
Neuren Pharmaceuticals Limited
Appendix 4D Half-Year Financial Report

30 June 2016

Name of entity

Neuren Pharmaceuticals Limited

ABN

72 111 496 130

Half-year ended

30 June 2016

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 2016, with the six months ended 30 June 2015 as the comparative period.

2. Results for announcement to the market

	30 June 2016 \$'000	30 June 2015 \$'000	% Change
2.1 Operating revenue	306	2,396	(87.2)%
2.2 Loss after tax from ordinary activities	(7,378)	(5,348)	(37.9)%
2.3 Net loss attributable to members	(7,378)	(5,348)	(37.9)%
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 consolidated net loss after tax increased from \$5.3 million to \$7.4 million, due to the following:			
• A decrease of \$1.5 million in grant revenue as the funding from the US government for brain injury studies reached the maximum in May 2015; and • Foreign exchange losses of \$0.2 million, as the Australian dollar strengthened against the US dollar, compared with foreign exchange gains of \$0.6 million in the six months ended 30 June 2015, as the Australian dollar weakened against the US dollar; partly offset by • Income tax benefit of \$0.9 million receivable under the Australian Research and Development Tax Incentive in respect of the year ended 31 December 2015 (six months ended 30 June 2015: \$0.4 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

	<u>June 2016</u>	<u>June 2015</u>
Net tangible assets per share	\$ 0.004	\$ 0.009

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 review report, which is included in the attached Interim Report, is unqualified and contains an emphasis of matter paragraph that draws attention to the disclosures regarding the going concern basis that are contained in note 2 to the interim financial statements.

2016
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 2016.

Directors' details

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

Dr Richard Treagus (Executive Chairman)
Mr Larry Glass (Executive Director and Chief Science Officer)
Mr Bruce Hancox (Non-executive Director)
Dr Trevor Scott (Non-Executive Director)

Review of Operations

Neuren Pharmaceuticals Limited ("Neuren" or the "Company"), and its subsidiaries (collectively the "Group") is a listed biopharmaceutical company, incorporated in New Zealand and listed on the Australian Securities Exchange, focusing on the development of drugs to treat neurodevelopmental disorders, neurodegenerative disorders and brain injury.

Key developments in the business during the six months to 30 June 2016 included:

- In January 2016, Neuren commenced a Rett syndrome Phase 2 paediatric trial in the United States. This is a double-blind, placebo-controlled trial using a maximum dose of up to 200mg/kg twice daily, enrolling girls aged 5 to 15 years and a longer treatment period than was used in Neuren's previous Phase 2 trial in adults and adolescents aged 16 to 45 years with Rett syndrome.
- In April 2016, Neuren announced top-line results from the Phase 2 clinical trial of trofinetide in moderate to severe traumatic brain injury (the "INTREPID" trial). The trial achieved its primary endpoint of confirming the good safety profile of trofinetide. The trial did not demonstrate a difference between drug and placebo in 3 core efficacy measures, which were the Extended Glasgow Outcome Scale (GOS-E), the Mayo-Portland Adaptability Inventory (MPAI-4) and mortality. However, superiority of drug over placebo was demonstrated in the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), which was one of the exploratory efficacy measures in the INTREPID trial. RBANS is a validated series of tests completed by the patient for assessing cognitive impairment that is commonly used in the diagnosis and tracking of dementia. RBANS has also been validated for use in moderate-to-severe TBI.
- In May 2016, Neuren met with the US Food and Drug Administration (FDA) to discuss the development programs for Rett syndrome (Division of Neurology Products) and Fragile X syndrome (Division of Psychiatry Products). Agreement was reached with the Division of Neurology Products on the construct of the primary outcome measure considered acceptable for use in a pivotal registration study of trofinetide for Rett syndrome. The measure, which is derived from the Motor Behavior Assessment used by clinicians in the Rett syndrome natural history study, has been carefully designed to capture potential improvement in the core signs and symptoms of Rett syndrome. In the meeting with the Division of Psychiatry Products (DPP), Neuren agreed to work with DPP to refine and validate some of the behavioural measures that form part of Neuren's Fragile X Syndrome Rating Scale. DPP also requested that Neuren provide data from planned non-clinical toxicity studies before commencing clinical trials in paediatric patients with Fragile X syndrome.
- In June 2016, IP Australia granted a new patent, covering the use of trofinetide for the treatment of Autism Spectrum Disorders, including Rett syndrome, Fragile X syndrome, Asperger syndrome and autism. This was the first patent granted from a series of applications in the major pharmaceutical markets that cover the use of trofinetide in Autism Spectrum Disorders until 2032.

