totalling NZ \$100,000 or more during the year, shown in bands denominated in Australian dollars, was as follows:

Excluding share based payments

	2021	2020
	\$'000	\$'000
\$100,000 - \$109,999	-	1
\$160,000 - \$169,999	1	-
\$170,000 - \$179,999	2	-
\$250,000 - \$259,999	-	1
\$270,000 - \$279,999	1	-
\$280,000 - \$289,999	-	1
\$290,000 - \$299,999	1	-
\$340,000 - \$349,999	-	1

Including share based payments

	2021	2020
	\$'000	\$'000
\$100,000 - \$109,999	-	1
\$160,000 - \$169,999	1	-
\$170,000 - \$179,999	1	-
\$350,000 - \$359,999	-	1
\$360,000 - \$369,999	1	-
\$380,000 - \$389,999	-	1
\$480,000 - \$489,999	1	-
\$500,000 - \$509,999	1	-
\$540,000 - \$549,999	-	1

Auditors

Grant Thornton New Zealand Audit Limited ('Grant Thornton') is the independent auditor of the Company. Audit fees in relation to the annual and interim financial statements were \$65,921 (2020: \$57,759). Grant Thornton did not receive any other fees in relation to other financial advice and services. No amounts were payable to an auditor by subsidiary companies in 2021 or 2020.

For and on behalf of the Board of Directors who authorised the issue of these consolidated financial statements on 23 February 2022.



Patrick Davies
Non-Executive Chair



Dr Trevor Scott
Director

**Neuren Pharmaceuticals Limited
Consolidated Financial Statements
for the year ended 31 December 2021**

Neuren Pharmaceuticals Limited

Consolidated Statement of Comprehensive Income

for the year ended 31 December 2021

	Note	2021 \$'000	2020 \$'000
Interest		41	147
Foreign exchange gain		398	-
Australian R&D tax incentive		3,197	717
Other income		-	100
Total income		3,636	964
Research and development costs		(9,516)	(7,763)
Corporate and administrative costs		(1,914)	(1,763)
Foreign exchange loss		-	(631)
Loss before income tax		(7,794)	(9,193)
Income tax	5	-	-
Loss after income tax		(7,794)	(9,193)
Other comprehensive loss, net of tax			
Amounts which may be subsequently reclassified to profit or loss:			
Exchange differences on translation of foreign operations		(4)	11
Total comprehensive loss for the year		(7,798)	(9,182)
Loss after tax attributable to Equity holders of the Company:			
		(7,794)	(9,193)
Total comprehensive loss attributable to Equity holders of the Company:			
		(7,798)	(9,182)
Basic loss per share	6	(\$0.066)	(\$0.086)
Diluted loss per share	6	(\$0.066)	(\$0.086)

The notes on pages 11 to 22 form part of these consolidated financial statements

Neuren Pharmaceuticals Limited

Consolidated Statement of Financial Position

as at 31 December 2021

	Note	2021 \$'000	2020 \$'000
ASSETS			
Current Assets:			
Cash and cash equivalents	7	36,783	24,188
Trade and other receivables	8	3,261	755
Total current assets		40,044	24,943
Non-current assets:			
Property, plant and equipment		12	10
Total non-current assets		12	10
TOTAL ASSETS		40,056	24,953
LIABILITIES AND EQUITY			
Current liabilities:			
Trade and other payables	9	803	753
Total current liabilities		803	753
Total liabilities		803	753
EQUITY			
Share capital	10	167,578	145,567
Other reserves		(9,448)	(10,284)
Accumulated deficit		(118,877)	(111,083)
Total equity attributable to equity holders		39,253	24,200
TOTAL LIABILITIES AND EQUITY		40,056	24,953

The notes on pages 11 to 22 form part of these consolidated financial statements

Neuren Pharmaceuticals Limited

Consolidated Statement of Changes in Equity

for the year ended 31 December 2021

	Share Capital	Share Option Reserve	Currency Translation Reserve	Accumulated Deficit	Total Equity
	\$'000	\$'000	\$'000	\$'000	\$'000
Equity as at 1 January 2020	126,426	2,186	(10,689)	(104,076)	13,847
Shares issued in capital raising	20,000	-	-	-	20,000
Shares issued in share purchase plan	216	-	-	-	216
Share issue costs	(1,075)	-	-	-	(1,075)
Transfer on expiry of options	-	(2,186)	-	2,186	-
Loan funded share payments	-	394	-	-	394
Transactions with owners	19,141	(1,792)	-	2,186	19,535
Loss after income tax	-	-	-	(9,193)	(9,193)
Other comprehensive loss	-	-	11	-	11
Total Comprehensive income for the year	-	-	11	(9,193)	(9,182)
Equity as at 31 December 2020	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)
Loan funded share 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 loss for the year	-	-	(4)	(7,794)	(7,798)
Equity as at 31 December 2021	167,578	1,234	(10,682)	(118,877)	39,253

