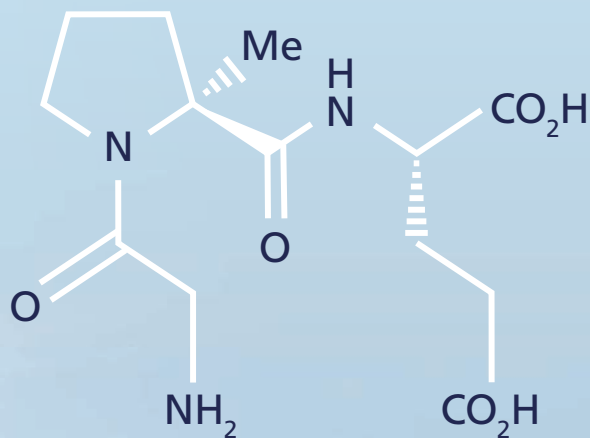


# ANNUAL REPORT 2014



neuren

pharmaceuticals

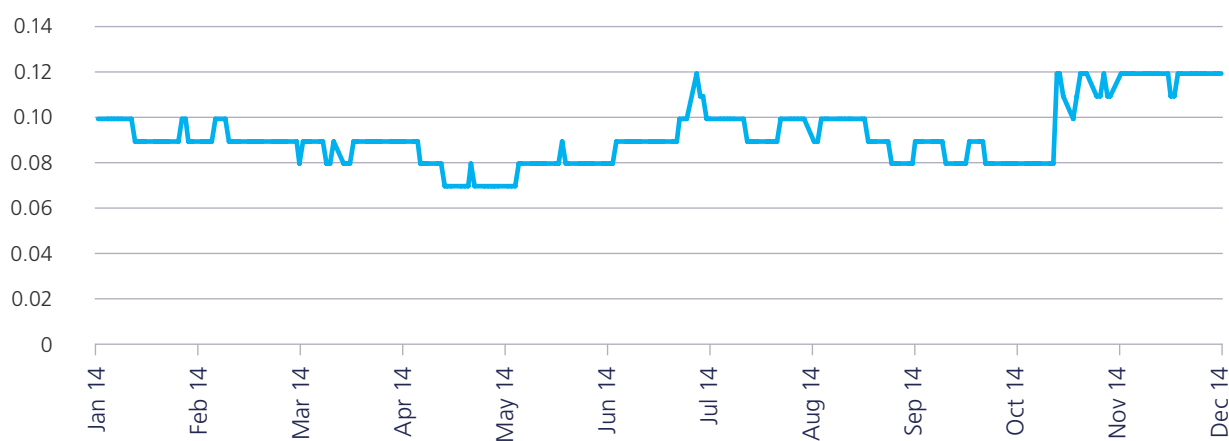
# COMPANY SNAPSHOT

**Neuren Pharmaceuticals (ASX: NEU) is a biopharmaceutical company focusing on the development of new therapies for brain injury, neurodevelopmental and neurodegenerative disorders.**

## **Business progress since 1 January 2014**

- Trofinetide proposed as International Non-proprietary Name (INN) for NNZ-2566
- Results from Phase 2 clinical trial in Rett syndrome successfully demonstrated clinical benefit from treatment with trofinetide
- Orphan Drug designation granted by FDA for trofinetide in Rett syndrome
- Orphan Drug applications to the European Medicines Agency (EMA) underway for both Rett syndrome and Fragile X syndrome
- Fragile X syndrome Phase 2 trial commenced
- Enrolment accelerated in moderate to severe traumatic brain injury Phase 2 trial
- Concussion Phase 2 trial commenced
- Grant award supporting Neuren's brain injury collaboration with the US Army increased by approximately US\$3 million and extended to 31 December 2015
- Neuren leadership team strengthened in technical and manufacturing aspects of pharmaceutical development

## Neuren share price in 2014



## Expected milestones for trofinetide in 2015

Rett syndrome	Meet with FDA to discuss remaining development requirements	H1 2015
	Decision from EMA on Orphan Drug application for Europe	H2 2015
Fragile X syndrome	Phase 2 trial top-line results	H2 2015
	Decision from EMA on Orphan Drug application for Europe	H2 2015
Moderate to severe TBI	Phase 2 trial top-line results	H2 2015
Concussion (mild TBI)	Phase 2 trial top-line results	H2 2015

## Product Development Pipeline

	Pre-clinical & Phase 1	Phase 2	Phase 3
Trofinetide: Rett syndrome	Completed	In Progress	Not Started
Trofinetide: Fragile X syndrome	Completed	In Progress	Not Started
Trofinetide: moderate to severe TBI	Completed	In Progress	Not Started
Trofinetide: Concussion (mild TBI)	Completed	In Progress	Not Started
NNZ-2591: Other neurological conditions	In Progress	Not Started	Not Started

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The Board of Directors is pleased to present the Annual Report of Neuren Pharmaceuticals Limited for the year ended 31 December 2014, authorised on 24 March 2015

For, and on behalf of, the Board



Dr Richard Treagus  
Chairman



Dr Trevor Scott  
Director

neuren

pharmaceuticals





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## CHAIRMAN'S LETTER



Since 1 January 2014 we have made substantial progress in Neuren's development and commercialisation strategy. In November, we reached a pivotal point in our history with the results from the first Phase 2 clinical trial of trofinetide, which successfully demonstrated clinical benefit in Rett syndrome.

As well as being the first Phase 2 trial of trofinetide, this was the first multi-site, sponsor-led clinical trial in Rett syndrome and was also the first trial in an adolescent and adult population. This was ground-breaking research and we are very grateful for the support and dedication of the trial subjects and their families, the International Rett Syndrome Foundation and the clinicians at Baylor College of Medicine, University of Alabama at Birmingham and Gillette Children's Specialty Healthcare. The results of the trial exceeded our expectations after only 28 days' treatment in a profoundly ill population, with the clinical benefit in the trial encompassing core symptoms of Rett syndrome and being observed in both clinician and caregiver assessments. Importantly, trofinetide was well tolerated and no safety concerns were identified.

Subsequent to the results, Neuren was able to obtain Orphan Drug designation from the FDA for trofinetide in Rett syndrome, which is extremely valuable commercially given seven years of market exclusivity that it confers. We have also commenced the process of applying for Orphan Drug designation in the European Union for both Rett syndrome and Fragile X syndrome.

On 2 March 2015, we announced that the FDA had declined our request for Breakthrough Therapy designation in Rett syndrome. Only 30% of Breakthrough Therapy requests have been granted historically, so the FDA sets a high bar for this designation. The data we submitted from our Phase 2 trial of 54 subjects was considered to be of insufficient statistical power to meet the FDA's requirements for Breakthrough Therapy at this time. This does not alter our view of the clinical benefit that was observed in the trial or our commitment to move our Rett syndrome program forward as expeditiously as possible. We and our expert advisors remain confident that we have a strong case for Breakthrough Therapy and we may submit further data to the FDA in the future. We will continue to work with the FDA under the Fast Track designation to determine the best and quickest way to progress the development of trofinetide for Rett syndrome patients.

We anticipate that 2015 will see further important milestones in Rett syndrome as we meet with the FDA to agree the remaining development requirements and as we actively pursue our Orphan Drug applications in Europe. Furthermore, 2015 will also see Neuren and trofinetide reach critical milestones with the completion of our Fragile X syndrome and brain injury Phase 2 trials.

