Neuren Pharmaceuticals Limited

Appendix 4D Half-Year Financial Report

30 June 2019

Name of entity

Neuren Pharmaceuticals Limited

ABN

72 111 496 130

Half-year ended

30 June 2019

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 2019, with the six months ended 30 June 2018 as the comparative period.

2. Results for announcement to the market

	30 June 2019 $'000	30 June 2018 $'000	% Change
2.1 Operating revenue	283	251	13%
2.2 Loss after tax from ordinary activities	(7,885)	(4,096)	93%
2.3 Net loss attributable to members	(7,885)	(4,096)	93%
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 increased from $4.1 million to $7.9 million. The increase of $3.8 million was due to an increase of $4.3 million in research and development costs, resulting from the completion of Neuren's manufacturing and non-clinical activities for the commencement of the Rett Syndrome Phase 3 trial, as well as expenditure to advance the manufacturing scale-up and non-clinical studies for NNZ-2591.

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 2019	June 2018
Net tangible assets per share	$ 0.1634	$ 0.1703

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.

2019
Interim Report
Neuren Pharmaceuticals Limited

Incorporated in New Zealand
ABN 72 111 496 130

Directors' Report

The Directors submit the financial report of Neuren Pharmaceuticals Limited for the six months ended 30 June 2019.

Directors' details

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

Dr Richard Treagus (Executive Chairman)
Dr Trevor Scott (Non-Executive Director)
Dianne Angus (Non-Executive Director)
Patrick Davies (Non-Executive Director)
Dr Jenny Harry (Non-Executive 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 new therapies for neurodevelopmental disorders with high un-met need, utilizing synthetic analogs of peptides that occur naturally in the brain. Neuren completed Phase 2 development of trofinetide for Rett syndrome and has completed a Phase 2 clinical trial in Fragile X syndrome. The programs in Rett syndrome and Fragile X syndrome 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 syndrome.

During the 6 months to 30 June 2019, very significant progress was made in both the development of trofinetide for Rett syndrome and the development of NNZ-2591 for multiple neurodevelopmental disorders.

In Rett syndrome, manufacturing of trofinetide has been a key element of the extensive preparation leading into the Phase 3 trial, requiring significant changes to the Phase 2 product supply arrangements and a substantial investment for manufacturing of both the drug substance as well as the finished drug product, packaging and distribution. ACADIA remains on target to commence the Phase 3 trial in the 4th quarter of 2019, which means that the timeline ACADIA published when the partnership was announced in August 2018 – commencing the trial in H2 2019 and subject to the results submitting a New Drug Application in 2021 – has remained unchanged. Neuren completed certain manufacturing activities and non-clinical studies, with ACADIA funding and executing the remaining development for trofinetide in North America.

There are two parts to ACADIA's Phase 3 program – 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). Neuren anticipates that patient enrolment will again benefit from strong support from the Rett community. In July 2019, ACADIA announced "LILAC-2" to follow LILAC, in which eligible patients who completed LAVENDER and LILAC will be able to continue to receive trofinetide.

In March 2019 the results of Neuren's Phase 2 study of trofinetide in pediatric Rett syndrome were published in Neurology®, the highly regarded peer-reviewed medical journal of the American Academy of Neurology. The publication was also the basis for an editorial in the journal titled "Turning the tide on targeted treatments for neurodevelopmental disorders".

In February and May 2019, Neuren announced positive results for NNZ-2591 in separate mouse models of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome. These are three debilitating neurodevelopmental disorders with no approved drug therapy. The cause of each disorder is a mutation or deletion in a different gene or chromosomal region, however they share an underlying impairment in the connections and signalling between brain cells. The aim of treatment with NNZ-2591 is to restore normal functional connectivity and signalling.

In July 2019, Neuren submitted applications for Orphan Drug designation to the FDA for each of Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome. Orphan Drug designation is a special status that the FDA may grant to a drug to treat a rare disease or condition. Orphan Drug designation qualifies the sponsor of the drug for incentives including 7 years of marketing exclusivity, plus 6 additional months if approved for pediatric use, as well as waiver of the prescription drug user fee for a marketing application.