The notes on pages 11 to 22 form part of these consolidated financial statements

Neuren Pharmaceuticals Limited

Consolidated Statement of Cash Flows

for the year ended 31 December 2021

	2021	2020
Note	\$'000	\$'000
Cash flows from operating activities:		
Receipts from Australian R&D Tax Incentive	2,521	491
Interest received	54	164
GST refunded	372	283
Receipts from government cash flow boost	-	100
Payments for employees and directors	(1,756)	(1,480)
Payments to other suppliers	(11,161)	(7,636)
Net cash flow used in operating activities	(9,970)	(8,078)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(10)	(6)
Net cash used in investing activities	(10)	(6)
Cash flows from financing activities:		
Proceeds from the issue of shares	10 23,281	20,216
Payment of share issue expenses	(1,106)	(1,075)
Net cash provided from financing activities	22,175	19,141
Net increase / (decrease) in cash	12,195	11,057
Effect of exchange rate changes on cash balances	400	(713)
Cash and cash equivalents at the beginning of the year	24,188	13,844
Cash and cash equivalents at the end of the year	36,783	24,188
Reconciliation with loss after income tax:		
(Loss) / Profit after income tax	(7,794)	(9,193)
<i>Non-cash items requiring adjustment:</i>		
Depreciation of property, plant and equipment	8	6
Loan funded share payments expense	840	394
Foreign exchange (gain)/loss	(404)	724
<i>Changes in working capital:</i>		
Trade and other receivables	(2,506)	(203)
Trade and other payables	(114)	194
Net cash used in operating activities	(9,970)	(8,078)

The notes on pages 11 to 22 form part of these consolidated financial statements

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements

for the year ended 31 December 2021

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 2022.

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 2021 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 2021 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 16.

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 loss after tax of \$7.8 million for the year ending 31 December 2021 and had negative operating cash flows of \$10.0 million for the year ended 31 December 2021. The Group had net assets at 31 December 2021 of \$39.3 million, including cash balances and receivables of \$40.0 million.

In September 2021, the Group announced the successful completion of a capital raise of \$20 million. The Group issued 9,756,098 fully paid ordinary shares at an issue price of \$2.05 per share to institutional investors in Australia and overseas. In October, the Group announced the completion of its Share Purchase Plan (SPP), raising \$3.3m and issuing 1,601,470 new fully paid ordinary shares at \$2.05 per share.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

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.

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 is no significant impact of changes in accounting policies for the year ended 31 December 2021.

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

Certain new standards, amendments and interpretations to existing standards have been published that are mandatory for later periods and which the Group has not adopted early. None are expected to materially impact the Group.

(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.

Inter-company transactions, balances and unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated. 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 cash flow hedges and 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 shareholders' 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.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

(d) Revenue

Revenue arises mainly from grants received and interest. Revenue is recognised either at a point in time or over time, when (or as) the Group satisfies performance obligations by transferring the promised goods or services to its customers.

Grants

Grants received are 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 the requirements under the grant agreement have been met. Any grants received for which the requirements under the grant agreement have not been completed are carried as liabilities until all the conditions have been fulfilled.

Interest income

Interest income is recognised on a time-proportion basis 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.

When a project reaches the stage where it is reasonably certain that future expenditure can be recovered through the process or products produced, development expenditure is recognised as a development asset using the following criteria:

- a product or process is clearly defined and the costs attributable to the product or process can be identified separately and measured reliably;
- the technical feasibility of the product or process can be demonstrated;
- the existence of a market for the product or process can be demonstrated and the Group intends to produce and market the product or process;
- adequate resources exist, or their availability can be reasonably demonstrated to complete the project and market the product or process.

In such cases the asset is amortised from the commencement of commercial production of the product to which it relates on a straight-line basis over the years of expected benefit. Research and development costs are otherwise expensed as incurred.

(f) Income tax

The income tax expense 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 and adjusted by changes in deferred tax assets and liabilities attributable to temporary differences between the tax bases of assets and liabilities and their carrying amounts in the financial statements, and to unused tax losses.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to apply when the assets are recovered 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. No deferred tax asset or liability is recognised in relation to these temporary differences if they arose 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 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 also reviewed whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. 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 exceeds the fair value less costs of disposal and value in use of the long-lived asset. Fair market value is determined using the anticipated cash flows discounted at a rate commensurate with the risk involved.

