
Neuren Pharmaceuticals Limited
Appendix 4D Half-Year Financial Report

30 June 2022

Name of entity

Neuren Pharmaceuticals Limited

ABN

72 111 496 130

Half-year ended

30 June 2022

1. Reporting Period

Neuren Pharmaceuticals Limited (“Neuren” or the “Company”) presents this financial report, including the interim consolidated financial statements, for the six months ended 30 June 2022, with the six months ended 30 June 2021 as the comparative period.

2. Results for announcement to the market

	30 June 2022 \$'000	30 June 2021 \$'000	Movement %
2.1 Total income	283	234	21%
2.2 Loss after tax from ordinary activities	(7,054)	(7,964)	11%
2.3 Net loss attributable to members	(7,054)	(7,964)	11%
2.4 Dividends and franked amount per security	nil	nil	n/a
2.5 Dividend record date	n/a	n/a	n/a

2.6 Explanation of results:

The Group’s net loss after income tax for the half-year ended 30 June 2022 was \$7.0 million, compared with \$8.0 million for the half-year ended 30 June 2021. Research and development costs decreased by \$2.4 million, with the higher expenditure in 2021 mainly due to the NNZ-2591 Phase 1 clinical trial and manufacture of the drug for clinical trials and non-clinical studies. This was partially offset by an increase in corporate and administrative costs of \$0.8 million, due to appointment of new personnel and timing of insurance premiums, and by an increase in share-based payments expense of \$0.7 million following the issue of new share options issued in February 2022.

A more detailed discussion of the activities undertaken in the period is set out in the Directors’ Report contained in the attached Interim Report.

3. Net Tangible Assets per Security

	<u>June 2022</u>	<u>June 2021</u>
Net tangible assets per share	\$ 0.2659	\$ 0.1454 ¹

4. Entities over which control has been gained or lost during the period:

None.

5. Details of dividends

Not applicable.

6. Details of dividend reinvestment plans

Not applicable.

7. Details of associates and joint venture entities

None.

8. Accounting standards

The interim financial statements have been prepared in accordance with *International Accounting Standard 34* and *NZ IAS 34 Interim Financial Reporting*.

9. Auditors review

The interim financial statements have been subject to independent review by the Company's auditors. The unqualified review report is included in the attached Interim Report.

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

⁺ See chapter 19 for defined terms.

Neuren Pharmaceuticals Limited
ABN 72 111 496 130

Incorporated in New Zealand

Interim Financial Report for the Half-Year ended
30 June 2022

Directors' Report

The Directors submit the interim financial report of Neuren Pharmaceuticals Limited for the half-year ended 30 June 2022.

Directors' details

The names of Directors who held office during or since the end of the half-year are:

Patrick Davies (Non-Executive Chair)
Dr Trevor Scott (Non-Executive Director)
Dianne Angus (Non-Executive Director)
Dr Jenny Harry (Non-Executive Director)
Jonathan Pilcher (Managing Director)

Review of Operations

Neuren Pharmaceuticals Limited ("Neuren" or the "Company"), and its subsidiaries (collectively the "Group") is a biopharmaceutical company, incorporated in New Zealand and listed on the Australian Securities Exchange (ASX: NEU).

Neuren is developing two new drug therapies to treat multiple serious neurological 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.

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™ clinical 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). In July 2022, Acadia submitted a New Drug Application (NDA) to the FDA for trofinetide to treat Rett syndrome in patients aged 2 years and older. A NDA with Orphan Drug Designation is eligible for Priority Review in 6 months, compared with the standard review period of 10 months. The Review period commences when FDA formally accepts the NDA for review, which is due 60 days after its submission. Neuren therefore anticipates a decision on approval in March 2023, provided the NDA is accepted and receives Priority Review. 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 May 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.

If the NDA is approved by the FDA, Neuren expects to earn over 2022 and 2023 for Rett syndrome in the US alone A\$118 million plus double-digit percentage royalties on net sales. The expected earnings in addition to royalties comprise:

- A milestone payment in 2022 of US\$10 million (A\$14 million at assumed exchange rate of 0.70) following acceptance of the NDA for review by the FDA;
- A milestone payment in 2023 of US\$40 million (A\$57 million), following the first commercial sale of trofinetide in the United States; and
- US\$33 million (A\$47 million) in 2023 as Neuren's one third share of the market value of a Priority Review Voucher, estimated as US\$100 million.