The detailed financial statements are presented on pages 3 to 10. All amounts in the Financial Statements are shown in Australian dollars unless otherwise stated.

Directors' Report

The group's net loss after income tax for the six months ended 30 June 2016 was \$7.4 million (six months ended 30 June 2015: \$5.3 million). The increased loss was mainly due to the following:

- A decrease of \$1.5 million in grant revenue as the funding from the US government for brain injury studies reached the maximum in May 2015; and
- Foreign exchange losses of \$0.2 million, due mainly to the Australian dollar strengthening against the US dollar, compared with foreign exchange gains of \$0.6 million in the six months ended 30 June 2015, due mainly to the revaluation of US dollar cash deposits and outstanding forward contracts to purchase US dollars, as the Australian dollar weakened against the US dollar; partly offset by:
- Income tax benefit of \$0.9 million receivable under the Australian Research and Development Tax Incentive in respect of the year ended 31 December 2015 (six months ended 30 June 2015: \$0.4 million).

The net loss per share for the six months to 30 June 2016 was 0.4 cents (six months to 30 June 2015: 0.3 cents) based on a weighted average number of shares outstanding of 1,767 million (six months to 30 June 2015: 1,655 million).

Cash reserves at 30 June 2016 were \$8.1 million (31 December 2015: \$16.6 million). Net cash used in operating activities was \$8.4 million (six months to 30 June 2015: \$4.6 million). Receipts from grants decreased by \$2.2 million, due to the decrease of \$1.5 million in grant revenue and the receipt during the 6 months to 30 June 2015 of receivables from the US government that were outstanding at 31 December 2014. Payments to other suppliers increased by \$1.5 million, due to the settlement of payables to research and development suppliers that were outstanding at 31 December 2015.

Corporations Act, Australia - Directors' declaration

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

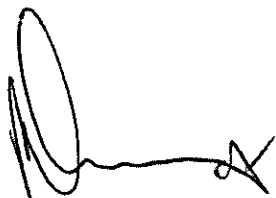
The accompanying financial statements of Neuren and its subsidiaries for the six months ended 30 June 2016 and the notes to those financial statements:

- comply with the XRB A1 (Tier 1) standards issued by the New Zealand Accounting Standards Review Board; and
- give a true and fair view of the financial position as at 30 June 2016 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 30 August 2016.

On behalf of the Board



Dr Richard Treagus
Executive Chairman

Interim Statement of Comprehensive Income (Unaudited)

for the six months ended 30 June 2016

Group	Six months Jun 2016 \$'000	Six months Jun 2015 \$'000
Revenue - interest income	144	200
Other income - grants	162	1,612
Foreign exchange gain	-	584
Total revenue and other income	306	2,396
Research and development costs	(6,674)	(6,509)
Corporate and administrative costs	(1,119)	(1,013)
Share based payments expense	(522)	(611)
Foreign exchange loss	(232)	-
Loss before income tax	(8,241)	(5,737)
Income tax benefit	863	389
Loss after income tax for the period	(7,378)	(5,348)
Other comprehensive income (expense), net of tax		
Disposal of Minority Interest	-	(221)
Exchange differences on translation of foreign operations	29	(38)
Total comprehensive loss for the period	(7,349)	(5,607)
Loss after tax attributable to equity holders of the company	(7,378)	(5,348)
Total comprehensive loss attributable to equity holders of the company	(7,349)	(5,607)
Basic and diluted loss per share	0.4 cents	0.3 cents

The accompanying notes form part of this financial report.