(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.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

(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, as follows:

Scientific equipment	4 years
Computer equipment	2-10 years
Office furniture, fixtures & fittings	3-4 years

(l) Intangible assets

Intellectual property

Costs in relation to protection and maintenance of intellectual property are expensed as incurred unless the project has yet to be recognised as commenced, in which case the expense is deferred and recognised as contract work in progress until the revenues and costs associated with the project are recognised.

Acquired patents, trademarks and licences have finite useful lives and are carried at cost less accumulated amortisation and impairment losses. Amortisation is calculated using the straight line method to allocate the cost over the anticipated useful lives, which are aligned with the unexpired patent term or agreement over trademarks and licences.

Acquired software

Acquired software licences are capitalised on the basis of the costs incurred to acquire and bring to use the specific software. These costs are amortised over their estimated useful lives.

(m) 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 has operated a loan funded share plan and equity performance rights 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 other reserve equity 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 and become exercisable. It recognises the impact of the revision of original estimates, 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.

(n) 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.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

(o) 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 financial asset and substantially all the risks and rewards are transferred.

A financial liability is derecognised when it is extinguished, discharged, cancelled or expires.

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 costs, finance income or other financial items, 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, trade and most other receivables fall into this category of financial instruments.

(p) Financial liabilities

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.

(q) Earnings per share

Basic and diluted earnings per share are calculated by dividing the profit attributable to equity holders of the Company by the weighted average number of ordinary shares outstanding during the period.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

3. Segment information

The Group operates as a single operating 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. Expenses

	2021 \$'000	2020 \$'000
Loss / (Profit) before income tax includes the following expenses:		
Depreciation – property, plant and equipment		
Computer equipment	8	6
Total depreciation	8	6
Remuneration of auditors		
Audit and review of financial statements (Grant Thornton NZ)	66	58
Total remuneration of auditors	66	58
Employee benefits expense		
Short-term benefits	1,093	974
Post-employment benefits	91	76
Other employee benefits	26	35
Share based payments	611	394
Total employee benefits expenses	1,821	1,479
Directors' compensation		
Short-term benefits	498	423
Post-employment benefits	23	10
Share based payments	229	-
Total Directors' compensation	750	433

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.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

5. Income tax

	2021 \$'000	2020 \$'000
Income tax		
Current tax	-	-
Deferred tax	-	-
	-	-
Numerical reconciliation of income tax to prima facie tax receivable:		
(Loss) / Profit before income tax	(7,794)	(9,193)
Tax at applicable rates 26.0% (2020: 27.5%)	(2,026)	(2,528)
Non-taxable Australian R&D tax incentive income	(831)	(197)
Non deductible expenses for R&D incentive	1,973	454
Deductible temporary differences and tax losses for which no deferred tax asset was recognised	884	2,271
Income tax	-	-
Gross tax losses for which no deferred tax asset has been recognised (a)	110,750	107,065

(a) Of these gross tax losses, \$63.3 million (2020: \$62.9 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.

6. 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 for the year attributable to the equity holders of the company by the weighted average number of shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of any dilutive potential ordinary shares into ordinary shares. The dilutive impact of loan funded shares has not been included in the weighted average number of ordinary shares for the purposes of calculating diluted earnings per share, as it does not meet the requirements for inclusion in NZ IAS 33.

	2021	2020
Loss after income tax attributable to equity holders (basic) - (\$'000)	(7,794)	(9,193)
Weighted average shares outstanding (basic) - (No.)	117,770,052	107,057,317
Basic loss per share	(\$0.066)	(\$0.086)
Loss after income tax attributable to equity holders (diluted) - (\$'000)	(7,794)	(9,193)
Weighted average shares outstanding (diluted) - (No.)	118,524,002	107,057,317
Diluted loss per share	(\$0.066)	(\$0.086)

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

7. Cash and cash equivalents

	2021	2020
	\$'000	\$'000
Cash	6,912	229
Demand and short-term deposits	29,871	23,959
	<u>36,783</u>	<u>24,188</u>

8. Trade and other receivables

	2021	2020
	\$'000	\$'000
Trade receivables	7	-
Other receivables	21	22
Interest receivables	3	16
Prepayments	1,837	-
Australian R&D tax incentive	1,393	717
	<u>3,261</u>	<u>755</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 and other transactions with that debtor over the past 12 months before 31 December 2021 as well as the corresponding historical credit losses during that period.

