# **Neuren Pharmaceuticals Limited**

# **Appendix 4D Half-Year Financial Report**

## 30 June 2015

# Name of entity

Neuren Pharmaceuticals Limited

ABN Half-year ended

72 111 496 130 30 June 2015

# 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 2015, with the six months ended 30 June 2014 as the comparative period.

#### 2. Results for announcement to the market

	30 June 2015 \$'000	30 June 2014 \$'000	% Change
2.1 Operating revenue	2,396	1,728	38.6%
2.2 Loss after tax from ordinary activities	(5,348)	(4,671)	(14.4)%
2.3 Net loss attributable to members	(5,348)	(4,656)	(14.9)%
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 \$4.7 million to \$5.3 million, due to the following:

- Research and development costs increased by \$2.1 million reflecting costs associated
  with the Fragile X syndrome clinical trial and the ongoing optimisation of the trofinetide
  commercial manufacturing process, partly offset by the completion of the Rett syndrome
  clinical trial;
- Foreign exchange gains of \$0.6 million, which are included in operating revenue, 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; and
- Income tax benefit of \$0.4 million receivable under the Australian Research and Development Tax Incentive.

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 2015	June 2014
Net tangible assets per share	\$ 0.009	\$ 0.013

4.	<b>Entities ov</b>	er which	control	has been	gained or	lost durin	g the	period:
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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.

<sup>&</sup>lt;sup>+</sup> See chapter 19 for defined terms. Appendix 4D Page 2

2015 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 2015.

#### 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, or the Group) is a publicly listed biopharmaceutical company focusing on the development of drugs for neurological disorders.

During the six months to 30 June 2015, Neuren made significant progress on the development of its lead drug candidate trofinetide for Rett syndrome, Fragile X syndrome, moderate-to-severe traumatic brain injury and mild traumatic brain injury (concussion). Key developments in the business since 1 January 2015 included:

- The World Health Organisation published "trofinetide" as the International Nonproprietary Name (INN), for glycyl-2-methyl-L-prolyl-L-glutamic acid, which was previously designated by Neuren as NNZ-2566.
- The US Food and Drug Administration (FDA) granted Orphan Drug designation to trofinetide for the treatment of Rett syndrome.
- Orphan designation in the European Union was granted for trofinetide in both Rett syndrome and Fragile X syndrome.
- Neuren conducted a meeting with the FDA on the remaining development of trofinetide for Rett syndrome, providing meaningful guidance for Neuren in all areas of the development program.

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.

The group's net loss after income tax for the six months ended 30 June 2015 was \$5.3 million (six months ended 30 June 2014: \$4.7 million). The increased loss was mainly due to the following:

- Research and development costs increased from \$4.4 million to \$6.5 million, reflecting costs associated with the Fragile X syndrome clinical trial and the ongoing optimisation of the trofinetide commercial manufacturing process, partly offset by the completion of the Rett syndrome clinical trial;
- Foreign exchange gains of \$0.6 million, 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. In the six months ended 30 June 2014, the Australian dollar strengthened against the US dollar, resulting in foreign exchange losses of \$0.5 million; and
- Income tax benefit of \$0.4 million (six months ended 30 June 2014: nil) receivable under the Australian Research and Development Tax Incentive.

During the period, the amount of grant revenue earned from the United States government reached the maximum under the grant award. No further amounts will be earned in future periods under that award.

The net loss per share for the six months to 30 June 2015 was 0.3 cents (six months to 30 June 2014: 0.3 cents) based on a weighted average number of shares outstanding of 1,655 million (six months to 30 June 2014: 1,542 million).

Cash reserves at 30 June 2015 were \$17.7 million (31 December 2014: \$20.8 million). Net cash used in operating activities was \$4.7 million, offset by \$1.0 million proceeds received from the exercise of share options. The weakening of the Australian dollar against the US dollar during the period resulted in a gain of \$0.6 million on the revaluation of US dollar cash reserves.

# **Directors' Report**

## 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 2015 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 2015 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 made in accordance with a resolution of the Board of Directors dated 25 August 2015.