Neuren's additional ongoing earnings from potential sales have two components:

- Double digit percentage royalties on net sales of trofinetide in all indications. The annual net sales are recorded in tiers and an escalating percentage is applied to each successive tier.
- Payments of up to US\$350 million (approximately A\$500 million) on achievement of a series of 4 thresholds of total annual net sales for all indications.

Directors' Report

Under the terms of the licence agreement with Acadia, Neuren retained all rights to trofinetide outside North America and has an 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 discussions are continuing.

In March 2022, Neuren received approval from the FDA for Investigational New Drug (IND) applications to commence Phase 2 clinical trials of NNZ-2591 for Phelan-McDermid syndrome (PMS), Angelman syndrome (AS) and Pitt Hopkins syndrome (PTHS). In July 2022, Neuren announced the commencement of its Phase 2 clinical trial of NNZ-2591 in AS. In August 2022, Neuren announced the commencement of Phase 2 clinical trials of NNZ-2591 for each of PMS and PTHS. Top-line results from all three trials are anticipated in H1 2023. Neuren is also planning a Phase 2 trial in a fourth disorder, Prader-Willi syndrome (PWS), with results targeted for H2 2023.

Based on its mechanism of action and positive results in animal models, NNZ-2591 has received Orphan Drug designation from the FDA in all four syndromes, which are serious neurodevelopmental disorders with no approved medicines. The estimated number of potential patients being targeted across these four disorders is more than five times larger than Rett syndrome. Neuren retains global rights to NNZ-2591.

The overall aim of these first trials is to expedite the generation of data that will enable the subsequent trials to be designed as registration trials. Prioritising fast enrolment of subjects, the AS trial is being conducted in Australia, whilst the PMS and PTHS trials are being conducted in the US. The open label Phase 2 trials will each enrol a single group of up to 20 children to examine safety, tolerability, pharmacokinetics and efficacy over 13 weeks of treatment with NNZ-2591. All subjects will receive NNZ-2591 as an oral liquid dose twice daily, with titration up to the target mg/kg during the first 6 weeks of treatment, subject to safety and tolerability. The treatment period is preceded by 4 weeks of observation to thoroughly examine the baseline characteristics prior to treatment, against which safety and efficacy will be assessed for each child. A follow up assessment will be made 2 weeks after the end of treatment.

The primary aim is to confirm the safety and pharmacokinetics of NNZ-2591 in pediatric patients. However, each trial will also assess the treatment impact across multiple efficacy measures to generate data to select the best primary efficacy endpoint or endpoints for the registration trials. The trials maximise the opportunity to demonstrate effects by focusing on pediatric patients and treating them for 13 weeks.

In order to expedite the overall development plan, in parallel with conducting the Phase 2 trials, Neuren is executing the additional development work required to be ready for Phase 3 development. This includes non-clinical toxicity studies to support longer clinical trials and commercial use of the product, as well as optimisation of the drug product and drug substance manufacturing arrangements.

The consolidated interim financial statements for the half-year are presented on pages 4 to 10. All amounts in the Financial Statements are shown in Australian dollars unless otherwise stated.

The Group's net loss after income tax for the half-year ended 30 June 2022 was \$7.0 million, compared with \$8.0 million for the half-year ended 30 June 2021. Research and development costs decreased by \$2.4 million, with the higher expenditure in 2021 mainly due to the NNZ-2591 Phase 1 clinical trial and manufacture of the drug for clinical trials and non-clinical studies. This was partially offset by an increase in corporate and administrative costs of \$0.8 million, due to appointment of new personnel and timing of insurance premiums, and by an increase in share-based payments expense of \$0.7 million following the issue of new share options issued in February 2022.

The net loss per share for the half-year to 30 June 2022 was \$0.056 (half-year to 30 June 2021: \$0.070) based on a weighted average number of shares outstanding of approximately 126 million (half-year to 30 June 2021: 114 million).

Cash reserves at 30 June 2022 were \$31.1 million (31 December 2021: \$36.8 million). Net cash used in operating activities was \$5.8 million (half-year to 30 June 2021: \$6.1 million).

Directors' Report

Directors' declaration

The Directors of Neuren Pharmaceuticals Limited ("Neuren") declare that:

The accompanying condensed consolidated financial statements of Neuren and its subsidiaries for the half-year ended 30 June 2022 and the notes to those condensed consolidated financial statements:

- comply with International Accounting Standard 34 and NZ IAS 34 *Interim Financial Reporting*; and
- present fairly, in all material respects, the financial position as at 30 June 2022 and of the performance for the half-year ended on that date of Neuren and its subsidiaries.