Interim Statement of Comprehensive Income (Unaudited)

for the six months ended 30 June 2016

Group	Unaudited as at Jun 2016 \$'000	Audited as at Dec 2015 \$'000
ASSETS		
Current Assets:		
Cash and cash equivalents	8,132	16,642
Current tax receivable	863	-
Trade and other receivables	31	34
Total current assets	9,026	16,676
Non-current assets:		
Property, plant and equipment	16	11
Intangible assets	181	217
Total non-current assets	197	228
TOTAL ASSETS	9,223	16,904
LIABILITIES AND EQUITY		
Current liabilities:		
Trade and other payables	1,648	2,502
Total liabilities	1,648	2,502
EQUITY		
Share capital	111,912	111,912
Other reserves	(7,213)	(7,764)
Accumulated deficit	(97,124)	(89,746)
Total equity attributable to equity holders	7,575	14,402
TOTAL LIABILITIES AND EQUITY	9,223	16,904

The accompanying notes form part of this financial report.

Interim Statement of Changes in Equity (Unaudited)

for the six months ended 30 June 2016

Group	Attributable to Equity Holders				Total \$'000	Minority Interest \$'000	Total Equity \$'000
	Share Capital	Share Option Reserve	Currency Translation Reserve	Accumulated Deficit			
	\$'000	\$'000	\$'000	\$'000			
Equity as at 1 January 2015	104,363	9,677	(10,593)	(84,148)	19,299	(221)	19,078
Shares issued on option exercise	1,051				1,051		1,051
Share issue costs expensed	(12)				(12)		(12)
Share based payments		611			611		611
Total comprehensive gain / (loss) for the period			(38)	(5,569)	(5,607)	221	(5,386)
Equity as at 30 June 2015	105,402	10,288	(10,631)	(89,717)	15,342		15,342
Equity as at 1 January 2016	111,912	2,889	(10,653)	(89,746)	14,402	-	14,402
Shares issued on option exercise							
Share issue costs expensed							
Share based payments		522			522		522
Total comprehensive gain / (loss) for the period			29	(7,378)	(7,349)		(7,349)
Equity as at 30 June 2016	111,912	3,411	(10,624)	(97,124)	7,575	-	7,575

The accompanying notes form part of this financial report.

Interim Statement of Cash Flows (unaudited)

for the six months ended 30 June 2014

Group	Six months Jun 2016 \$'000	Six months Jun 2015 \$'000
Cash flows from operating activities:		
Receipts from grants	162	2,316
Interest received	150	179
GST refunded	76	44
Payments to employees and directors	(1,035)	(903)
Payments to other suppliers	(7,746)	(6,243)
Net cash used in operating activities	(8,393)	(4,607)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(10)	(3)
Net cash used in investing activities	(10)	(3)
Cash flows from financing activities:		
Proceeds from the exercise of options	-	1,051
Payments for share issue expenses	-	(12)
Net cash from financing activities	-	1,039
Net decrease in cash held	(8,403)	(3,571)
Effect of exchange rate changes on cash balances	(107)	399
Cash at the beginning of the period	16,642	20,824
Cash at the end of the period	8,132	17,652
Reconciliation with loss after income tax:		
Loss after income tax	(7,378)	(5,348)
Items requiring adjustment:		
Depreciation and amortisation	41	47
Share based payments	522	611
Foreign exchange loss/(gain)	136	(439)
Movements in working capital	(1,714)	522
Net cash used in operating activities	(8,393)	(4,607)

The accompanying notes form part of this financial report.

1. Nature of business

Neuren Pharmaceuticals Limited ("Neuren" or the "Company"), and its subsidiaries (collectively the "Group") is a biopharmaceutical company focusing on the development of drugs to treat neurodevelopmental disorders, neurodegenerative disorders and brain injury.