On behalf of the Board, I wish to thank you for your ongoing support as we continue to progress the development and commercialisation of trofinetide for both patients and shareholders.

**Dr Richard Treagus**  
Chairman

# OPERATING REVIEW

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Neuren's strategy is to demonstrate the broad therapeutic applicability of its patented drug candidates in brain injury, neurodevelopmental and neurodegenerative disorders, and to progress selected applications towards commercialisation in world markets.

## Neuren's strategy

Neuren's strategy is to demonstrate the broad therapeutic applicability of its patented drug candidates in brain injury, neurodevelopmental and neurodegenerative disorders, and to progress selected applications towards commercialisation in world markets. The selected applications have four crucial attributes: solid scientific rationale, significant unmet medical need, compelling market opportunity and the potential for favourable regulatory treatment with a clear path to approval.

Neuren is in Phase 2 clinical development of trofinetide to treat four different conditions; Rett syndrome, Fragile X syndrome, moderate to severe traumatic brain injury and concussion. Currently there are no drugs approved for any of these conditions and there are few drugs in late-stage clinical development. Some drugs that are approved for other indications are sometimes used to treat selected symptoms, but none are more than modestly effective and none are disease-modifying. Trofinetide provides Neuren an opportunity potentially to achieve the first approved therapy for one or more of these important indications.

As these are serious medical conditions with unmet need, drugs being developed to treat them may qualify for favourable regulatory pathways intended to expedite the development and approval of therapeutically important drugs. The US Food and Drug Administration (FDA) has granted to Neuren:

- Orphan drug designation for trofinetide in each of Rett syndrome and Fragile X Syndrome
- Fast Track designation for trofinetide in each of Rett Syndrome, Fragile X Syndrome and moderate to severe TBI

In December 2014 Neuren also applied for Breakthrough Therapy designation for trofinetide in Rett syndrome, however the FDA determined that the clinical data submitted in our application from our first small clinical trial was not sufficiently powered to meet the threshold for that program. Neuren may submit additional data in the future.

Neuren has also commenced the process of Orphan Drug applications to the European Medicines Agency for trofinetide in both Rett syndrome and Fragile X syndrome. Orphan Drug designation in the European Union qualifies the sponsor of the drug for 10 years of marketing exclusivity following marketing authorisation.

The marketing exclusivity periods are extremely valuable for the commercialisation of Orphan Drugs. They provide additional protection, along with patents, against generic competitors and potentially can continue to provide protection after patent expiry.

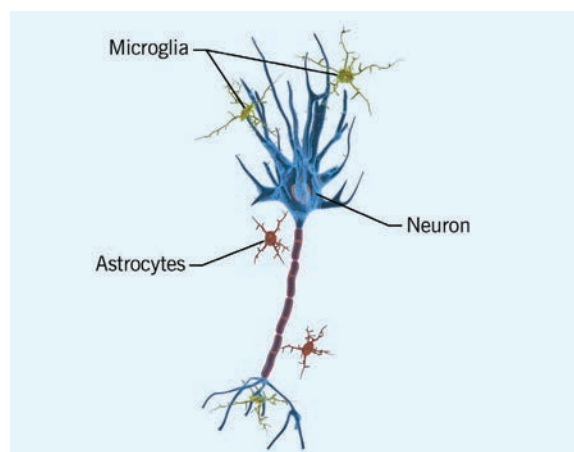
**Orphan Drug** designation is a special status that the FDA may grant to a drug to treat a rare disease or condition. Amongst other incentives, Orphan Drug designation qualifies the sponsor of the drug for 7 years of marketing exclusivity and various development incentives including waiver of the prescription drug user fee for a marketing application.

A drug may be designated as a **Fast Track** product if it is intended for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Fast Track designation is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

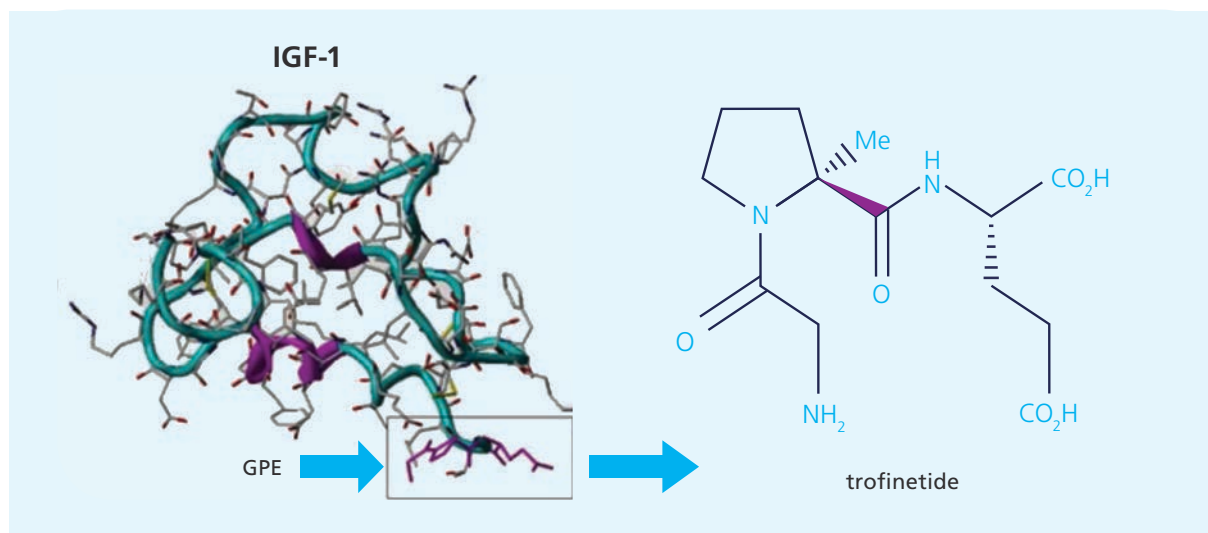
**Breakthrough Therapy** is an expedited program, intended to streamline drug development and regulatory review of innovative new medicines that address unmet medical needs for serious diseases or conditions. The criteria for Breakthrough Therapy require preliminary clinical evidence indicating that the drug may demonstrate a substantial improvement over existing therapies on at least one clinically significant endpoint. Breakthrough Therapy designation conveys all of the Fast Track program features, as well as a commitment that FDA will work closely with the sponsor on an efficient drug development program.

## The science behind Neuren's products

Trofinetide is the name proposed by the World Health Organisation for our lead clinical-stage drug candidate (previously designated by Neuren as NNZ-2566). It is an analog of a molecule which is derived from IGF-1 and occurs naturally in the brain. IGF-1 is a growth factor stimulated by growth hormone. In the central nervous system, IGF-1 is produced by both of the major types of brain cells – neurons and glia. IGF-1 in the brain is critical both for normal development and for responding to injury and disease.



# OPERATING REVIEW continued



In the brain, IGF-1 gets broken down into two separate molecules. One, often referred to as glypromate or GPE, comprises the last three peptides of IGF-1. GPE affects glial cells (astrocytes and microglia) while IGF-1 itself mostly affects neurons.

Trofinetide is Neuren's chemically modified form of GPE that can mimic GPE's natural function in the brain. The small modification results in the drug having an increased half-life in the circulation, better stability for easier storage and shipping, and suitability for use as an oral medication, whereas GPE itself and IGF-1 can only be administered by injection.