In the Directors' opinion there are reasonable grounds to believe that Neuren will be able to pay its debts as and when they become due and payable.

This report is signed and the declaration is made in accordance with a resolution of the Board of Directors dated 23 August 2022.

On behalf of the Board



Patrick Davies
Non-Executive Chair



Dr Trevor Scott
Director

Neuren Pharmaceuticals Limited

Consolidated Interim Statement of Comprehensive Income For the half-year ended 30 June 2022

	Note	Half-year ended	
		Jun 2022 \$'000	Jun 2021 \$'000
Interest		55	24
Foreign exchange gain		228	210
Total income		283	234
Research and development costs		(4,610)	(6,960)
Corporate and administrative costs		(1,577)	(821)
Share based payment expense		(1,150)	(417)
Loss before income tax		(7,054)	(7,964)
Income tax expense		-	-
Loss after income tax for the period		(7,054)	(7,964)
Other comprehensive expense, net of tax			
Amounts which may be reclassified to profit or loss:			
Exchange differences on translation of foreign operations		(17)	(12)
Total comprehensive loss for the period		(7,071)	(7,976)
Loss after tax attributable to Equity holders of the Company		(7,054)	(7,964)
Total comprehensive loss attributable to Equity holders of the Company		(7,071)	(7,976)
Basic and diluted loss per share	3	(\$0.056)	(\$0.070)

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Statement of Financial Position As at 30 June 2022

	As at 30 Jun 2022 \$'000	As at 31 Dec 2021 \$'000
ASSETS		
Current Assets:		
Cash and cash equivalents	31,088	36,783
Trade and other receivables	3,484	3,261
Total current assets	<u>34,572</u>	<u>40,044</u>
Non-current assets:		
Property, plant and equipment	18	12
Total non-current assets	<u>18</u>	<u>12</u>
TOTAL ASSETS	<u>34,590</u>	<u>40,056</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Trade and other payables	1,096	803
Total current liabilities	<u>1,096</u>	<u>803</u>
Total liabilities	<u>1,096</u>	<u>803</u>
EQUITY		
Share capital	167,740	167,578
Other reserves	(8,315)	(9,448)
Accumulated deficit	(125,931)	(118,877)
Total equity attributable to equity holders	<u>33,494</u>	<u>39,253</u>
TOTAL LIABILITIES AND EQUITY	<u>34,590</u>	<u>40,056</u>

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Statement of Changes in Equity For the half-year ended 30 June 2022

	Share Capital \$'000	Share Option Reserve \$'000	Currency Translation Reserve \$'000	Accumulated Deficit \$'000	Total \$'000
Equity as at 1 January 2021	145,567	394	(10,678)	(111,083)	24,200
Share based payments	-	417	-	-	417
Transactions with owners	-	417	-	-	417
Loss after income tax	-	-	-	(7,964)	(7,964)
Other comprehensive expense	-	-	(12)	-	(12)
Total comprehensive income for the period	-	-	(12)	(7,964)	(7,976)
Equity as at 30 June 2021	145,567	811	(10,690)	(119,047)	16,641
Equity as at 1 January 2022	167,578	1,234	(10,682)	(118,877)	39,253
Reversal of share issue costs	162	-	-	-	162
Share based payments	-	1,150	-	-	1,150
Transactions with owners	162	1,150	-	-	1,312
Loss after income tax	-	-	-	(7,054)	(7,054)
Other comprehensive expense	-	-	(17)	-	(17)
Total comprehensive income for the period	-	-	(17)	(7,054)	(7,071)
Equity as at 30 June 2022	167,740	2,384	(10,699)	(125,931)	33,494

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Cash Flow Statement For the half-year ended 30 June 2022