Directors' Report

Neuren is currently undertaking the manufacturing development and non-clinical studies required before submitting an Investigational New Drug (IND) Application for NNZ-2591 in the United States, aiming to commence Phase 2 clinical trials in the second half of 2020 after completing a Phase 1 trial in Australia. The NNZ-2591 program is benefiting from the extensive experience gained by Neuren during the development of trofinetide for Rett syndrome and Fragile X syndrome.

In February 2019, the board appointed Torreya, a global investment bank specialising in life sciences, as Neuren's corporate advisor to evaluate all potential corporate transactions, for individual products, defined territories, or Neuren's entire business. A formal process commenced in April and is presently underway, engaging with third parties in the US, Europe and Japan.

The Sharing Agreement with Lanstead Capital, which was part of the capital raising in 2017, concluded in June 2019 with the final settlement received in July 2019. The aggregate amount received from Lanstead Capital throughout the course of the arrangement was $12.2 million. This delivered to Neuren additional cash funding of $2.2 million, with no additional shares issued to Lanstead Capital.

The consolidated interim financial statements 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 six months ended 30 June 2019 was $7.9 million, compared with $4.1 million for the six months ended 30 June 2018. The increase of $3.8 million was due to an increase of $4.3 million in research and development costs, resulting from the completion of Neuren's manufacturing and non-clinical activities for the commencement of the Rett Syndrome Phase 3 trial, as well as expenditure to advance the manufacturing scale-up and non-clinical studies for NNZ-2591.

The net loss per share for the six months to 30 June 2019 was $0.079 (six months to 30 June 2018: $0.042) based on a weighted average number of shares outstanding of 100 million (six months to 30 June 2018: 98 million).

Cash reserves at 30 June 2019 were $17.3 million (31 December 2018: $23.6 million). Net cash used in operating activities was $7.9 million (six months to 30 June 2018: $4.0 million). The increase of $3.9 million was mainly in payments to other suppliers, due to the higher research and development expenditure.

Cash generated from financing activities was $1.6 million, received from the settlements from the Sharing Agreement with Lanstead Capital. For the six months to 30 June 2018, cash generated from financing activities of $10.6 million comprised settlements of $5.3 million from Lanstead Capital and $5.3 million received in May 2018 from the issue of ordinary shares at $4.00 per share under an exclusivity agreement with ACADIA.

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 six months ended 30 June 2019 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 2019 and of the performance for the six months 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 27 August 2019.

On behalf of the Board

Dr Richard Treagus, Executive Chairman

Consolidated Interim Statement of Comprehensive Income

For the six months ended 30 June 2019

Group	Note	Six months Jun 2019 $'000	Six months Jun 2018 $'000
Interest		235	44
Foreign exchange gain		48	207
Total revenue		283	251
Research and development costs		(6,939)	(2,642)
Corporate and administrative costs		(968)	(1,254)
Loss on financial assets measured at fair value through profit or loss	4	(261)	(451)
Loss before income tax		(7,885)	(4,096)
Income tax benefit		-	-
Loss after income tax for the period		(7,885)	(4,096)
Other comprehensive expense, net of tax			
Amounts which may be reclassified to profit or loss:			
Exchange differences on translation of foreign operations		(6)	(36)
Total comprehensive loss for the period		(7,891)	(4,132)
Loss after tax attributable to Equity holders of the Company		(7,885)	(4,096)
Total comprehensive loss attributable to Equity holders of the Company		(7,891)	(4,132)
Basic and diluted loss per share	3	($0.079)	($0.042)

The accompanying notes form part of this financial statement.

Consolidated Interim Statement of Financial Position

As at 30 June 2019

Group	Note	Unaudited as at Jun 2019 $'000	Audited as at Dec 2018 $'000
ASSETS			
Current Assets:			
Cash and cash equivalents		17,267	23,576
Trade and other receivables		820	942
Financial assets measured at fair value through profit or loss	4	-	2,121
Total current assets		18,087	26,639
Non-current assets:			
Property, plant and equipment		12	2
Intangible assets		-	1
Total non-current assets		12	3
TOTAL ASSETS		18,099	26,642
LIABILITIES AND EQUITY			
Current liabilities:			
Trade and other payables		1,321	1,973
Total liabilities		1,321	1,973
EQUITY			
Share Capital		126,426	126,426
Other reserves		(8,503)	(8,497)
Accumulated deficit		(101,145)	(93,260)
Total equity attributable to equity holders		16,778	24,669
TOTAL LIABILITIES AND EQUITY		18,099	26,642

The accompanying notes form part of this financial statement.