In the brain, the role of IGF-1 and GPE is to facilitate the brain's development and maintain the biological balance required for normal functioning. These processes have evolved over millions of years and are still being extensively researched by scientists.

During development, the brain and the cells that make it up change rapidly and in complex ways. IGF-1 and GPE play a significant role in regulating these changes. In the mature brain, IGF-1 and GPE both play an important role in responding to disease, stress and injury. Whereas most drugs typically exert a specific effect on a specific target, trofinetide exerts diverse effects which can help to control or normalise abnormal biological processes in the brain.

Although different conditions – brain injury, neurodevelopmental disorders and neurodegenerative diseases – can result in very different symptoms and outcomes, many share common, underlying pathological features.

These include inflammation, over-activation of microglia, dysfunction of synapses (the connections between neurons through which information is transmitted) and reduced levels of IGF-1. In other words, diseases and conditions caused by different mechanisms often result in the same pathology at the cellular and molecular level.

## 1. Inflammation

Inflammation in the brain – often referred to as neuroinflammation – is perhaps the most common pathological feature of central nervous system disorders. Much of it is the result of excess production of molecules called inflammatory cytokines. These are prominent in brain injuries, neurodevelopmental disorders such as Rett and Fragile X syndromes as well as autism, neurodegenerative diseases like Alzheimer's and Parkinson's and even so-called "normal" aging.

Neuroinflammation places significant stress on brain cells. Stress can disrupt normal cellular processes such as information signalling, increase energy requirements beyond the ability of the cells to meet their metabolic needs, disturb electrical functions which can lead to seizures and other abnormalities and even result in premature cell death.

In animal models ranging from brain injury and stroke to Fragile X syndrome to age-associated cognitive impairment, trofinetide has shown an ability to significantly reduce the levels of inflammatory cytokines. This has resulted in improvement in a wide range of symptoms including post-traumatic seizures, anxiety, memory impairment and hyperactivity.



## 2. Over-activation of microglia

Microglia are the resident immune cells in the brain. Once thought to serve primarily a sentinel function – responding to infection and damaged cells by surrounding and removing them – it is now known that they play a central role in maintaining synapses during development and in mature brains by pruning dendrites, the many small extensions of neurons that form synapses. Microglia are also a key source of IGF-1. Due to this wide-ranging maintenance function, they have appropriately been referred to as the “constant gardeners” of the brain.

Microglia are not only activated in response to infection and injury. They also are activated by inflammation that accompanies acute brain injury and chronic conditions. In this activated state, they not only lose their ability to effectively perform their normal function in synaptic maintenance but also produce more inflammatory cytokines which can further compound the damage to neurons and other brain cells.

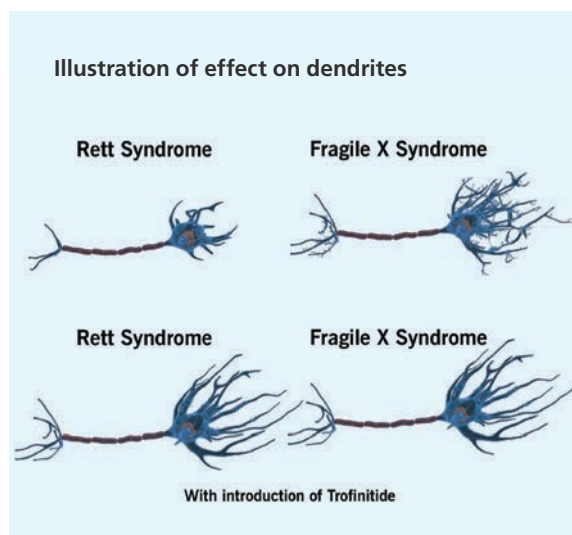
Trofinetide has been shown to normalise microglial biology and function in both acute and chronic conditions. Restoring normal microglial activity has resulted in improved synaptic structure as well as correction of imbalance in synaptic signalling and cell-to-cell communication. This has led to reversal of symptoms such as impaired memory, anxiety, hyperactivity and compromised social behaviour.

## 3. Dysfunction of synapses

Neurons communicate with each other by chemical and electrical signals transmitted via synapses. Normal synaptic function is essential for healthy brain function and underlies memory, cognition, behaviour and other brain activities. Normal synaptic function requires that the dendrites (part of the neurons) which form synapses are appropriately formed as well as that excitatory and inhibitory signals are kept in balance.

When dendritic structure and synaptic signalling are abnormal, virtually all brain activities can be negatively impacted. Synaptic dysfunction has been identified as a core feature of many conditions including acute brain injury, neurodevelopmental disorders and neurodegenerative diseases.

For example, in Rett syndrome dendrites are sparse and immature while in Fragile X syndrome, dendritic branching is excessive although the dendrites are also immature. Trofinetide increases the length and branching of dendrites in a model of Rett syndrome while increasing pruning of excess branching in Fragile X syndrome. In the Fragile X animal model, aberrant synaptic signalling was normalised within 15 minutes of the first dose.



## 4. Reduced levels of IGF-1

As previously mentioned, IGF-1 levels in the brain have been reported to be depressed in a number of conditions, particularly in Rett and Fragile X syndromes and brain injury. In these conditions, the critical role of IGF-1 and GPE in maintaining and repairing brain cells and synapses is impaired.

In the Fragile X model, in which the IGF-1 level is depressed, trofinetide increased the amount of IGF-1 to normal levels. This was accompanied by normalised synaptic signalling and complete reversal of cognitive and behavioural abnormalities.

In a model of Rett syndrome, increasing IGF-1 levels has been reported to correct deficits in dendritic spines and, in isolated cells from human Rett syndrome patients, both IGF-1 and GPE are able to partially reverse the deficits in cellular function.

Summarising, trofinetide helps to correct four of the hallmark pathological features of many central nervous system disorders: inflammation, over-activation of microglia, dysfunction of synapses and reduced levels of IGF-1. By simultaneously targeting multiple processes, trofinetide works to restore the natural balance of brain function.

Neuren's second patented drug candidate, 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 shown encouraging results in well-validated preclinical models of cognitive impairment, Fragile X syndrome, traumatic brain injury, stroke, Parkinson's disease, peripheral neuropathy and multiple sclerosis.

## OPERATING REVIEW continued

### Neuren's product development programs for trofinetide

#### Rett syndrome

Rett syndrome is a neurological disorder that occurs almost exclusively in females following apparently normal development for the first six months of life. Typically, between 6 to 18 months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication. Many patients have recurrent seizures. They experience a variety of motor problems including increased muscle tone (spasticity) and abnormal movements. Most Rett syndrome patients live well into adulthood and generally require life-long medical care and 24 hour a day supportive care as they grow older. In addition to direct costs for medical and related services, costs for institutional and special education services as well as the financial and emotional impact on families are very large. Rett syndrome is caused by mutations on the X chromosome on a gene called *MECP2*. There are more than 200 different mutations found on the *MECP2* gene that interfere with its ability to generate a normal gene product. Rett syndrome strikes all racial and ethnic groups and occurs worldwide in approximately 1 in every 10,000 live female births. There are currently no approved medicines for the treatment of Rett syndrome.

In November 2014, Neuren announced top-line results from its Phase 2 clinical trial in Rett syndrome, which successfully demonstrated clinical benefit from treatment with trofinetide. Neuren's trial was conducted at Baylor College of Medicine, University of Alabama at Birmingham and Gillette Children's Specialty Healthcare. This was the first multi-site, sponsor-led clinical trial in Rett syndrome and was the first trial in an adolescent and adult population.

