Neuren Pharmaceuticals Limited

Appendix 4D Half-Year Financial Report

30 June 2021

Name of entity

Neuren Pharmaceuticals Limited

ABN

72 111 496 130

Half-year ended

30 June 2021

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 2021, with the six months ended 30 June 2020 as the comparative period.

2. Results for announcement to the market

		30 June 2021 $'000	30 June 2020 $'000	Movement %
2.1	Operating revenue	234	554	(58%)
2.2	Loss after tax from ordinary activities	(7,964)	(4,761)	(67%)
2.3	Net loss attributable to members	(7,964)	(4,761)	(67%)
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 tax for the half-year ended 30 June 2021 was $8.0 million, compared with $4.8 million for the half-year ended 30 June 2020, predominately due to an increase of $2.3 million in research and development costs. The higher expenditure in 2021 was mainly due to the NNZ-2591 Phase 1 and Phase 2 clinical trials, manufacture of the drug for clinical trials and non-clinical studies. In addition, share-based payments expense for the half-year ended 30 June 2021 was $0.4m, compared with nil for 2020, while foreign exchange gains decreased by $0.2 million.

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

	June 2021	June 2020
Net tangible assets per share	$ 0.1415	$ 0.0886

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 generally accepted accounting practice in New Zealand 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.

Neuren Pharmaceuticals Limited

ABN 72 111 496 130

Incorporated in New Zealand

Interim Financial Report for the Half-Year ended 30 June 2021

Directors' Report

The Directors submit the interim financial report of Neuren Pharmaceuticals Limited for the half-year ended 30 June 2021.

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) (Appointed 14 June 2021)

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, none of which have any approved medicines. Neuren's potential therapies utilize synthetic analogs of neurotrophic peptides that occur naturally in the brain.

The lead drug compound, Trofinetide, is currently in a Phase 3 clinical trial in the United States for Rett syndrome and has completed a Phase 2 clinical trial in Fragile X syndrome. Both programs have each received Fast Track designation by the US Food and Drug Administration (FDA) and Orphan Drug designation in both the United States and the European Union. Neuren has granted an exclusive license to Acadia Pharmaceuticals Inc. (Acadia) for the development and commercialization of trofinetide in North America, whilst retaining all rights outside North America. The development and commercialisation of trofinetide in North America is fully funded by Acadia and Neuren is eligible to 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 New Drug Application for trofinetide. In addition, Neuren has free and full access to all data for use in countries outside North America. Positive results from the Phase 3 trial should enable Neuren to commercialise trofinetide in Europe and Asia, as well as enabling a New Drug Application in the US.

During the 6 months to 30 June 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 and Pitt Hopkins syndromes.

Neuren continues to drive towards the three key drivers of future value:

The Rett syndrome Phase 3 program involves treatment of approximately 180 females aged 5 to 20 with trofinetide or placebo for 12 weeks to evaluate efficacy and safety (the "LAVENDER" study), following which patients are eligible to continue treatment with trofinetide for 40 weeks to provide longer-term safety data (the "LILAC" study). Acadia recently completed enrolment of subjects and top-line results from the LAVENDER study are expected in Q4 of 2021. Positive results potentially will enable a New Drug Application to the FDA, which should be eligible for "Priority Review" in an abbreviated period of 6 months.

Neuren is preparing to start Phase 2 clinical trials of NNZ-2591 for Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome, each of which has no approved therapy. Based on its mechanism of action and positive results in animal models, NNZ-2591 has received Orphan Drug designation from the FDA and the European Medicines Agency for each of these three disorders. A fourth disorder, Prader-Willi syndrome was also added to the development pipeline in February 2021 following compelling positive results in a pre-clinical model of the syndrome.

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

Directors' Report

have also been completed. In June 2021, Neuren conducted three pre- Investigational New Drug (IND) meetings with the FDA Office of Neuroscience to discuss the proposed Phase 2 clinical trials for NNZ-2591 in pediatric patients with each of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome. The clear and constructive guidance from the FDA enabled Neuren to proceed with preparing IND applications for clearance to start the trials. Subject to that clearance, the Phase 2 trials will commence as planned in H2 2021.

The consolidated interim financial statements for the half-year are presented on pages 3 to 8. 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 2021 was $8.0 million, compared with $4.8 million for the half-year ended 30 June 2020, predominately due to an increase of $2.3 million in research and development costs. The higher expenditure in 2021 was mainly due to the NNZ-2591 Phase 1 and Phase 2 clinical trials, manufacture of the drug for clinical trials and non-clinical studies. In addition, share-based payments expense for the half-year ended 30 June 2021 was $0.4m, compared with nil for 2020, while foreign exchange gains decreased by $0.2 million.

