Neuren Pharmaceuticals Limited

Appendix 4D Half-Year Financial Report

30 June 2020

Name of entity

Neuren Pharmaceuticals Limited

ABN

72 111 496 130

Half-year ended

30 June 2020

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 2020, with the six months ended 30 June 2019 as the comparative period.

2. Results for announcement to the market

		30 June 2020 $'000	30 June 2019 $'000	% Change
2.1	Operating revenue	554	283	96%
2.2	Loss after tax from ordinary activities	(4,761)	(7,885)	40%
2.3	Net loss attributable to members	(4,761)	(7,885)	40%
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 2020 was $4.8 million, compared with $7.9 million for the half-year ended 30 June 2019, predominately due to a decrease of $2.7 million in research and development costs. This was due to lower expenditure for manufacturing and non-clinical activities relating to the Rett Syndrome Phase 3 trial, partially offset by an increase in expenditure in 2020 for the NNZ-2591 non-clinical studies and Phase 1 trial, including manufacture of the required drug.

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 2020	June 2019
Net tangible assets per share	$ 0.0886	$ 0.1634

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 2020

Directors' Report

The Directors submit the interim financial report of Neuren Pharmaceuticals Limited for the half-year ended 30 June 2020.

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)
Dr Richard Treagus (Executive Chair - Resigned 26 May 2020)

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 new therapies for five neurodevelopmental disorders that emerge in early childhood and are characterized by impaired connections and signalling between brain cells. No approved therapies are currently available for these debilitating disorders. Neuren's potential therapies utilize synthetic analogs of neurotrophic peptides that occur naturally in the brain. 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. The 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. Neuren is advancing the development of its second drug candidate NNZ-2591 for Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndromes. Based on its mechanism of action and positive results in animal models, NNZ-2591 has received Orphan Drug designation from the FDA for each of these disorders.

During the 6 months to 30 June 2020, 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.

ACADIA commenced the Rett syndrome Phase 3 program in October 2019. The 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). Results from the LAVENDER study are expected in the second half of 2021. Positive results potentially will enable a New Drug Application, which should be eligible for "Priority Review" by the FDA in an abbreviated period of 6 months. ACADIA has also established "LILAC-2" under which eligible patients who complete LAVENDER and LILAC will be able to continue to receive trofinetide during the period before marketing approval. Enrolment of new patients in LAVENDER was paused temporarily in March 2020, due to the measures taken in the US to combat the COVID-19 pandemic. Enrolment was re-initiated in June 2020.

In March 2020, the FDA granted Rare Pediatric Disease (RPD) designation to trofinetide for the treatment of Rett syndrome. Upon FDA approval of a product with RPD designation, the sponsor may be eligible to receive a Priority Review Voucher, which can be used to obtain FDA review of a New Drug Application for another product in an expedited period of six months. The voucher may also be sold for use by another company. Under the terms of the Licence Agreement between Neuren and ACADIA, Neuren will receive from ACADIA one third of the market value of a Priority Review Voucher. In January 2020, the Report to Congressional Committees on FDA's Priority Review Voucher Programs noted that vouchers were sold in April 2019 and July 2019 for US$105 million and US$95 million respectively.

Neuren commenced its first clinical trial of NNZ-2591 in May 2020. The Phase 1 trial, conducted in Australia, will assess safety, tolerability and pharmacokinetics in healthy adult volunteers. In addition, Neuren continued to execute a program of non-clinical studies for NNZ-2591. Data from these studies and the Phase 1 trial will form part of the Investigational New Drug (IND) application to the FDA in order to proceed with Phase 2 trials in 2021.

In April 2020 a new patent was granted by the Israel Patent Office covering trofinetide to treat Rett syndrome, Fragile X syndrome and autism. This first patent for trofinetide in Israel expires in 2032, with the potential for patent term extension of up to 5 years.

In May 2020 Neuren announced the appointment of Jon Pilcher and Patrick Davies as Chief Executive Officer and non-executive Chair respectively, with Richard Treagus standing down after more than 7 years as Executive Chairman to enable him to focus on his other business interests.

Directors' Report

There are three key value-drivers for Neuren that may potentially crystallise over the next two years:

- ACADIA's Rett syndrome Phase 3 results and New Drug Application for trofinetide in the US;
- Selecting the optimum commercial outcome for trofinetide outside North America using the US regulatory package; and
- Phase 2 clinical results for NNZ-2591 to confirm the positive effects seen in the animal models of all three indications.

The consolidated interim financial statements for the half-year are presented on pages 3 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 2020 was $4.8 million, compared with $7.9 million for the half-year ended 30 June 2019, predominately due to a decrease of $2.7 million in research and development costs. This was due to lower expenditure for manufacturing and non-clinical activities relating to the Rett Syndrome Phase 3 trial, partially offset by an increase in expenditure in 2020 for the NNZ-2591 non-clinical studies and Phase 1 trial, including manufacture of the required drug. In addition, foreign exchange gains increased by $0.4 million and there was no amount recognised in the half-year ended 2020 (2019: $0.3 million) on the fair value of the remaining settlements from the Sharing Agreement with Lanstead Capital which concluded in June 2019.