53 subjects aged 16 to 45 years completed the double-blind placebo-controlled trial. Two different dose levels of trofinetide were tested: 35mg/kg twice per day and 70mg/kg twice per day. The primary endpoint for the trial was to evaluate the safety and tolerability of each of the two dose levels of trofinetide as compared to placebo. The trial was also enriched with a number of outcome measures that provided insight into efficacy. These included 6 core measures in 4 efficacy domains. The analysis plan was pre-specified and submitted to the FDA before the data was unblinded. The analysis compared clinical responses in the core measures for each subject individually, as well as the mean clinical responses for each treatment group.

Evidence of clinical benefit in the group-level analysis required improvement in at least 2 core outcome measures from 2 different efficacy domains, with no clinically significant worsening in all other core measures.



This requirement was exceeded at day 26 in the higher dose (70mg/kg) group, with 3 measures from 3 different efficacy domains achieving the target: the Motor-Behavior Assessment Change Index, the Clinical Global Impression of Improvement and the Caregiver Top 3 Concerns. The pre-specified criterion of no clinically significant worsening in the remaining 3 core endpoints was also met.

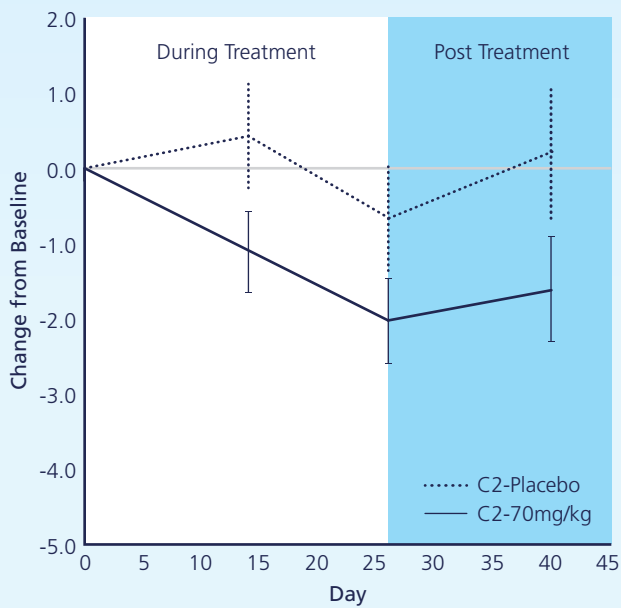
Additionally, for the 70mg/kg dose group the pre-specified criterion of benefit was achieved in the subject-level efficacy analysis, in which the changes in 6 core outcome measures for each subject were combined in a subject-specific efficacy score and the mean efficacy scores were then compared for trofinetide and placebo.

The probability of observing this combined degree of clinical benefit both in the group-level and subject-level analyses and no clinically significant worsening in any endpoint purely by chance (the "false-positive" rate) was determined as 2.3% ( $p=0.023$ ) by permutation testing. In the permutation testing, randomly simulated allocations of patients to trofinetide and placebo were repeated 1000 times and positive outcomes in the data were counted.

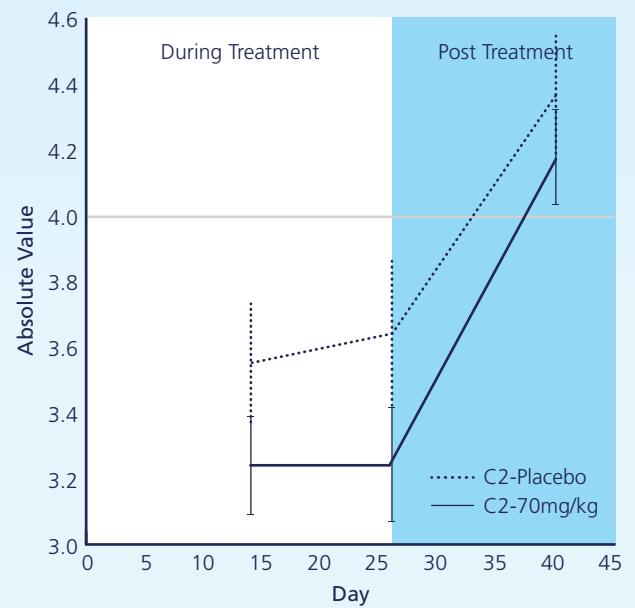
Both dose levels showed trends of increasing effect with the duration of treatment. Trofinetide was well tolerated and no safety concerns were identified.

## Measures that met improvement criteria compared with placebo:

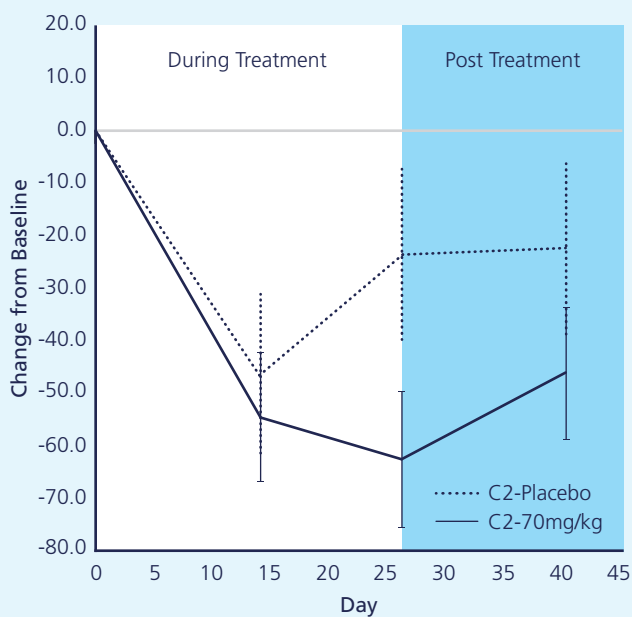
**Motor Behaviour Assessment Change Index<sup>1</sup>**



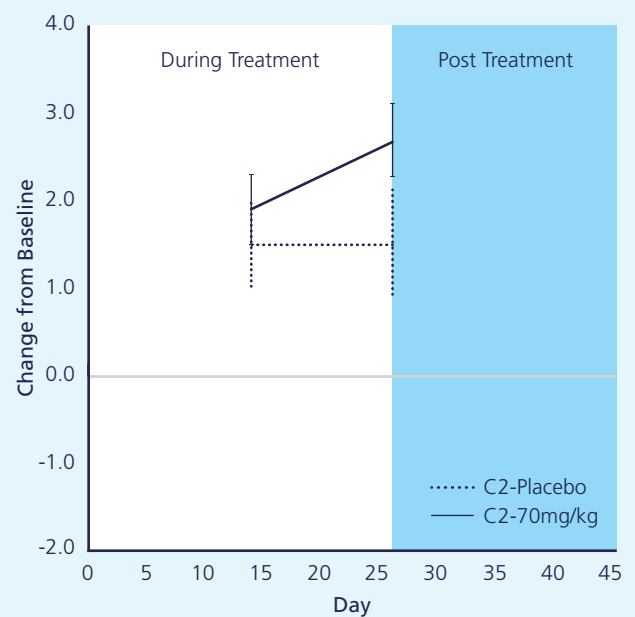
**Clinical Global Impression of Improvement<sup>1</sup>**



**Caregiver Top 3 Concerns<sup>1</sup>**



**Mean Subject-Level Efficacy Score**



<sup>1</sup> A decrease indicates increasing benefit

# OPERATING REVIEW continued

Neuren expects to meet with the FDA in the first half of 2015 to discuss the remaining requirements to complete the development of trofinetide in Rett syndrome.

