

## Neuren reports financial results for 2013

### Highlights of the year:

- **Strategy**
  - Therapeutic focus of NNZ-2566 and NNZ-2591 expanded from acute brain injury to chronic neurological conditions
  - Placement and Share Purchase Plan raised A\$23 million to fund four Phase 2 trials through to completion
  - Leadership team reorganised and strengthened; corporate office moved from New Zealand to Melbourne, Australia
- **NNZ-2566 in Rett Syndrome**
  - Phase 2 trial commenced in the US in April 2013 – on track to report results in H2 2014
  - Fast Track designation received from the US Food and Drug Administration (FDA)
- **NNZ-2566 in Fragile X Syndrome**
  - Phase 2 trial commenced in the US in January 2014 – results expected in H1 2015
  - Fast Track and Orphan Drug designation received from FDA
  - Second drug molecule, NNZ-2591, shown to normalise Fragile X characteristics in validated pre-clinical model
- **US Patent and Trademark Office issued two new patents covering NNZ-2566 and one new patent covering NNZ-2591**
- **Financials**
  - Cash reserves at 31 December 2013 – NZ\$26.5 million
  - Net loss before non-cash impairment charge – NZ\$9.1 million
  - Operating cash outflow – NZ\$8.4 million
  - Reporting currency changed to Australian dollars from 1 January 2014

**Melbourne, Australia, 27 February 2014:** Neuren Pharmaceuticals (ASX: NEU) today reported its financial results for the year to 31 December 2013 and highlighted the significant business progress made during the year.

Neuren Executive Chairman Richard Treagus commented “Neuren closed 2013 in a strong financial position with cash reserves of NZ\$26.5 million and with our clinical trials on schedule. We look forward to making further progress in 2014 towards realising the value of NNZ-2566 for patients and shareholders.”

During 2013 Neuren made significant progress in the implementation of its corporate strategy. The strategy is designed to increase the value of Neuren's key assets, NNZ-2566 and NNZ-2591, by extending the therapeutic focus from acute brain injury to chronic neurological conditions requiring longer term dosing. During the year Neuren's board and management team was reorganised and strengthened in order to execute the strategy, and the corporate office was moved from New Zealand to Melbourne, Australia. In October, Neuren successfully completed a placement of new shares to institutional and sophisticated investors which, together with a Share Purchase Plan, provided funds of \$23 million. These funds ensure that four Phase 2 trials of NNZ-2566 in Rett Syndrome, Fragile X Syndrome, Traumatic Brain Injury and Concussion are all fully funded through to completion in 2014 and 2015.

Neuren initiated a Phase 2 trial of NNZ-2566 in Rett Syndrome in April 2013. Enrolment is expected to be completed in the first half of 2014, with top-line results announced in the second half of 2014. Neuren's Rett Syndrome program has received Fast Track designation from the US Food and Drug Administration (FDA), which is designed to expedite the development and review of important new medicines. Neuren also intends to seek orphan drug designation from the FDA after completing the current clinical trial.

Neuren commenced a Phase 2 clinical trial of NNZ-2566 in Fragile X Syndrome in January 2014. Enrolment is expected to be completed by the end of 2014, with top-line results announced in the first half of 2015. The FDA has granted orphan drug designation to NNZ-2566 for treatment of Fragile X 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 seven years of marketing exclusivity following approval as well as various development incentives including waiver of the prescription drug user fee for a marketing application. Neuren has also received Fast Track designation from the FDA.

During the year Neuren also published results from testing in a validated pre-clinical model of Fragile X Syndrome, in which NNZ-2591 was shown to reverse the differences between normal (wild-type) mice and *fmr1* knockout mice, normalising known Fragile X neuronal, behavioural and biochemical characteristics.

During 2013, the US Patent and Trademark Office issued three new patents covering oral formulations of NNZ-2566, a method for treating a cognitive disorder or a memory disorder with NNZ-2566 and the use of NNZ-2591 for the treatment of peripheral neuropathy.

NNZ-2566 is now covered by 8 issued US patents covering the composition, oral formulation and methods of use, with additional patent applications pending. NNZ-2591 is covered by 3 issued US patents. All patents are owned by Neuren and no royalties are payable to third parties. Expiry dates of the patents range between 2022 and 2030.

Consistent with an increasing focus on and investment in the development of its key assets, NNZ-2566 and NNZ-2591, Neuren announced today that it will not invest in any further development of Motiva™ (Nefiracetam). Neuren is currently in discussions with the licensor of the Motiva intellectual property to determine any future actions, however in Neuren's consolidated financial statements for 2013 the intellectual property intangible asset has been written down through a non-cash impairment charge of NZ\$3.2 million. Neuren is also currently reviewing the strategic options for the

anti-cancer programs conducted by its subsidiary Perseis Therapeutics in order to realise maximum value from the intellectual property.