On behalf of the Board

Dr Richard Treagus

**Executive Chairman** 

# Interim Statement of Comprehensive Income (Unaudited) for the six months ended 30 June 2015

Group	Six months Jun 2015 A\$'000	Six months Jun 2014 A\$'000
Revenue - interest income	200	303
Other income - grants	1,612	1,425
Foreign Exchange Gain	584	-
Total revenue and other income	2,396	1,728
Research and development costs	(6,509)	(4,379)
Corporate and administrative costs	(1,013)	(1,104)
Share based payments expense	(611)	(388)
Foreign exchange loss	1.	(497)
Impairment loss	24	(31)
Loss before income tax	(5,737)	(4,671)
Income tax benefit	389	-
Loss after income tax for the period	(5,348)	(4,671)
Other comprehensive income (expense), net of tax		
Disposal of Minority Interest	(221)	21
Exchange differences on translation of foreign operations	(38)	26
Total comprehensive loss for the period	(5,607)	(4,645)
Loss after tax attributable to:		
Equity holders of the company	(5,348)	(4,656)
Minority interest	-	(15)
	(5,348)	(4,671)
Total comprehensive loss attributable to:		
Equity holders of the company	(5,607)	(4,630)
Minority interest	-	(15)
	(5,607)	(4,645)
Basic and diluted loss per share	0.3 cents	0.3 cents
	:	



# Interim Statement of Financial Position (Unaudited)

as at 30 June 2015

Group	As at Jun 2015 A\$'000	As at Dec 2014 A\$'000
ASSETS		
Current Assets:		
Cash and cash equivalents	17,652	20,824
Current tax receivable	389	20,824
Trade and other receivables	410	963
Total current assets	18,451	21,787
Non-current assets:		
Property, plant and equipment	22	29
Intangible assets	253	290
Total non-current assets	275	319
TOTAL ASSETS	18,726	22,106
LIABILITIES AND EQUITY		
Current liabilities:		
Trade and other payables	3,384	3,028
Total liabilities	3,384	3,028
EQUITY	722 722	
Share capital Other reserves	105,402	104,363
Accumulated deficit	(343) (89,717)	(916) (84,148)
Accumulated deficit	(65,717)	(64,146)
Total equity attributable to equity holders	15,342	19,299
Minority interest in equity		(221)
Total equity	15,342	19,078
TOTAL LIABILITIES AND EQUITY	18,726	22,106



# Interim Statement of Changes in Equity (Unaudited) for the six months ended 30 June 2015

Attributable	to Equity	Holders
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Group	Share Capital	Share Option	Currency Translation	Accumulated Deficit	Total	Minority Interest	Total Equity
	A\$'000	Reserve A\$'000	Reserve A\$'000	A\$'000	A\$'000	A\$'000	A\$'000
Equity as at 1 January 2014	102,177	10,098	(518)	(87,156)	24,601	(202)	24,399
Shares issued on option exercise	1,140				1,140		1,140
Share issue costs expensed	(67)				(67)		(67)
Share based payments		388			388		388
Total comprehensive loss for the period			26	(4,656)	(4,630)	(15)	(4,645)
Equity as at 30 June 2014	103,250	10,486	(492)	(91,812)	21,432	(217)	21,215
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 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



# Interim Cash Flow Statement (Unaudited)

for the six months ended 30 June 2015

Group	Six months Jun 2015 A\$'000	Six months Jun 2014 A\$'000
Cash flows from operating activities:		
Receipts from grants	2,316	2,044
Interest received	179	307
GST refunded	44	141
Payments to employees	(668)	(485)
Payments to other suppliers	(6,478)	(4,605)
Net cash used in operating activities	(4,607)	(2,598)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(3)	(20)
Purchase of intangible assets	-	(3)
Net cash used in investing activities	(3)	(23)
Cash flows from financing activities:		
Proceeds from the exercise of options	1,051	1,140
Payments for share issue expenses	(12)	(67)
Net cash from financing activities	1,039	1,073
Net decrease in cash held	(3,571)	(1,548)
Effect of exchange rate changes on cash balances	399	(366)
Cash at the beginning of the period	20,824	24,379
Cash at the end of the period	17,652	22,465
Reconciliation with loss after income tax:	•	
Loss after income tax	(5,348)	(4,671)
Items requiring adjustment:	(3,348)	(4,071)
Depreciation and amortisation	47	54
Impairment loss	٠,	31
Share based payments	611	388
Lease incentive amortisation	-	-
Foreign exchange loss	(439)	415
Movements in working capital	522	1,185
Net cash used in operating activities	(4,607)	(2,598)



for the six months ended 30 June 2015

#### 1. Nature of business

Neuren Pharmaceuticals Limited (Neuren or the Company, and its subsidiaries, or the Group) is a publicly listed biopharmaceutical company focusing on the development of drugs for neurological disorders. The drugs target brain injury, neurodevelopmental disorders and neurodegenerative disorders.

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 25 August 2015.

#### 2. Summary of significant accounting policies

These general-purpose interim financial statements are for the six months ended 30 June 2015 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.

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 2014 and the unaudited financial statements for the six months ended 30 June 2014. There is no cyclical seasonality of interim operations.

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 2014.

#### New standards first applied in the period

The Company has adopted External Reporting Board Standard A1 Accounting Standards Framework (For-profit Entities Update) (XRB A1). XRB A1 establishes a for-profit tier structure and outlines which suite of accounting standards entities in different tiers must follow. The Company is a Tier 1 entity. There was no impact on the current or prior year financial statements.