	Half-year ended	
	Jun 2022 \$'000	Jun 2021 \$'000
Cash flows from operating activities:		
Interest received	33	33
GST refunded	132	149
Payments for employees and directors	(1,275)	(784)
Payments to other suppliers	(4,706)	(5,543)
Net cash used in operating activities	(5,816)	(6,145)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(10)	(8)
Net cash used in investing activities	(10)	(8)
Cash flows from financing activities:		
Payment of share issue expenses	(2)	-
Net cash used in financing activities	(2)	-
Net decrease in cash	(5,828)	(6,153)
Effect of exchange rate changes on cash balances	133	185
Cash and cash equivalents at the beginning of the period	36,783	24,188
Cash and cash equivalents at the end of the period	31,088	18,220
Reconciliation with loss after income tax:		
Loss after income tax	(7,054)	(7,964)
<i>Non-cash items requiring adjustment:</i>		
Depreciation of property, plant and equipment	4	4
Share based payments expense	1,150	417
Foreign exchange gain	(149)	(197)
Movements in working capital	233	1,595
Net cash used in operating activities	(5,816)	(6,145)

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Interim Financial Statements For the half-year ended 30 June 2022

1. Nature of the business

Neuren Pharmaceuticals Limited (“Neuren” or the “Company”), and its subsidiaries (collectively the “Group”) is a biopharmaceutical company developing new drug therapies to treat multiple serious neurodevelopmental disorders with high unmet need.

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 operates in Australia and its ordinary shares are listed on the Australian Securities Exchange (ASX code: NEU).

These consolidated interim financial statements were approved for issue by the Board of Directors on 23 August 2022.

2. Summary of significant accounting policies

Basis of preparation

These condensed consolidated interim financial statements are for the half-year ended 30 June 2022 and have been prepared in accordance with, and comply with International Accounting Standard 34 and NZ IAS 34 *Interim Financial Reporting*.

The Group is a Tier 1 for-profit entity under the External Reporting Board Accounting Standards Framework in New Zealand.

No new Standards were adopted in the current year.

There have been no significant changes in accounting policies during the current period. The accounting policies that materially affect the measurement of the Consolidated Statement of Comprehensive Income, Consolidated Statement of Financial Position, Consolidated Statement of Changes in Equity and the Consolidated Statement of Cash Flows have been applied on a basis consistent with those used in the audited financial statements for the year ended 31 December 2021 and the unaudited interim financial statements for the half-year ended 30 June 2022. There is no cyclical seasonality of interim operations.

The functional and presentation currency of the Group is Australian dollars.

These interim financial statements do not include all the notes of the type normally included in an annual financial report. Accordingly, this interim report is to be read in conjunction with the annual report for the year ended 31 December 2021.

Going concern assumption

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 \$7.0 million for the period ended 30 June 2022 and had negative operating cash flows for the period of \$5.8 million. The Group had cash of \$31.1 million at 30 June 2022.

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 the financial statements. The 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 trofinetide or 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.

Key judgements and estimates

The preparation of financial statements requires management to make judgements and estimates. Cash and cash equivalents include term deposits of \$27.2 million with 3-month or less maturities which are held to meet short-term cash commitments, rather than for investment or other purposes.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Interim Financial Statements For the half-year ended 30 June 2022

3. Loss per share

	Jun-22	Jun-21
Consolidated		
Loss after income tax attributable to equity holders (\$'000)	(7,054)	(7,964)
Weighted average shares outstanding (basic and diluted) (No.)	125,965,676	114,486,011
Basic and diluted loss per share	(\$0.056)	(\$0.070)

4. Share capital

	Half-year Jun-22	Year Dec-21
Consolidated	Shares	Shares
Issued share capital		
Ordinary shares on issue at beginning of period	128,965,676	117,608,108
Shares issued in private placement	-	9,756,098
Shares issued in Share Purchase Plan	-	1,601,470
Ordinary shares on issue at end of period	128,965,676	128,965,676

Issued ordinary shares comprised 125,965,676 shares quoted on the Australian Securities Exchange and 3,000,000 treasury shares held in trust under a Loan Funded Share plan.

Share based payments

During the half-year to 30 June 2022 \$1.2 million (30 June 2021: \$0.4 million) was recognised in share-based payments expense.

3.0 million unvested Loan Funded Shares are held in trust for Key Management Personnel (KMP). The exercise price for these unvested Loan Funded Shares is \$1.84 per share.

On 3 February 2022, options to acquire 1,450,000 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
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%
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%

Each of these vesting conditions shall be tested separately from the other vesting conditions.

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, a dividend yield of 0%, an expected life of 2.75 years, and an annual risk-free interest rate of 1.40%. 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 of 3 February 2022, as this period is reflective of the anticipated volatility in the future.