The International Rett Syndrome Foundation (IRSF) provided advice to Neuren on clinical trial strategy, introductions to leading clinical investigators and funding to contribute towards the cost of Neuren's first Rett syndrome trial. Support from advocacy organisations such as IRSF in facilitating communication with patients, families and investigators are an important factor that assists with the successful implementation of Neuren's development programs.

## Fragile X syndrome

Fragile X syndrome is the most common inherited cause of intellectual disability and the most common known cause of autism. It affects 1 out of 4,000 males and 1 out of 6-8,000 females. Fragile X syndrome is due to a gene mutation on the X chromosome that impacts the FMRP protein, which is responsible for regulating the synapses of nerve cells. Clinically, Fragile X syndrome is characterised by intellectual disability, hyperactivity and attentional problems, autistic symptoms, anxiety, emotional lability and epilepsy. Generally, males are more severely affected than females. Currently, there are no medicines approved for the treatment of Fragile X syndrome.

Neuren's Phase 2 double-blind, placebo-controlled clinical trial of trofinetide in Fragile X syndrome commenced in the United States in January 2014. The trial aims to enrol approximately 60 male subjects, with top-line results expected to be available in the second half of 2015. The trial is designed to assess the safety, tolerability and efficacy of trofinetide in treating symptoms of Fragile X syndrome.

The FDA has granted Fast Track designation and Orphan Drug designation to Neuren for trofinetide in Fragile X syndrome.

## Brain injury

Each year, approximately 1.7 million people sustain a traumatic brain injury (TBI) in the US alone. Of these, 25% are classified as moderate to severe while the remaining 75% are classified as mild TBI or concussion. TBI is a contributing factor in one-third of all injury-related deaths. Moderate to severe TBI frequently leaves patients with profound physical, emotional and cognitive disabilities, often requiring life-long institutional or other supportive care. Concussion also can result in long-term or permanent impairments and disabilities. The direct and indirect costs of TBI are estimated to exceed US\$48 billion per year in the US, with no approved drug therapies available and few in development.

Concussion is common among young adults participating in contact sports but the incidence is also high in young children, older people and the military. Recognition of the health impacts of concussions, both in the short term and the long term, and the extent of the serious unmet need for addressing the impacts has been heightened in recent times.

The serious impact of concussions in sporting codes has become a high-profile issue. Well-known players have retired following repeated concussions and in the United States, concussions and resulting neurocognitive conditions suffered by players have been the subject of litigation.

In animal models, trofinetide has been shown to inhibit inflammatory cytokines, pathological microglial activation, apoptosis and necrosis, which are key features of the biology of TBI. As a result, it improves functional recovery, preserves cognitive function and inhibits post-injury seizures, addressing symptoms that are of primary concern in TBI patients. Neuren's partnership with the US Army has made it feasible to target with trofinetide both moderate to severe TBI and concussion.

Neuren's collaborative relationship with the US Army Medical Research & Materiel Command (USAMRMC) and the Walter Reed Army Institute of Research (WRAIR) began in 2004. WRAIR conducted ground-breaking work to define the pharmacology and mechanisms of action of trofinetide, elaborating its effects on neuroinflammation and microglial activation as well as its effects in models of TBI and non-convulsive seizures. The USAMRMC also has provided regulatory support, technical advice and grants to Neuren in support of the development of trofinetide for TBI. The majority of Neuren's direct third-party costs associated with the clinical trials in moderate to severe TBI and concussion are being reimbursed through the grants. In July 2014, Neuren announced that the grants had been increased by approximately US\$3 million and extended to 31 December 2015.

## Moderate to severe TBI trial

Neuren's ongoing Phase 2 clinical trial ("*INTREPID-2566*") using the intravenous dosage form of trofinetide in moderate to severe TBI aims to enrol 260 subjects. The rate of enrolment accelerated in 2014 as Neuren increased the number of US trauma centres participating in the trial and two large clinical studies that were directly competing for subjects at some of the trial sites completed enrolment. At 3 March 2015, enrolment had reached 211 subjects. Top-line results are expected to be available in the second half of 2015.

The FDA has granted Fast Track designation to Neuren for trofinetide in moderate to severe TBI.

## Concussion trial

Concussion disrupts the normal functioning of the brain. The symptoms that may be manifested reflect underlying pathologic changes at the cellular and molecular level. In particular, concussion often results in neuroinflammation, metabolic changes, altered cerebral blood flow and impaired neuronal, axonal and microglial function. Symptoms of concussion are generally grouped into four categories: cognitive function (thinking and remembering), physical (such as headache, dizziness and balance problems), emotional (such as depressed mood, anxiety and anger) and sleep disturbances.



As well as assessing safety and brain injury biomarkers, Neuren has included outcome measures designed to assess these symptoms in its Phase 2 clinical trial of the oral dosage form of trofinetide in concussion.

The trial commenced in September 2014 with the US Army's 82nd Airborne Division at Fort Bragg in North Carolina. The trial will be expanded to include civilian trial sites in 2015. Neuren aims to enrol 132 subjects and report top-line results in the second half of 2015.

#### Potential in additional neurological conditions

In large part because of the commonality of underlying pathologic processes, Neuren believes that a product which proves to be safe and effective in Rett syndrome, Fragile X syndrome, or TBI may have good potential as a therapy in a wide range of other neurological disorders. Trofinetide and NNZ-2591 could be good candidates for other neurodevelopmental disorders such as Angelman syndrome and idiopathic autism, or neurodegenerative disorders such as Parkinson's disease and multiple sclerosis.

NNZ-2591 has a number of pharmacological attributes that make it an attractive candidate for further development. These include excellent oral bioavailability (approximately 100%), likely suitability for development of a solid oral dosage form and potential for improved stability compared to other peptide-like compounds. Initial development activities are focusing on optimisation of manufacturing processes and physical attributes. In June 2014 the US Patent and Trademark Office issued a Notice of Allowance for a new patent covering NNZ-2591 improving impaired cognitive performance. This was the fourth US patent to be issued covering NNZ-2591, with expected expiries between 2026 and 2031.

#### Finance

Summary of consolidated financial results for the year to 31 December 2014

	2014 \$m	2013 \$m
Grant income	2.9	4.8
Interest income	0.6	0.2
Foreign exchange gain	0.9	-
<b>Total revenue</b>	<b>4.4</b>	<b>5.0</b>
Research & Development	(10.0)	(8.6)
Corporate & Administration	(1.6)	(1.7)
Share based payments amortisation	(0.9)	(0.6)
Foreign exchange loss	-	(1.4)
Depreciation & amortisation	(0.1)	(0.4)
Impairment loss	(0.1)	(2.7)
<b>Loss before and after tax</b>	<b>(8.3)</b>	<b>(10.4)</b>
<b>Operating cash outflow</b>	<b>(6.4)</b>	<b>(7.1)</b>
New share capital	2.2	26.2
Effect of exchange rates on cash balances	0.7	0.2
<b>Cash at 31 December</b>	<b>20.8</b>	<b>24.4</b>

Neuren's reporting currency was changed from New Zealand dollars to Australian dollars from 1 January 2014. This change followed the transfer of the Company's business from Auckland, New Zealand to Melbourne, Australia. The prior period comparative numbers have been restated in Australian dollars in order to provide meaningful comparable information.