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 (2020: nil).

9. Trade and other payables

	2021	2020
	\$'000	\$'000
Trade payables	245	167
Accruals	209	323
Employee benefits	349	263
	<u>803</u>	<u>753</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 work done but not invoiced at each reporting date.

10. Share capital

	2021	2020	2021	2020
	Shares	Shares	\$'000	\$'000
Issued Share Capital				
Ordinary shares on issue at beginning of year	117,608,108	102,668,413	145,567	126,426
Shares issued under Loan Funded Share Plan	-	3,000,000	-	-
Shares bought back under Loan Funded Share Plan	-	(2,500,000)	-	-
Shares issued in private placement	9,756,098	14,285,723	20,000	20,000
Share issued in Share Purchase Plan	1,601,470	153,972	3,281	216
Share issue expenses - issue costs	-	-	(1,270)	(1,075)
	<u>128,965,676</u>	<u>117,608,108</u>	<u>167,578</u>	<u>145,567</u>

In September 2021, the Group issued 9,756,098 fully paid ordinary shares at an issue price of \$2.05 per share in a placement to institutional in Australia and overseas. In October 2021, the Group issued 1,601,470 fully paid ordinary

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

shares at an issue price of \$2.05 in the Share Purchase Plan (SPP). The issue price of \$2.05 per share for the placement and the SPP represented a discount of 8.9% to the last closing price of \$2.25 on 9 September 2021.

At 31 December 2021 3.0 million ordinary shares (31 December 2020: 3.0 million 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

No securities were issued under any share based payment plans in 2021 or 2020. There were no equity-settled share based payments expensed in the Statement of Comprehensive Income in 2021 or 2020.

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 2021 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 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 a relevant period.

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

	Loan Funded Shares	Weighted Average Exercise Price	Exercisable	Weighted Average Exercise Price
Outstanding at 31 December 2019	1,000,000	\$1.76	-	-
Expired and bought back	(1,000,000)	\$1.76	-	-
Issued	3,000,000	\$1.84	-	-
Outstanding at 31 December 2020	3,000,000	\$1.84	-	-
Expired and bought back	-	-	-	-
Issued	-	-	-	-
Outstanding at 31 December 2021	3,000,000	\$1.84	-	-

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

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

11. 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.

12. Commitments and contingencies

(a) Legal claims

The Group had no significant legal matter contingencies as at 31 December 2021 or at 31 December 2020.

(b) Commitments

The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 31 December 2021 (2020: nil).

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. At 31 December 2020, the Group had commitments under product development contracts amounting to approximately \$5.0 million, comprising approximately US\$2.6 million, GBP 0.4 million and AU \$0.9 million.

(c) Contingent liabilities

The Group had no contingent liabilities at 31 December 2021 or at 31 December 2020 that require disclosure.

13. Related party transactions

(a) Key Management Personnel

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

	2021	2020
	\$'000	\$'000
Short-term benefits	1,340	1,349
Post-employment benefits	83	73
Other long-term benefits	26	35
Share based payment compensation	840	394
	<u>2,289</u>	<u>1,851</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. Interests in and amounts due from subsidiaries are set out in Note 11. All amounts due between entities in the Group are payable on demand and bear no interest.

14. Events after reporting date

As at the date of these consolidated financial statements authorised for issue, there are no events arising since 31 December 2021 that require disclosure.

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Notes to the Consolidated Financial Statements (continued)

15. Financial instruments and risk management

(a) Categories of financial instruments

<i>Financial assets</i>		At amortised cost		At fair value	Total
		Floating Interest Rate	Non-Interest Bearing	through profit or loss Non-Interest Bearing	
		\$'000	\$'000	\$'000	\$'000
2021					
Cash and cash equivalents	7	36,783	-	-	36,783
Trade and other receivables	8	-	30	-	30
Total financial assets		36,783	30	-	36,813
2020					
Cash and cash equivalents	7	24,188	-	-	24,188
Trade and other receivables	8	-	37	-	37
Total financial assets		24,188	37	-	24,225
Financial liabilities		2021	2020		
Amortised cost - Non-Interest Bearing:		\$'000	\$'000		
Trade and other payables	9	454	490		

At 31 December 2021, the reporting value of all financial instruments approximated to the 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 changes in market prices, such as foreign exchange rates and interest rates will affect the Group's income or the value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimising the return.

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 (2020: None).