The net loss per share for the half-year to 30 June 2021 was $0.070 (half-year to 30 June 2020: $0.048) based on a weighted average number of shares outstanding of approximately 114 million (half-year to 30 June 2020: 100 million).

Cash reserves at 30 June 2021 were $18.2 million (31 December 2020: $24.2 million). Net cash used in operating activities was $6.1 million (half-year to 30 June 2020: $5.1 million). The increase of $1.0 million was mainly in payments to other suppliers, due to the higher research and development expenditure.

Corporations Act, Australia - Directors' declaration

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

The accompanying financial statements of Neuren and its subsidiaries for the half-year ended 30 June 2021 and the notes to those financial statements:

- comply with the XRB A1 (Tier 1) standards issued by the New Zealand Accounting Standards Review Board for for-profit reporting entities; and
- present fairly, in all material respects, the financial position as at 30 June 2021 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 24 August 2021.

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 2021

	Note	Half-year ended Jun 2021 $'000	Jun 2020 $'000
Interest		24	85
Foreign exchange gain		210	419
Other income		-	50
Total income		234	554
Research and development costs		(6,585)	(4,236)
Corporate and administrative costs		(1,196)	(1,079)
Share based payment expense		(417)	-
Loss before income tax		(7,964)	(4,761)
Income tax expense		-	-
Loss after income tax for the period		(7,964)	(4,761)
Other comprehensive expense, net of tax			
Amounts which may be reclassified to profit or loss:			
Exchange differences on translation of foreign operations		(12)	7
Total comprehensive loss for the period		(7,976)	(4,754)
Loss after tax attributable to Equity holders of the Company		(7,964)	(4,761)
Total comprehensive loss attributable to Equity holders of the Company		(7,976)	(4,754)
Basic and diluted loss per share	3	($0.070)	($0.048)

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Statement of Financial Position
As at 30 June 2021

	As at 30 Jun 2021 $'000	As at 31 Dec 2020 $'000
ASSETS		
Current Assets:		
Cash and cash equivalents	18,220	24,188
Trade and other receivables	762	755
Total current assets	18,982	24,943
Non-current assets:		
Property, plant and equipment	14	10
Total non-current assets	14	10
TOTAL ASSETS	18,996	24,953
LIABILITIES AND EQUITY		
Current liabilities:		
Trade and other payables	2,355	753
Total current liabilities	2,355	753
Total liabilities	2,355	753
EQUITY		
Share capital	145,567	145,567
Other reserves	(9,879)	(10,284)
Accumulated deficit	(119,047)	(111,083)
Total equity attributable to equity holders	16,641	24,200
TOTAL LIABILITIES AND EQUITY	18,996	24,953

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 2021

	Share Capital $'000	Share Option Reserve $'000	Currency Translation Reserve $'000	Accumulated Deficit $'000	Total $'000
Equity as at 1 January 2020	126,426	2,186	(10,689)	(104,076)	13,847
Expired options	-	(2,186)	-	2,186	-
Transactions with owners	-	(2,186)	-	2,186	-
Loss after income tax	-	-	-	(4,761)	(4,761)
Other comprehensive expense	-	-	7	-	7
Total comprehensive income for the period	-	-	7	(4,761)	(4,754)
Equity as at 30 June 2020	126,426	-	(10,682)	(106,651)	9,093
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

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Cash Flow Statement
For the half-year ended 30 June 2021

	Half-year ended	
	Jun 2021 $'000	Jun 2020 $'000
Cash flows from operating activities:		
Receipts from government grants and tax incentives	-	50
Interest received	33	106
GST refunded	149	123
Payments for employees and directors	(784)	(757)
Payments to other suppliers	(5,543)	(4,668)
Net cash flow used in operating activities	**(6,145)**	**(5,146)**
Cash flows from investing activities:		
Purchase of property, plant and equipment	(8)	(6)
Net cash used in investing activities	**(8)**	**(6)**
Cash flows from financing activities:		
Proceeds from the issue of shares	-	144
Net cash provided from financing activities	**-**	**144**
Net decrease in cash	**(6,153)**	**(5,008)**
Effect of exchange rate changes on cash balances	185	336
Cash and cash equivalents at the beginning of the period	24,188	13,844
Cash and cash equivalents at the end of the period	**18,220**	**9,172**
Reconciliation with loss after income tax:		
Loss after income tax	(7,964)	(4,761)
Non-cash items requiring adjustment:		
Depreciation of property, plant and equipment	4	3
Share based payments expense	417	-
Foreign exchange gain	(197)	(329)
Movements in working capital	1,595	(59)
Net cash used in operating activities	**(6,145)**	**(5,146)**

The accompanying notes form part of this financial statement.