The consolidated loss after tax was \$8.3 million (2013: \$10.4 million). The loss decreased by \$2.1 million, mainly due to the following:

- An increase of \$1.4 million in research and development costs, with higher costs for the Rett syndrome and Fragile X syndrome clinical trials partly offset by lower costs for the Intrepid clinical trial; and
- A decrease of \$1.9 million in grant revenue from the US government, reflecting the lower costs for the Intrepid trial; offset by:
- An increase of \$0.4 million in interest income due to higher cash balances following the share placement in October 2013;
- Foreign exchange gains of \$0.9 million (2013: loss of \$1.4 million), mainly due to an increase in value of US dollar denominated cash balances, following the strengthening of the US dollar against the Australian dollar; and
- A non-cash Impairment loss in 2013 of \$2.7 million following a review of the carrying value of the acquired intellectual property related to Motiva™.

Cash reserves at 31 December 2014 were \$20.8 million (2013: \$24.4 million). Net cash used in operating activities decreased from \$7.1 million to \$6.4 million, due to a reduction in payments for staff and directors. The exercise of share options provided net cash from financing activities of \$2.2 million. In 2013, net cash provided from financing activities was \$26.2 million, comprising \$3.6 million from the exercise of share options and \$23.5 million from a share placement and share purchase plan, less issue expenses of \$0.9 million.

# LEADERSHIP TEAM

## Board



**Dr Richard Treagus**  
Executive Chairman  
*BScMed, MBChB,  
MPharmMed, MBA*

Dr Treagus joined the Neuren Board as Executive Chairman on 31 January 2013. He is a physician and entrepreneur, with more than 20 years' experience in all aspects of the international biopharmaceutical industry. He is a business builder with a track record of delivering strong commercial outcomes and shareholder returns. He has held senior executive roles with pharmaceutical organisations in South Africa and Australia and has successfully established numerous pharmaceutical business partnerships in the US, Europe and Asia. Dr Treagus served as Chief Executive of the ASX-listed company Acrux Limited until 2012.

Under his leadership Acrux gained FDA approval for three drug products and concluded the largest product licensing deal in the history of the Australian biotech industry; a transaction with Eli Lilly worth US\$335m plus royalties. Acrux is now a leading Australian biotechnology company and has been profitable since 2010. In 2010 Dr Treagus was awarded the Ernst and Young Entrepreneur-of-the-Year (Southern Region) in the Listed Company Category and in subsequent years has served on the judging panel.



**Bruce Hancox**  
Non-Executive Director  
*BCom*

Mr Hancox joined the Neuren Board in March 2012. Mr Hancox has had a long and distinguished career in business in New Zealand and Australia. He was for many years involved with Brierley Investments Limited as General Manager, Group Chief Executive and Chairman. He also served as a director of many Brierley subsidiaries in New Zealand, Australia and the United States. Since 2006 he has pursued various private investment interests and has been a director of, and consultant to, a number of companies. He has acted as an advisor on a number of takeover situations. From 2007 to 30 April 2013 he was a director of Australian listed company Retail Food Group Limited and in February 2014 he became a director of Australian listed company Medical Australia Limited.



**Larry Glass**  
Executive Director and  
Chief Science Officer  
*BA (Biology)*

Mr Glass joined Neuren in 2004 and has been an Executive Director since May 2012. He has more than 30 years' experience in the life sciences industry, including clinical trials, basic and applied research, epidemiologic studies, diagnostics and pharmaceutical product development. Before he joined Neuren, he worked as an independent consultant for a number of biotech companies in the US and internationally providing management, strategic and business development services. Prior to that, he was CEO of a contract research organisation ("CRO") that provided preclinical research and clinical trials support for major pharmaceutical and biotechnology companies and the US government. For a number of years, the CRO operated as a subsidiary of a NYSE-listed company and was subsequently sold to a European biopharmaceutical enterprise which was then acquired by Johnson & Johnson. Mr Glass is a biologist with additional graduate training in epidemiology and biostatistics.



**Dr Trevor Scott**  
Non-Executive Director  
*MNZM, LL.D (Hon), BCom, FCA,  
FNZIM, DF Inst D*

Dr Scott joined the Neuren Board in March 2002. He is the founder of T.D. Scott and Co., an accountancy and consulting firm, which he formed in 1988. He is an experienced advisor to companies across a variety of industries. Dr Scott serves on numerous corporate boards and is chairman of several. He chairs Neuren's Audit Committee and Remuneration Committee as an independent director.

## Management



**Jon Pilcher**  
Chief Financial Officer  
*BSc (Hons), ACA*

Jon joined Neuren in August 2013 from Acrux (ASX: ACR) where, as CFO & Company Secretary, he was a member of the leadership team for eleven years. That period included Acrux's IPO and listing on the ASX, the development and FDA approval of three novel pharmaceutical products and a transforming licensing deal with Eli Lilly in 2010. Jon is a Chartered Accountant and holds a degree in Biotechnology from the University of Reading in the UK. He formerly spent seven years in a series of senior financial positions in the R&D and corporate functions of international pharmaceutical groups Medeva and Celltech (now part of UCB).

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**James Shaw**  
Vice President, Clinical Operations  
*BSc (Hons), MBA*

James joined Neuren in August 2013 and brings twenty years of development and commercialisation experience in the pharmaceutical industry, having worked for both large Pharma and Clinical Research Organisations. Before joining Neuren, he was CEO of a Clinical Research and Site Management Organisation providing full service clinical trial support in Australia and New Zealand. Prior to that he spent 7 years with Quintiles in Sydney and Singapore working across Business Development and Operational leadership roles. James brings a global focus to drug development, having led product teams from Phase II through to FDA submission and commercialisation during six years with AstraZeneca at their global headquarters in the UK.

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**Dr Joe Horrigan**  
Vice President, Clinical Development and Medical Affairs

Dr. Joe Horrigan is a pediatric neuropsychiatrist. Prior to joining Neuren in 2013, Dr. Horrigan served as Assistant Vice President and Head of Medical Research for Autism Speaks, the largest science and advocacy organisation in the US devoted to autism spectrum disorders (ASD). In this role he was responsible for developing and implementing a comprehensive strategy in the area of translational medical research in ASD, focusing primarily on Phase I-IV clinical trials. Prior to joining Autism Speaks, Dr. Horrigan worked for almost 10 years at GlaxoSmithKline, where he was a Senior Director in the Neurosciences Medicines Development Center. In that capacity, he played a lead role in the development and execution of Phase II-IV clinical development programs across several therapeutic areas in neurology and psychiatry. He also co-founded and led the company-wide Medicines for Children Advisory Network at GlaxoSmithKline. Dr. Horrigan is also a Clinical Associate Professor in the Department of Psychiatry at the University of North Carolina at Chapel Hill.