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 have been approved for issue by the Board of Directors on 30 August 2016.

2. Summary of significant accounting policies

These general-purpose interim financial statements are for the six months ended 30 June 2016 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 Company is a Tier 1 for-profit entity under the External Reporting Board Accounting Standards Framework.

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, Statement of Financial Position and the 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 2015 and the unaudited financial statements for the six months ended 30 June 2015. There is no cyclical seasonality of interim operations.

The functional and presentation currency of the Company and 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 2015.

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 \$7.3m for the period ended 30 June 2016 and had net assets and cash balances at 30 June 2016 of \$7.6 million and \$8.1 million respectively. During the period ended 30 June 2016, the Group continued to invest in research and development and in the three months ended 30 June 2016 used cash of \$2.9 million in operating activities. The Group received R&D Tax Incentive of approximately \$0.9 million in August 2016 and expects to receive grant revenue of approximately US\$0.8 million from rettsyndrome.org in September 2016. In addition, the Group expects to receive new share capital funding of approximately \$0.9 million from the exercise of share options that expire in October 2016. The Directors intend that the Group will enter into a commercial partnering arrangement in 2017, the timing and terms of which are presently unknown. Should the commercial partnering arrangement nature and/or timing differ from the current intention, the

Directors would consider securing other sources of funding, including additional capital, depending on circumstances at the time.

After making enquiries, and considering the existence of the material uncertainty described above, the Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future and continue to adopt the going concern basis in preparing these financial statements. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or to the amounts and classification of liabilities that may be necessary should the Group be unable to continue as a going concern.

New standards first applied in the period

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

Certain new standards, amendments and interpretations to existing standards have been published that are mandatory for later periods and which the Group has not adopted early. The key items applicable to the Group are:

NZ IFRS 9 'Financial Instruments' (effective from 1 January 2018) addresses classification and measurement of financial assets and liabilities and is available for early adoption immediately. NZ IFRS 9 replaces the multiple classification and measurement models in IAS 39 'Financial Instruments: Recognition and Measurement' with a single model that has only two classification categories: amortised cost and fair value. The consolidated entity is assessing the potential impact of NZ IFRS 9 'Financial Instruments' on its financial statements.

NZ IFRS 16 'Leases' (effective from 1 January 2019) removes the distinction between operating and finance leases for lessees and brings almost all leases on balance sheet, recognising a right-of-use asset and a corresponding lease liability. This is available for early adoption immediately.

There are no other standards, amendments, or interpretations to existing standards, issued but not yet effective, which are expected to impact the Group. There were no new standards, adopted by the group for the first time for the financial year beginning on or after 1 January 2016, which had a material impact on the group.

3. Loss before income tax

The loss before income tax includes:

Group	Jun 2016 \$'000	Jun 2015 \$'000
Depreciation	(5)	(9)
Amortisation of intangible assets		
- Intellectual property	(36)	(37)
Foreign exchange gain/(loss) on revaluation of forward contracts	(9)	94

At 30 June 2016, there were two forward contracts to convert Australian dollars to US dollars outstanding, as detailed in the table below. Adjustment of these financial instruments to fair value as measured at 30 June 2016 resulted in a loss of approximately \$9,000. This fair value measurement is categorised within Level 2 of the fair value hierarchy. Fair value was determined using forward exchange rates at the balance sheet date, with the resulting value discounted back to present value. At 30 June 2016, the balance sheet value of all financial instruments was equivalent to the fair value.