#### Summary of financial results for the year to 31 December 2013

	2013	2012
	NZ\$m	NZ\$m
Grant income	5.7	5.3
Interest income	0.2	0.3
<b>Total revenue</b>	<b>5.9</b>	<b>5.6</b>
Research & Development	(9.5)	(8.1)
Corporate & Administration	(2.4)	(1.5)
Foreign exchange loss	(1.6)	(0.2)
Patent costs	(0.3)	(0.2)
Depreciation & amortisation	(0.4)	(0.4)
Share based payments amortisation	(0.8)	(1.7)
<b>Loss before impairment charge</b>	<b>(9.1)</b>	<b>(6.5)</b>
Motiva impairment charge	(3.2)	0.0
<b>Loss before and after tax</b>	<b>(12.3)</b>	<b>(6.5)</b>
Operating cash outflow	(8.4)	(3.7)
New share capital	30.0	0.5
Foreign exchange loss	(1.6)	(0.1)
<b>Cash at 31 December</b>	<b>26.5</b>	<b>6.5</b>

The consolidated loss after tax for the year ended 31 December 2013 was NZ\$12.3 million (2012: NZ\$6.5 million). The increased loss was due to the following:

- A non-cash Impairment loss of \$3.2 million following a review of the carrying value of the acquired intellectual property related to Motiva;
- An increase of \$1.4 million in research and development costs, mainly attributable to the Rett Syndrome clinical trial and the Traumatic Brain Injury clinical trial;
- An increase of \$1.4 million in accounting foreign exchange losses, due to the translation of Australian dollar cash reserves into New Zealand dollars at the year-end exchange rate, solely for the purpose of reporting financial results in New Zealand dollars; and
- An increase of \$0.9 million in corporate and administration costs, mainly due to the appointment of an additional executive director and higher legal and travel costs; offset by
- A decrease of \$0.9 million in share based payment expense, due to the completion of the amortisation of vested share options; and
- An increase of \$0.3 million in grant revenue from the US government, reflecting higher costs in the Traumatic Brain Injury trial.

Cash reserves at 31 December 2013 were NZ\$26.5 million (2012: NZ\$6.5 million). Operating cash outflow increased to \$8.4 million (2012: \$3.7 million) due to the higher development and corporate costs and US government grant of \$1.6 million earned but not received at 31 December 2013.

Financing cash inflow increased to \$30.0 million (2012: \$0.5 million) due to the capital raising and to proceeds from the exercise of options of \$4.0 million (2012: \$0.5 million).

In order to better reflect Neuren's business environment and risks, its reporting currency will change from New Zealand dollars to Australian dollars, effective from 1 January 2014.

### **About NNZ-2566**

NNZ-2566 is a synthetic analogue of a naturally occurring neurotrophic peptide derived from IGF-1, a growth factor produced by brain cells. In animal models, NNZ-2566 exhibits a wide range of important effects including inhibiting neuroinflammation, normalising the role of microglia and correcting deficits in synaptic function. In the Fragile X model, these actions resulted in statistically significant improvement in all core anatomic and behavioural features of the disorder that were assessed. NNZ-2566 is being developed both in intravenous and oral formulations for a range of acute and chronic conditions. The intravenous form of NNZ-2566 is presently in a Phase II clinical trial in patients with moderate to severe traumatic brain injury. The oral form of NNZ-2566 is in Phase II trials in Rett Syndrome and Fragile X Syndrome. All three programs have received Fast Track designation from the US FDA and the Fragile X Syndrome program has also received Orphan Drug designation. Neuren intends to implement a Phase II clinical trial with the oral form of NNZ-2566 in patients with concussion (mild traumatic brain injury).

### **About NNZ-2591**

NNZ-2591 is a synthetic analogue of a naturally occurring neuropeptide, which has been shown to have neuroprotective and nootropic (memory enhancing) effects in multiple animal models. NNZ-2591 has excellent oral bioavailability and is currently being assessed as a clinical candidate for the treatment of chronic neurological disorders. NNZ-2591 is protected by both composition of matter and therapeutic use patents, as well as a number of pending applications.

### **About Neuren**

Neuren Pharmaceuticals Limited (Neuren) is a publicly listed biopharmaceutical company focusing on the development of new therapies for brain injury, neurodevelopmental and neurodegenerative disorders. The novel drugs target chronic conditions such as Rett Syndrome and Fragile X Syndrome as well as acute neurological injuries. Neuren presently has a clinical stage molecule, NNZ-2566 in two Phase 2 clinical trials as well as NNZ-2591 in pre-clinical development.

#### *Forward-looking Statements*

*This ASX-announcement contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Neuren to be materially different from the statements in this announcement.*

#### **For more information, please contact:**

Dr Richard Treagus, Executive Chairman: [rtreagus@neurenpharma.com](mailto:rtreagus@neurenpharma.com) +61 417 520 509

Jon Pilcher, CFO & Company Secretary: [jpilcher@neurenpharma.com](mailto:jpilcher@neurenpharma.com) +61 438 422 271