During the year, the US dollar fluctuated against the Australian dollar. A foreign exchange gain of \$398,000 is included in results for the year ended 31 December 2021 (2020: loss \$631,000). The majority of the gain relates to gains on the translation for reporting purposes of the Group's US dollar cash reserves into Australian dollars.

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

	2021	2020
	\$'000	\$'000
Assets		
US dollars	6,905	8,686
Liabilities		
US dollars	38	46

An increase of 10% in the cross rate of the US dollar against the Australian dollar as at the reporting date would have increased the consolidated loss after income tax by \$624,000 (2020: \$785,000). A decrease of 10% in the cross rate of

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

the US dollar against the Australian dollar as at the reporting date would have decreased the consolidated loss after income tax by \$763,000 (2020: \$960,000).

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:

Financial Assets	2021	2020
	\$'000	\$'000
Cash and cash equivalents		
Australian dollar cash deposits	29,888	15,502
Australian dollar interest rate	0.17%	0.48%
US dollar cash deposits	6,898	8,686
US dollar interest rate	-%	0.07%

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 10% change in average market interest rates would have changed reported loss after tax by approximately \$5,100 (2020: \$8,000).

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, are generally repayable within 1 – 2 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 risk

The Group manages its capital, which is its equity, to ensure that the Group entities are able to meet their estimated commitments as they fall due. In this regard, the Company raised additional equity capital during 2021, as described in Note 10. Capital risk is impacted by the material uncertainties described in Note 1.

16. 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 2021 the Group has recorded other revenue of \$3.2 million (2020: \$0.7 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.

Loan Funded Shares

The Group measures the fair value of loan funded shares with employees 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.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Financial Statements (continued)

Additional Information

Equity Securities Held by Directors as at 23 February 2022

Director	Interests in Ordinary Shares		Interests in Loan Funded Shares
	Direct	Indirect	Indirect
Trevor Scott	1,000,000	2,589,784	-
Dianne Angus	30,000	-	-
Patrick Davies	-	220,940	-
Jenny Harry	-	29,663	-
Jonathan Pilcher ¹	-	398,207	1,500,000

¹ Jon Pilcher has an interest in 1.5 million Loan Funded Shares held by Neuren Trustee Limited. As detailed in Note 10 to the Financial Statements, the Loan Funded Shares are subject to vesting conditions and repayment of a loan amounting to \$1.84 per share before they can be transferred to Jon.

Directors of subsidiary companies at 31 December 2021

	Jon Pilcher	Larry Glass	Trevor Scott
Neuren Pharmaceuticals Inc.	√	√	
Neuren Pharmaceuticals (Australia) Pty Ltd	√	√	
Neuren Trustee Limited			√

Australian Stock Exchange Disclosures

Neuren Pharmaceuticals Limited is incorporated in New Zealand under the Companies Act 1993.

The Company is not subject to Chapters 6, 6A, 6B and 6C of the Corporations Act, Australia, dealing with the acquisition of shares (such as substantial holdings and takeovers).

Limitations on the acquisition of shares are imposed under New Zealand law are as follows:

- (a) In general, securities in the Company are freely transferable and the only significant restrictions or limitations in relation to the acquisition of securities are those imposed by New Zealand laws relating to takeovers and overseas investment.
- (b) The New Zealand Takeovers Code creates a general rule under which the acquisition of 20% or more of the voting rights in the Company or the increase of an existing holding of 20% or more of the voting rights of the Company can only occur in certain permitted ways. These include a full takeover offer in accordance with the Takeovers Code, a partial takeover in accordance with the Takeovers Code, an acquisition approved by an ordinary resolution, an allotment approved by an ordinary resolution, a creeping acquisition (in certain circumstances), or compulsory acquisition of a shareholder holding 90% or more of the shares.
- (c) The New Zealand Overseas Investment Act 2005 and Overseas Investment Regulations 2005 (New Zealand) regulate certain investments in New Zealand by overseas interests. In general terms, the consent of the New Zealand Overseas Investment Office may be required where an 'overseas person' acquires shares in the Company that amount to 25% or more of the shares issued by the Company, or if the overseas person already holds 25% or more, the acquisition increases that holding.

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 7 to 23 which comprise the consolidated statement of financial position as at 31 December 2021, 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 2021 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. 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 Directors' Report (but does not include the consolidated financial statements and our auditor's report thereon), which we obtained prior to the date of this auditor's report and the annual report which is expected to be made available to us after that date.

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 connections 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. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

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/standards/assurance-standards/auditing-standards/auditors-responsibilities/audit-report-1/>



Grant Thornton New Zealand Audit Limited

**R Campbell
Auckland**

23 February 2022