Neuren Pharmaceuticals Limited

Notes to the Consolidated Interim Financial Statements For the half-year ended 30 June 2022

4. Share capital (continued)

Details of the options to acquire ordinary shares during the half year ended 30 June 2022, the estimated fair value and variable inputs into the valuation model are shown in the following table:

Number of shares under option	1,450,000
Issue date	3 February 2022
Exercise price per share option ¹	\$3.46
Share price on date of valuation	\$3.90
Fair value per share option	\$2.03
Estimated future volatility	77.58%

¹ 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.

5. Commitments and contingencies

(a) Legal claims

The Group had no significant legal matter contingencies at 30 June 2022 or 30 June 2021.

(b) Commitments

The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 30 June 2022 (30 June 2021: nil).

As at 30 June 2022, the Group had commitments under product development contracts at the end of the reporting period but not recognised as liabilities amounting to approximately \$7.4 million, comprising approximately US \$4.5 million, GBP 0.2 million and AU \$0.6 million.

(c) Contingent liabilities

The Group had no contingent liabilities at 30 June 2022 or at 30 June 2021 that require disclosure.

6. Key management personnel

Key management personnel remuneration is disclosed in the annual financial report.

During the half-year ended 30 June 2022, 750,000 share options were issued to key management personnel.

7. Segment information

The Group has a single reportable segment and internal management reporting systems present financial information as a single segment. The segment is involved in the development of pharmaceutical products. The Board of the Company has been identified as the chief operation decision maker. The Board assesses the financial performance and position of the Group and makes strategic decisions.

8. Events after balance date

As at the date of approving these consolidated interim financial statements there are no events arising since 30 June 2022 that require disclosure.

Independent Review Report

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To the Shareholders of Neuren Pharmaceuticals Limited

Report on the Condensed Consolidated Interim Financial Statements

We have reviewed the accompanying condensed consolidated interim financial statements of Neuren Pharmaceuticals Limited and its subsidiaries (the 'Group') on pages 4 to 10 which comprise the consolidated interim statement of financial position as at 30 June 2022, and the consolidated interim statement of comprehensive income, consolidated interim statement of changes in equity and consolidated interim cash flow statement for the six month period then ended, and notes to the condensed consolidated interim financial statements, including a summary of significant accounting policies.

Director's Responsibility for the condensed consolidated Interim Financial Statements

The Directors are responsible for the preparation and fair presentation of these condensed consolidated interim financial statements in accordance with New Zealand equivalents to International Accounting Standard 34 *Interim Financial Reporting* ('NZ IAS 34'), issued in New Zealand by the New Zealand Accounting Standards Board, and for such internal control as the Directors determine is necessary to enable the preparation and fair presentation of condensed consolidated interim financial statements that are free from material misstatement, whether due to fraud or error.

Our Responsibility

Our responsibility is to express a conclusion on the condensed consolidated interim financial statements based on our review. We conducted our review in accordance with NZ SRE 2410, *Review of Financial Statements Performed by the Independent Auditor of the Entity*. NZ SRE 2410 requires us to conclude whether anything has come to our attention that causes us to believe that the condensed consolidated interim financial statements, taken as a whole, are not prepared in all material respects, in accordance with NZ IAS 34. As the auditor of Neuren Pharmaceuticals Limited, NZ SRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual consolidated financial statements.

A review of condensed consolidated interim financial statements in accordance with NZ SRE 2410 is a limited assurance engagement. The auditor performs procedures, primarily consisting of making enquiries of management and others within the entity, as appropriate and applying analytical procedures, and evaluates the evidence obtained.

The procedures performed in a review are substantially less than those performed in an audit conducted in accordance with International Standards on Auditing (New Zealand). Accordingly, we do not express an audit opinion on these condensed consolidated interim financial statements.

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

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that these condensed consolidated interim financial statements on pages 4 to 10 do not present fairly, in all material respects, the consolidated interim financial position of Neuren Pharmaceuticals Limited as at 30 June 2022, and its consolidated interim financial performance and consolidated interim cash flows for the six month period then ended, in accordance with NZ IAS 34.

Restriction on use of our report

This report on the condensed consolidated interim financial statements is made solely to the shareholders, as a body. Our limited assurance work has been undertaken so that we might state to the shareholders, as a body those matters which we are required to state to them in an independent review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than Neuren Pharmaceuticals Limited and the shareholders, as a body, for our work, for this report or for the conclusion we have formed.

Grant Thornton New Zealand Audit Limited**Ryan Campbell**

Partner

Auckland**23rd August 2022**