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**Clive Blower**  
Vice President, Product Development and Technical Affairs  
*BSc (Hons), PhD*

Clive joined Neuren in August 2014 from Acrux, bringing over twenty years of global drug development experience. Clive was at Acrux for seven years as Director of Product Development and Technical Affairs and then Chief Operating Officer. During this period he led the CMC (Chemistry, Manufacturing and Controls) development of the company's lead product through Phase 3 clinical trials, FDA approval and commercial launch. Clive formerly served in senior management positions at Hospira Inc. (previously Faulding Pharmaceuticals, then Mayne Pharma), including leading the Injectable Drug Development Group. He earned a Doctorate in Chemistry from Monash University in 1992 and has experience in all stages of drug development, from concept to commercialisation, having contributed to the development and launch of more than 25 pharmaceutical products.

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# CORPORATE GOVERNANCE STATEMENT

Neuren's board of directors ("Board") aims to ensure that the Company and its subsidiaries (the "Group") operates with a corporate governance framework and practices that promote an appropriate governance culture throughout the organisation and that are relevant, practical and cost-effective for the current size and stage of development of the business.

A description of the framework and practices is set out below, laid out under the structure of the ASX Listing Rules and the Corporate Governance Principles (the "Principles") and Recommendations (the "Recommendations") 2<sup>nd</sup> Edition, issued by the ASX Corporate Governance Council in June 2010.

## Principle 1. Lay solid foundations for management and oversight

The Board is responsible for the overall corporate governance of the Group. The Board acts on behalf of and is accountable to the shareholders. The Board seeks to identify the expectations of shareholders as well as other regulatory and ethical expectations and obligations. The Board is responsible for identifying areas of significant business risk and ensuring mechanisms are in place to manage those risks adequately. In addition, the Board sets the overall strategic goals and objectives, and monitors achievement of goals.

The Board appoints the principal executive officer, currently the Executive Chairman. The Board has delegated the responsibility for the operation and administration of the Group to the Executive Chairman and senior management. The Board ensures that the management team is appropriately qualified to discharge its responsibilities.

## Principle 2. Structure the Board to add value

The Board currently has four members, as set out in the table below, and is highly engaged in the oversight and direction of the business. Details of the relevant skills, experience and expertise of each Board member are set out on page 12 of this report.

	Appointment	Role	Independent	Committees
Richard Treagus	January 2013	Executive Chairman	No <sup>1</sup>	
Larry Glass	Board – May 2012 Management – 2004	Executive director and Chief Science Officer	No <sup>1</sup>	
Bruce Hancox	March 2012	Non-executive director	No <sup>1</sup>	Member of Audit Committee and Remuneration Committee
Trevor Scott	March 2002	Non-executive director	Yes	Chair of Audit Committee and Remuneration Committee

<sup>1</sup> Richard Treagus and Larry Glass are not considered independent due to their executive roles. Bruce Hancox is not considered independent because he provides financial advisory services, including to a substantial shareholder in Neuren.

The Board ensures management's objectives and activities are aligned with the expectations and risks identified by the Board through a number of mechanisms including the following:

- establishment of the overall strategic direction and leadership of the Group;
- approving and monitoring the implementation by management of the Group's strategic plan to achieve those objectives;
- reviewing performance against its stated objectives, by receiving regular management reports on business situation, opportunities and risks;
- monitoring and review of the Group's controls and systems including those concerned with regulatory matters to ensure statutory compliance and the highest ethical standards; and
- review and adoption of budgets and forecasts and monitoring the results against stated targets.

The Board sets the corporate strategy and financial targets with the aim of creating long-term value for shareholders.

The Board reviews the performance of the Executive Chairman at least annually and the Executive Chairman is responsible for reviewing at least annually the performance of senior management. Formal performance reviews for 2014 were deferred to the first half of 2015, due to key performance milestones occurring in the period between October 2014 and February 2015.



When assessing its membership, the Board seeks to achieve a mix of commercial and financial skills, as well as experience in the international pharmaceutical industry and in directing a listed company. The directors believe that the current structure, small size and membership profile of the Board provides the maximum value to the business at this stage of its development, notwithstanding that they do not follow the Recommendations under Principle 2. The Board currently does not have a majority of independent directors (Recommendation 2.1), the Chairman is not independent (Recommendation 2.2) and the Chair and principal executive officer roles are not separate (Recommendation 2.3). The Board will continue to assess the optimum membership and structure for the business as it grows and develops.

The Board has not considered it necessary or value-adding to establish a separate Nomination Committee (Recommendation 2.4). The selection and appointment of directors is considered by the Board itself. The Board determines the terms and conditions relating to the appointment and retirement of directors on a case by case basis. The Board may also engage an external consultant where appropriate to identify and assess suitable candidates who meet the Board's specifications.

The performance of the Board, its committees and individual directors is regularly reviewed to ensure that the Board has the appropriate mix of independence, expertise and experience. A formal review was not undertaken during 2014, however a review is scheduled for the first half of 2015.

For the purposes of the proper performance of their duties, Directors are entitled to seek independent professional advice at the Company's expense on prior approval of the Chairman.

### Principle 3. Promote ethical and responsible decision-making

The Board has established a Code of Conduct, which requires that Board members and executives:

- will act honestly, in good faith and in the best interests of the whole Company
- owe a fiduciary duty to the Company as a whole
- have a duty to use due care and diligence in fulfilling the functions of office and exercising the powers attached to that office
- will undertake diligent analysis of all proposals placed before the Board
- will act with a level of skill expected from Directors and key executives of a publicly listed Company
- will use the powers of office for a proper purpose, in the best interests of the Company as a whole
- will demonstrate commercial reasonableness in decision-making
- will not make improper use of information acquired as Directors and key executives

- will not disclose non-public information except where disclosure is authorised or legally mandated
- will keep confidential information received in the course of the exercise of their duties and such information remains the property of the Company from which it was obtained and it is improper to disclose it, or allow it to be disclosed, unless that disclosure has been authorised by the person from whom the information is provided, or required by law
- will not take improper advantage of the position of Director or use the position for personal gain or to compete with the Company
- will not take advantage of Company property or use such property for personal gain or to compete with the Company
- will protect and ensure the efficient use of the Company's assets for legitimate business purposes
- will not allow personal interests, or the interest of any associated person, to conflict with the interests of the Company
- have an obligation to be independent in judgement and actions and Directors will take all reasonable steps to be satisfied as to the soundness of all decisions of the Board
- will make reasonable enquiries to ensure that the Company is operating efficiently, effectively and legally, towards achieving its goals
- will not engage in conduct likely to bring discredit upon the Company
- will encourage fair dealing by all employees with the Company's customers, suppliers, competitors and other employees
- will encourage the reporting of unlawful/unethical behaviour and actively promote ethical behaviour and protection for those who report violations in good faith
- will give their specific expertise generously to the Company
- have an obligation, at all times, to comply with the spirit, as well as the letter of the law and with the principles of this Code of Conduct

At this stage of the Group's development, considering the very small size of the workforce and the specialist nature of most positions, the Board has chosen not to establish a formal diversity policy or formal objectives for gender diversity, in order to follow Recommendations 3.2 and 3.3. The Group does not discriminate on the basis of age, ethnicity or gender and when a position becomes vacant the Group seeks to employ the best candidate available for the position. The Group currently has 11 employees and consultants, with a number of different cultural backgrounds, of which 4 are women. Currently no board members or senior executives are women.

# CORPORATE GOVERNANCE STATEMENT continued

## **Principle 4. Safeguard integrity in financial reporting**

The Board has established an Audit Committee, which currently consists of the two non-executive directors, Trevor Scott and Bruce Hancox. The independent director Trevor Scott chairs the Committee. The Audit Committee consists of only non-executive directors and is chaired by an independent director as suggested in Recommendation 4.2, but it does not have at least 3 members or a majority of independent members. The Committee met twice during the year, attended by all members.