Consolidated Interim Statement of Changes in Equity

For the six months ended 30 June 2019

Group	Attributable to Equity Holders				
	Share Capital	Share Option Reserve	Currency Translation Reserve	Accumulated Deficit	Total Equity
	$'000	$'000	$'000	$'000	$'000
Equity as at 1 January 2018	121,136	3,293	(10,625)	(97,440)	16,364
Shares issues in private placement	5,306	-	-	-	5,306
Share issue costs expensed	(16)	-	-	-	(16)
Exercised options	-	(1,107)	-	1,107	-
Transactions with owners	5,290	(1,107)	-	1,107	5,290
Loss after income tax	-	-	-	(4,096)	(4,096)
Other comprehensive expense	-	-	(36)	-	(36)
Total comprehensive loss for the period	-	-	(36)	(4,096)	(4,132)
Equity as at 30 June 2018	126,426	2,186	(10,661)	(100,429)	17,522
Equity as at 1 January 2019	126,426	2,186	(10,683)	(93,260)	24,669
Shares issued in private placement	-	-	-	-	-
Share issue costs expensed	-	-	-	-	-
Exercised options	-	-	-	-	-
Transactions with owners	-	-	-	-	-
Loss after income tax	-	-	-	(7,885)	(7,885)
Other comprehensive expense	-	-	(6)	-	(6)
Total comprehensive Loss for the period	-	-	(6)	(7,885)	(7,891)
Equity as at 30 June 2019	126,426	2,186	(10,689)	(101,145)	16,778

The accompanying notes form part of this financial statement.

Consolidated Interim Cash Flow Statement

For the six months ended 30 June 2019

Group	Six months Jun 2019 $'000	Six months Jun 2018 $'000
Cash flows from operating activities:		
Interest received	235	46
GST refunded	47	35
Payments to employees and directors	(763)	(694)
Payments to other suppliers	(7,418)	(3,367)
Net cash used in operating activities	(7,899)	(3,980)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(12)	-
Net cash used in investing activities	(12)	-
Cash flows from financing activities:		
Proceeds from the issue of shares	1,566	10,588
Payments for share issue expenses	-	(16)
Net cash from financing activities	1,566	10,572
Net increase / (decrease) in cash held	(6,345)	6,592
Effect of exchange rate changes on cash balances	37	108
Cash at the beginning of the period	23,576	4,706
Cash at the end of the period	17,268	11,406
Reconciliation with loss after income tax:		
Loss after income tax	(7,885)	(4,096)
Items requiring adjustment:		
Depreciation and amortisation	3	39
Share based payments	-	-
Foreign exchange (gain)	(41)	(143)
Loss on financial assets	261	451
Movements in working capital	(237)	(231)
Net cash used in operating activities	(7,899)	(3,980)

The accompanying notes form part of this financial statement.

Notes to the Consolidated Interim Financial Statements

For the six months ended 30 June 2019

1. Nature of 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 27 August 2019.

2. Summary of significant accounting policies

Basis of preparation

These general-purpose consolidated interim financial statements are for the six months ended 30 June 2019 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.

Standards adopted in the current year

The Group adopted NZ IFRS 16 'Leases' as at 1 January 2019. The Group does not have any qualifying lease agreements, therefore there is no impact on the consolidated financial statements for the current period.

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 2018 and the unaudited financial statements for the six months ended 30 June 2019. 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 2018.

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 $7.9 million for the period ended 30 June 2019 and had negative

2. Summary of significant accounting policies (Continued)

operating cash flows for the period of $7.9 million. The Group had cash of $17.3 million at 30 June 2019. 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.