The net loss per share for the half-year to 30 June 2020 was $0.048 (half-year to 30 June 2019: $0.079) based on a weighted average number of shares outstanding of approximately 100 million (half-year to 30 June 2019: 100 million).

Cash reserves at 30 June 2020 were $9.2 million (31 December 2019: $13.8 million). Net cash used in operating activities was $5.1 million (half-year to 30 June 2019: $7.9 million). The decrease of $2.8 million was mainly in payments to other suppliers, due to the lower research and development expenditure.

Cash generated from financing activities was $0.1 million, received for subscription of new ordinary shares in the capital raise. The remaining funds from the capital raise were received after 30 June 2020 when the new ordinary shares were issued (see further details below). For the half-year to 30 June 2019, cash generated from financing activities was $1.6 million, received from settlements from the Sharing Agreement with Lanstead Capital.

On 29 June 2020, the Group announced the successful completion of a capital raise of $20 million, with $19 million net of costs received after 30 June 2020. On 6 July 2020, the Group issued 14,285,723 fully paid ordinary shares at an issue price of $1.40 per share to institutional and sophisticated investors in Australia, New Zealand, Hong Kong and the United Kingdom. The funds raised will enable the Group to fund plans to generate valuable Phase 2 clinical trial data for NNZ-2591.

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 2020 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 2020 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 25 August 2020.

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 2020

	Note	Half-year ended Jun 2020 $'000	Jun 2019 $'000
Interest		85	235
Foreign exchange gain		419	48
Other income		50	-
Total income		554	283
Research and development costs		(4,236)	(6,939)
Corporate and administrative costs		(1,079)	(968)
Loss on financial assets measured at fair value through profit or loss		-	(261)
Loss before income tax		(4,761)	(7,885)
Income tax expense		-	-
Loss after income tax for the period		(4,761)	(7,885)
Other comprehensive expense, net of tax			
Amounts which may be reclassified to profit or loss:			
Exchange differences on translation of foreign operations		7	(6)
Total comprehensive loss for the period		(4,754)	(7,891)
Loss after tax attributable to Equity holders of the Company		(4,761)	(7,885)
Total comprehensive loss attributable to Equity holders of the Company		(4,754)	(7,891)
Basic and diluted loss per share	3	($0.048)	($0.079)

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Statement of Financial Position
As at 30 June 2020

	As at 30 Jun 2020 $'000	As at 31 Dec 2019 $'000
ASSETS		
Current Assets:		
Cash and cash equivalents	9,172	13,844
Trade and other receivables	509	552
Total current assets	9,681	14,396
Non-current assets:		
Property, plant and equipment	13	10
Total non-current assets	13	10
TOTAL ASSETS	9,694	14,406
LIABILITIES AND EQUITY		
Current liabilities:		
Trade and other payables	601	559
Total current liabilities	601	559
Total liabilities	601	559
EQUITY		
Share capital	126,426	126,426
Other reserves	(10,682)	(8,503)
Accumulated deficit	(106,651)	(104,076)
Total equity attributable to equity holders	9,093	13,847
TOTAL LIABILITIES AND EQUITY	9,694	14,406

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 2020

	Share Capital AUD$'000	Share Option Reserve AUD$'000	Currency Translation Reserve AUD$'000	Accumulated Deficit AUD$'000	Total AUD$'000
Equity as at 1 January 2019	126,426	2,186	(10,683)	(93,260)	24,669
Loss after income tax	-	-	-	(7,885)	(7,885)
Other comprehensive expense	-	-	(6)	-	(6)
Total comprehensive income for the period	-	-	(6)	(7,885)	(7,891)
Equity as at 30 June 2019	126,426	2,186	(10,689)	(101,145)	16,778
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

The accompanying notes form part of this financial statement.

Neuren Pharmaceuticals Limited

Consolidated Interim Cash Flow Statement
For the half-year ended 30 June 2020

	Half-year ended	
	Jun 2020	Jun 2019
	$'000	$'000
Cash flows from operating activities:		
Receipts from government grants and tax incentives	50	-
Interest received	106	235
GST refunded	123	47
Payments for employees and directors	(757)	(763)
Payments to other suppliers	(4,668)	(7,418)
Net cash flow used in operating activities	**(5,146)**	**(7,899)**
Cash flows from investing activities:		
Purchase of property, plant and equipment	(6)	(12)
Net cash used in investing activities	**(6)**	**(12)**
Cash flows from financing activities:		
Proceeds from the issue of shares	144	1,566
Net cash provided from financing activities	**144**	**1,566**
Net decrease in cash	**(5,008)**	**(6,345)**
Effect of exchange rate changes on cash balances	336	37
Cash and cash equivalents at the beginning of the period	13,844	13,844
Cash and cash equivalents at the end of the period	**9,172**	**7,536**
Reconciliation with loss after income tax:		
Loss after income tax	(4,761)	(7,885)
Non-cash items requiring adjustment:		
Depreciation of property, plant and equipment	3	3
Foreign exchange gain	(329)	(41)
Loss on financial assets	-	261
Movements in working capital	(59)	(237)
Net cash used in operating activities	**(5,146)**	**(7,899)**