Other amendments to IFRSs effective for the financial year ending 31 December 2015 are not expected to have a material impact on the group.



for the six months ended 30 June 2015

#### 3. Loss before income tax

The loss before income tax includes:

Group	A\$'000	A\$'000
Depreciation	(9)	(14)
Amortisation of intangible assets - Intellectual property	(37)	(40)
Impairment of intangible assets - Intellectual property	-	(31)
Foreign exchange gain/(loss) on revaluation of forward contracts	94	(140)

lun 2015

lun 2014

The impairment charge of approximately \$31,000 in the prior period related to the write down to nil recoverable value of the intellectual property owned by the subsidiary Perseis Therapeutics Limited.

At 30 June 2015, one forward contract to convert Australian dollars to US dollars was outstanding, as detailed in the table below. Adjustment of this financial instrument to fair value as measured at 30 June 2015 resulted in a gain of approximately \$94,000. 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 2015, the balance sheet value of all financial instruments was equivalent to the fair value.

Settlement date Buy US dollars Sell Australian dollars Contract rate 31 August 2015 \$3,000,000 \$3,797,468 0.79

## 4. Share capital

Consolidated	Jun 2015 Shares	Dec 2014 Shares
Issued share capital		
Ordinary shares on issue at beginning of period	1,625,241,426	1,512,528,963
Shares issued in Loan Funded Share Plan	20,000,000	30,000,000
Shares issued on option exercise	42,806,757	82,712,463
Ordinary shares on issue at end of period	1,688,048,183	1,625,241,426



for the six months ended 30 June 2015

At 30 June 2015, options were outstanding to acquire 72,900,000 shares at a weighted average price of \$0.0156 per share (31 December 2014: 115,706,757 shares at a weighted average price of \$0.0189 per share).

During the period to 30 June 2015, Equity Performance Rights (EPRs) to acquire 1,308,901 shares were granted to an executive as a long-term incentive. During the period to 30 June 2014, EPRs to acquire 3,309,892 shares were granted to executives as long-term incentives. The EPRs may be exercised at nil exercise price after 3 years. At 30 June 2015 the total number of EPRs outstanding was 14,234,178.

#### 5. Commitments and contingencies

#### (a) Operating leases

The current commitment relates to two leases of premises. One lease expires on 1 December 2015 and the second lease has 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 2015 A\$'000	Dec 2014 A\$'000
Non-cancellable operating lease commitments		
Not later than one year	99	128
Later than one year and not later than five years	49	85
Later than five years	-	-
	148	213

#### (b) Legal claims

The Group had no significant legal or other contingencies as at 30 June 2015, 30 June 2014, or 31 December 2014.

#### (c) Capital commitments

The Company was not committed to the purchase of any property, plant or equipment as at 30 June 2015 (30 June 2014 and 31 December 2014: nil).

## 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 entirely received from the United States federal government.



for the six months ended 30 June 2015

#### 7. Related Party transactions

During the period to 30 June 2015, 20 million shares were issued under the Company's Loan Funded Share Plan as a long-term incentive for Key Management Personnel (KMP). During the period to 30 June 2014, 30 million shares were issued under the Loan Funded Share Plan as a long-term incentive for KMP. The loan funded shares are held in trust for a vesting period of three years and transfer to the beneficiary is subject to the achievement of certain performance criteria. In addition, as detailed in Note 4, equity performance rights (EPRs) were granted to KMP.

Share based payments expense of \$610,843 (six months ended 30 June 2014: \$387,704) was recognised in the Statement of Comprehensive Income in respect of the loan funded shares and EPRs.

During the period to 30 June 2015, Larry Glass exercised options to acquire 20 million ordinary shares at \$0.03 per share and paid exercise proceeds of \$600,000 to Neuren. In addition, Mr Glass sold to Neuren's largest shareholder options to acquire 35 million shares, receiving sale proceeds of \$4,795,000.

# 8. Events after balance date

As at the date of this financial report there were no events arising since 30 June 2015 that require disclosure.





# Independent Review Report

to the shareholders of Neuren Pharmaceuticals Limited

# Report on the Interim Financial Statements

We have reviewed the accompanying 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 2015, and the interim statement of comprehensive income, the interim statement of changes in equity and the interim statement of cash flows statements for the period ended on that date, and a summary of significant accounting policies and selected explanatory notes.

# Directors' Responsibility for the Interim Financial Statements

The Directors of the Company are responsible 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 auditor performs 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 and providers of other related assurance services 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 financial statements of the Company 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 Company's shareholders, 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 an accountants' 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 Company and the Company's shareholders, as a body, for our review procedures, for this report or for the conclusions we have formed.

Chartered Accountants 25 August 2015

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