Notes to the Consolidated Interim Financial Statements
For the half-year ended 30 June 2021

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 PwC 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 24 August 2021.

2. Summary of significant accounting policies

Basis of preparation

These general-purpose consolidated interim financial statements are for the half-year ended 30 June 2021 and have been prepared in accordance with, and comply with, generally accepted accounting practice in New Zealand, 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.

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 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 2020 and the unaudited interim financial statements for the half-year ended 30 June 2021. 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 2020.

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 $8.0 million for the period ended 30 June 2021 and had negative operating cash flows for the period of $6.1 million. The Group had cash of $18.2 million at 30 June 2021.

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. In the United States, enrolment of new patients in the trofinetide Phase 3 LAVENDER study was re-initiated in June 2020 after it was temporarily paused by ACADIA in March 2020 due to COVID-19 restrictions and risks. 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.

Notes to the Consolidated Interim Financial Statements
For the half-year ended 30 June 2021

3. Loss per share

Consolidated	Jun-21	Jun-20
Loss after income tax attributable to equity holders ($'000)	(7,964)	(4,761)
Weighted average shares outstanding (basic and diluted) (No.)	114,486,011	100,168,413
Basic and diluted loss per share	($0.070)	($0.048)

4. Share capital

Consolidated	Half-year Jun-21 Shares	Year Dec-20 Shares
Issued share capital		
Ordinary shares on issue at beginning of period	117,608,108	102,668,413
Shared 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	-	14,285,723
Shares issued in Share Purchase Plan	-	153,972
Ordinary shares on issue at end of period	117,608,108	117,608,108

Issued ordinary shares comprised 114,608,108 shares quoted on the Australian Securities Exchange and 3,000,000 unquoted shares held in trust under a Loan Funded Share plan.

Loan Funded Shares
During the half-year to 30 June 2021, $0.4 million was recognised in share-based payments expense, in respect of the 3.0 million unvested Loan Funded Shares held in trust for Key Management Personnel (KMP).

5. Commitments and contingencies

(a) Legal claims
The Group had no significant legal matter contingencies at 30 June 2021 or 30 June 2020.

(b) Commitments
The Group was not committed to the purchase of any property, plant or equipment or intangible assets as at 30 June 2021 (30 June 2020: nil).

As at 30 June 2021, the Group had commitments under product development contracts at the end of the reporting period but not recognised as liabilities amounting to approximately $7.5 million, comprising approximately US $4.4 million, GBP 0.2 million and AU $1.3 million.

(c) Contingent liabilities
The Group had no contingent liabilities at 30 June 2021 or at 30 June 2020 that require disclosure.

6. 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 from 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.

7. Events after balance date
As at the date of approving these consolidated interim financial statements there are no events arising since 30 June 2021 that require disclosure.

Independent Review Report

Grant Thornton New Zealand Audit Limited
L4, Grant Thornton House
152 Fanshawe Street
P O Box 1961
Auckland 1140

T +64 9 308 2570

www.grantthornton.co.nz

To the Shareholders of Neuren Pharmaceuticals Limited

Report on the Consolidated Interim Financial Statements

We have reviewed the accompanying consolidated interim financial statements of Neuren Pharmaceuticals Limited and its subsidiaries (the Group) on pages 3 to 8 which comprise the consolidated interim statement of financial position as at 30 June 2021, and the consolidated interim statement of comprehensive income, consolidated interim statement of changes in equity and consolidated interim statement of cash flows for the six months then ended, and notes to the financial statements, including a summary of significant accounting policies.

Director's Responsibility for the consolidated Interim Financial Statements

The Directors are responsible for the preparation and fair presentation of these consolidated interim financial statements in accordance with New Zealand Equivalents to International Financial Reporting Standard 34 *Interim Financial Reporting* (NZ IAS 34), and for such internal control as the Directors determine is necessary to enable the preparation and fair presentation of 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 consolidated interim financial statements based on our review. We conducted our review in accordance NZ SRE 2410, *Review of Historical 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 consolidated 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 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 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 consolidated interim financial statements on pages 3 to 8 do not present fairly, in all material respects, the consolidated interim financial position of Neuren Pharmaceuticals Limited as at 30 June 2021, and its consolidated interim financial performance and consolidated interim cash flows for the six month period then ended, in accordance with NZ IAS 34.

Grant Thornton New Zealand Audit Limited

Grant Thornton

Ryan Campbell
Partner
Auckland

24 August 2021