3. Loss per share

	Jun 2019	Jun 2018
Consolidated		
Loss after income tax attributable to equity holders ($'000)	(7,885)	(4,096)
Weighted average shares outstanding (basic and diluted) (No.)	100,168,413	97,890,573
Basic and diluted loss per share	($0.079)	($0.042)

4. Financial Assets measured at fair value through profit or loss

Consolidated	6 months Jun 2019 $'000	Year Dec 2018 $'000
Current		
Equity Derivative	-	2,121

Reconciliation of the fair values at the end of the current financial year are set out below:

	6 months Jun 2019 $'000	Year Dec 2018 $'000
Opening fair value	2,121	12,466
Cash settlements receivable	(1,860)	(6,424)
Net loss through profit or loss	(261)	(3,921)
Closing fair value	-	2,121

Financial instruments classified under the equity derivative arrangement were measured at fair value using a fair value hierarchy reflecting the nature of the inputs used in making the measurements. These financial assets are classified as level 2.

4. Financial Asset measured at fair value through profit or loss (Continued)

In July 2017, Neuren completed a placement of new ordinary shares, the subscribers for which included Lanstead Capital. Neuren entered into a Sharing Agreement with Lanstead Capital, under which Neuren's economic interest was an equity derivative, determined and payable in 18 monthly cash settlements commencing in September 2017. In August 2018, Neuren and Lanstead Capital agreed to pause settlements for 4 months, which resulted in the final settlement occurring in June 2019.

The calculation of each monthly settlement was dependent upon the volume weighted average price at which Neuren's shares were traded during the 20 days prior to the settlement date (VWAP). If the VWAP for each settlement was equal to $1.77 per share (Benchmark Price), Neuren received $472,222 (one eighteenth of $8.5 million). If the VWAP for each settlement was higher than the Benchmark Price, Neuren received proportionately more than $472,222 and if the VWAP for each settlement was lower than the Benchmark Price, Neuren received proportionately less than $472,222. $10.7 million was received from the 18 settlements, compared with $8.5 million that would have been received if the VWAP had been the Benchmark Price. This delivered to Neuren an additional $2.2 million in cash funding, with no additional shares issued to Lanstead Capital.

The key assumption for the calculation of the fair value of the equity derivative was the estimated VWAP applicable to each future settlement. For the fair value on recognition, the VWAP was assumed to be $1.22 per share, which was the traded price of Neuren's shares on 17 July 2017. For the fair value at 31 December 2018, the VWAP was assumed to be $1.40 per share, which was the traded price of Neuren's shares on 31 December 2018. The fair value calculations were adjusted to reflect the time value of money and the estimated credit risk associated with the counterparty. At 30 June 2019, the equity derivative had expired. The final settlement amount calculated in June 2019 of $293,462 was received by Neuren in July 2019 and was therefore included in trade and other receivables at 30 June 2019.

5. Share capital

Consolidated	6 months Jun 2019 Shares	Year Dec 2018 Shares
Issued share capital		
Ordinary shares on issue at beginning of period	102,668,413	101,840,020
Shares bought back under Loan Funded Share Plan	-	(501,607)
Shares issued in private placement	-	1,330,000
Ordinary shares on issue at end of period	102,668,413	102,668,413

5. Share capital (Continued)

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 have been forfeited. In respect of 1,000,000 Loan Funded Shares, for which the exercise price is $1.64 per share, the directors deferred testing of the vesting conditions until the expiry of the loan on 7 May 2020, or an earlier date determined by the directors.

6. Commitments and contingencies

(a) Legal claims

The Group had no significant legal or other contingencies as at 30 June 2019, or 31 December 2018.

(b) Commitments

At 30 June 2019, the Group had commitments under contracts for the manufacture of trofinetide amounting to approximately US$1.7 million. Commitments under contract for the manufacture of NNZ-2591 and non-clinical toxicology studies amounted to approximately US$0.7 million. The commitments are expected to become payable during the period to January 2020.

7. 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.

8. Events after balance date

As at the date of approving these consolidated interim financial statements there are no other events arising since 30 June 2019 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 10 which comprise the consolidated interim statement of financial position as at 30 June 2019, 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 10 do not present fairly, in all material respects, the consolidated interim financial position of Neuren Pharmaceuticals Limited as at 30 June 2019, 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 Partnership

Ryan Campbell
Partner
Auckland

27 August 2019