The accompanying notes form part of this financial statement.

Notes to the Consolidated Interim Financial Statements
For the half-year ended 30 June 2020

1. Nature of the business

Neuren Pharmaceuticals Limited ("Neuren" or the "Company"), and its subsidiaries (collectively the "Group") is a biopharmaceutical company developing drugs to treat 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 25 August 2020.

2. Summary of significant accounting policies

Basis of preparation

These general-purpose consolidated interim financial statements are for the half-year ended 30 June 2020 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 2019 and the unaudited interim financial statements for the half-year ended 30 June 2020. 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 2019.

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 $4.8 million for the period ended 30 June 2020 and had negative operating cash flows for the period of $5.1 million. The Group had cash of $9.2 million at 30 June 2020.

On 29 June 2020, the Group announced the successful completion of a capital raise of $20 million, with $19 million net of costs received after 30 June 2020. On 6 July 2020, the Group issued 14,285,723 fully paid ordinary shares at an issue price of $1.40 per share to institutional and sophisticated investors in Australia, New Zealand, Hong Kong and the United Kingdom. The funds raised will enable the Group to fund plans to generate Phase 2 clinical trial data for NNZ-2591.

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.

3. Loss per share

Consolidated	Jun-20	Jun-19
Loss after income tax attributable to equity holders ($'000)	(4,761)	(7,885)
Weighted average shares outstanding (basic and diluted) (No.)	100,168,413	100,168,413
Basic and diluted loss per share	($0.048)	($0.079)

4. Share capital

Consolidated	Half-year Jun-20 Shares	Year Dec-19 Shares
Issued share capital		
Ordinary shares on issue at beginning and end of period	102,668,413	102,668,413

Issued ordinary shares comprised 100,168,413 shares quoted on the Australian Securities Exchange and 2,500,000 unquoted shares held in trust under a Loan Funded Share plan.

In respect of 1,500,000 Loan Funded Shares, which had an exercise price of $1.84 per share, the loans expired on 30 May 2019 and the shares were forfeited. In respect of 1,000,000 Loan Funded Shares, for which the exercise price is $1.64 per share, the loans expired on 7 May 2020 and the shares were forfeited. The balance of the share option reserve in respect of these Loan Funded Shares has been transferred to retained earnings at 30 June 2020. On 14 July 2020 these shares were bought back by the Group and cancelled. In accordance with the terms of the Loan Funded Share Plan, the consideration for the shares bought back was equal to the outstanding loan balances.

5. Commitments and contingencies

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

(b) Commitments
As at 30 June 2020, the Group had commitments under product development contracts at the end of the reporting period but not recognised as liabilities amounting to approximately $5.4 million, comprising approximately US $2.4 million, GBP 0.5 million and AU $1.0 million.

(c) Contingent liabilities
The Group had no contingent liabilities at 30 June 2020 or at 30 June 2019 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.

Notes to the Consolidated Interim Financial Statements
For the half-year ended 30 June 2020

7. Events after balance date

On 29 June 2020, the Group announced the successful completion of a capital raise of $20 million, with $19 million net of costs received after 30 June 2020. On 6 July 2020, the Group issued 14,285,723 fully paid ordinary shares at an issue price of $1.40 per share to institutional and sophisticated investors in Australia, New Zealand, Hong Kong and the United Kingdom.

Following approval at the Annual Shareholders' Meeting, on 13 July 2020, the Group issued 3 million unquoted ordinary shares to Neuren Trustee limited under the Loan Funded Share Plan at an issue price of $1.84 per share.

As disclosed in Note 4 above, on 14 July 2020, the Group bought back and cancelled 2.5 million forfeited Loan Funded Shares.

As at the date of approving these consolidated interim financial statements there are no events other than those mentioned above arising since 30 June 2020 that require disclosure.

Independent Review Report

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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 9 which comprise the consolidated interim statement of financial position as at 30 June 2020, 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 of the Company 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 9 do not present fairly, in all material respects, the consolidated interim financial position of Neuren Pharmaceuticals Limited as at 30 June 2020, 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 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 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

Grant Thornton

Ryan Campbell
Partner
Auckland

25 August 2020