Settlement date	Buy US dollars	Sell Australian dollars	Contract rate
8 August 2016	\$1,000,000	\$1,324,503	0.755
9 August 2016	\$1,000,000	\$1,374,570	0.7275

4. Share capital

Consolidated	6 months Jun 2016 Shares	Year Dec 2015 Shares
Issued share capital		
Ordinary shares on issue at beginning of period	1,767,003,738	1,625,241,426
Shares issued in Loan Funded Share Plan	-	20,000,000
Shares issued on option exercise	-	51,206,757
Shares issued in private placement	-	70,555,555
Ordinary shares on issue at end of period	<u>1,767,003,738</u>	<u>1,767,003,738</u>

At 30 June 2016 and at 31 December 2015, options were outstanding to acquire 62,000,000 ordinary shares at a weighted average price of \$0.0149 per share and Equity Performance Rights to acquire 14,234,178 ordinary shares at nil exercise price were outstanding.

5. Commitments and contingencies

(a) Operating leases

The current commitment relates to one lease of premises, with a term of two years and six months commencing September 2014, with an option to renew for a further term of three years, and annual CPI reviews throughout.

Group	Jun 2016 \$'000	Dec 2015 \$'000
Non-cancellable operating lease commitments		
Not later than one year	49	74
Later than one year and not later than five years	-	12
Later than five years	-	-
	<u>49</u>	<u>86</u>

(b) Legal claims

The Group had no significant legal or other contingencies as at 30 June 2016, or 31 December 2015.

(c) Capital commitments

The Company was not committed to the purchase of any property, plant or equipment as at 30 June 2016 or 31 December 2015.

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. Grant income was received from rettsyndrome.org in the period ended 30 June 2016 and from the United States federal government in the period ended 30 June 2015.

7. Events after balance date

As at the date of this financial report there were no events arising since 30 June 2016 that require disclosure.



Independent Review report

to the shareholders of Neuren Pharmaceuticals Limited

Report on the Interim Financial Statements

We have reviewed the accompanying Group financial statements of Neuren Pharmaceuticals Limited ("the Company") on pages 3 to 10, which comprise the interim statement of financial position as at 30 June 2016, and the interim statement of comprehensive income, the interim statement of changes in equity and the interim statement of cash flows for the period ended on that date, and a summary of significant accounting policies and selected explanatory notes. The Group comprises the Company and the entities it controlled at 30 June 2016 or from time to time during the financial year.

Directors' Responsibility for the Interim Financial Statements

The Directors of the Company are responsible on behalf of the Company for the preparation and presentation of these financial statements in accordance with New Zealand Equivalent to International Accounting Standard 34 Interim Financial Reporting (NZ IAS 34) and for such internal controls as the Directors determine are necessary to enable the preparation of 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 accompanying financial statements based on our review. We conducted our review in accordance with the New Zealand Standard on Review Engagements 2410 *Review of Financial Statements Performed by the Independent Auditor of the Entity* (NZ SRE 2410). NZ SRE 2410 requires us to conclude whether anything has come to our attention that causes us to believe that the financial statements, taken as a whole, are not prepared in all material respects, in accordance with NZ IAS 34. As the auditors of the Company, NZ SRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial statements.

A review of financial statements in accordance with NZ SRE 2410 is a limited assurance engagement. The auditors perform procedures, primarily consisting of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. 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) and International Standards on Auditing. Accordingly we do not express an audit opinion on these financial statements. We are independent of the Group. Other than in our capacity as auditors we have no relationship with, or interests in, the Group.

Emphasis of matter

Without modifying our conclusion, we draw attention to Note 2 in the interim financial statements which indicates that the ability of the Group to continue in operational existence is dependent upon achieving cash flow forecasts and entering into a commercial partnering arrangement in 2017. These conditions indicate the existence of a material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that these financial statements of the Group are not prepared, in all material respects, in accordance with NZ IAS 34.

Restriction on Distribution or Use

This report is made solely to the Shareholders of Neuren Pharmaceuticals Limited, as a body. Our review work has been undertaken so that we might state to the Company's Shareholders those matters which we are required to state to them in our 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 the Shareholders, as a body, for our review procedures, for this report, or for the conclusion we have formed.

For and on behalf of:

Chartered Accountants
30 August 2016

Auckland