The Committee operates under a charter approved by the Board, a summary of which is available on the Neuren website. It is responsible for undertaking a broad review of, ensuring compliance with, and making recommendations in respect of, the Group's internal financial controls and legal compliance obligations. It is also responsible for:

- review of audit assessment of the adequacy and effectiveness of internal controls over the Company's accounting and financial reporting systems, including controls over computerised systems;
- review of the audit plans and recommendations of the external auditors;
- evaluating the extent to which the planned scope of the audit can be relied upon to detect weaknesses in internal control, fraud and other illegal acts;
- review of the results of audits, any changes in accounting practices or policies and subsequent effects on the financial statements and make recommendations to management where necessary and appropriate;
- review of the performance and fees of the external auditor;
- audit of legal compliance including trade practices, corporations law, occupational health and safety and environmental statutory compliance, and compliance with the Listing Rules of the ASX;
- supervision of special investigations when requested by the Board;

In undertaking these tasks the Audit Committee meets separately with management and external auditors where required.

## **Principle 5. Make timely and balanced disclosure**

Neuren is required to comply with the continuous disclosure requirements as set out in the ASX Listing Rules, disclosing to the ASX any information that a reasonable person would expect to have a material effect on the price or value of Neuren's securities, unless certain exemptions from the obligation to disclose apply. When analysts or investors are briefed on the business, no material information that has not been disclosed to the ASX is included in the briefing.

The Board has approved policies and procedures to ensure that it complies with its disclosure obligations and that disclosure is timely, factual, clear and objective. The Board has designated the company secretary as the person primarily responsible for implementing and monitoring those policies and procedures. A summary of the policies and procedures is available on the Neuren website. All information disclosed to the ASX is placed on the Neuren website after it has been published by the ASX.

## **Principle 6. Respect the rights of shareholders**

The Board strives to communicate effectively with shareholders, give them ready access to balanced and understandable information about the business and make it easy for them to participate in shareholder meetings. Where possible electronic communication methods are used and shareholders are encouraged to use those methods. All announcements, presentations, financial information and meetings materials disclosed to the ASX are placed on Neuren's website, so that current and historical information can be accessed readily. The Board seeks practical ways to promote informed participation at shareholder meetings, providing access to clear and comprehensive meeting materials and electronic proxy voting.

### Principle 7. Recognise and manage risk

The Board has established policies for the oversight and management of material business risks, a summary of which is available on the Neuren website.

The Board requires management to design and implement the risk management and internal control system to manage the Group's material business risks and report to it on whether those risks are being managed effectively. The Board received that report from management on 24 March 2015.

Notwithstanding that the New Zealand Companies Act 1993 does not require it, the Board also seeks assurances in writing from the Executive Chairman and the Chief Financial Officer that the annual financial statements present a true and fair view, in all material respects, of the Group's financial condition and operational results and are in accordance with NZ GAAP and that this is founded on a sound system of risk management and internal control that is operating effectively in all material respects with regard to financial reporting risks. The Board received those assurances on 24 February 2015.

### Principle 8. Remunerate fairly and responsibly

Neuren believes having highly skilled and motivated people will allow the organisation to best pursue its mission and achieve its goals for the benefit of shareholders and stakeholders more broadly. The ability to attract and retain the best people is critical to the Company's future success. The Board believes remuneration policies are a key part of ensuring this success.

The Board has established a Remuneration Committee, which currently consists of the two non-executive directors, Trevor Scott and Bruce Hancox. The independent director Trevor Scott chairs the Committee. The Remuneration Committee is chaired by an independent director as suggested in Recommendation 8.2, but it does not have at least 3 members or a majority of independent members. The Committee met twice during 2014, with all members attending.

The Committee operates under a charter approved by the Board, a summary of which is available on the Neuren website. It is responsible for undertaking a broad review of, ensuring compliance with, and making recommendations in respect of, the Group's remuneration policies. It is also responsible for:

- setting and reviewing compensation policies and practices of the Company;
- setting and reviewing all elements of remuneration of the directors and members of the executive team; and
- setting and reviewing long term incentive plans for employees and/or directors.

In undertaking these tasks the Remuneration Committee meets separately with management where required.

The Remuneration Committee assesses the appropriateness of the nature and amount of remuneration on a regular basis by reference to relevant employment market conditions, with the overall objective of ensuring maximum shareholder benefit from the retention of a high quality Board and executive team. To assist in achieving these objectives, the Remuneration Committee links the nature and amount of executive emoluments to the Company's performance. Long-term incentive arrangements have been provided by participation in a share option plan and a loan funded share plan to ensure key executives are aligned with shareholders through an interest in the long-term growth and value of the Company.

Non-executive director fees are determined by the Board within the aggregate limit for directors' fees approved by shareholders. The current remuneration level is A\$50,000 per year with an additional A\$10,000 for committee chairs. Non-executive directors receive no retirement allowances. New Zealand Companies Act disclosures with regard to the remuneration of directors and executives are set out in the Directors' Report on page 20.

# DIRECTORS' REPORT

## Principal Activities

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.

## Performance Overview

During 2014 Neuren made significant progress on the development of NNZ-2566 for Rett syndrome, Fragile X syndrome, moderate to severe traumatic brain injury and mild traumatic brain injury (concussion). Key developments in the business included:

- Top-line results from the Phase 2 clinical trial in Rett syndrome successfully demonstrated clinical benefit from treatment with NNZ-2566;
- Applications were submitted to the US Food and Drug Administration (FDA) for Orphan Drug designation and Breakthrough Therapy designation for NNZ-2566 in Rett syndrome;
- A Phase 2 clinical trial of NNZ-2566 in Fragile X Syndrome commenced in the United States.
- A Phase 2 clinical trial of NNZ-2566 in concussion commenced with the US Army's 82nd Airborne Division at Fort Bragg in North Carolina, as a continuation of the collaboration between Neuren and the US Army on the development of potential therapies for traumatic brain injury;
- The grant award supporting Neuren's collaboration with the US Army was increased by approximately US\$3 million and extended to 31 December 2015;
- Dr Clive Blower joined the leadership team as Vice-President: Product Development and Technical Affairs, supporting Neuren's strategy to optimise the technical attributes, manufacturing process and commercial product supply of NNZ-2566 as it progresses towards the final stages of development.

Effective 1 January 2014, the Company's functional currency and the Group's presentation currency changed from New Zealand dollars to Australian dollars. The change in functional currency resulted from the transfer of the Company's place of business from Auckland, New Zealand to Melbourne, Australia and it reflects the underlying transactions, events and conditions that are relevant to the Company.

The detailed financial statements are presented on pages 20 to 43. All amounts in the Financial Statements are shown in Australian dollars unless otherwise stated.

The Group's loss after tax attributable to equity holders of the Company for the year ended 31 December 2014 was \$8,297,000 (2013: \$10,436,000). The loss decreased by \$2.1 million, mainly due to the following:

- An increase of \$1.4 million in research and development costs, with higher costs for the Rett syndrome and Fragile X syndrome clinical trials partly offset by lower costs for the Intrepid clinical trial; and
- A decrease of \$1.9 million in grant revenue from the US government, reflecting the lower costs for the Intrepid trial; offset by:
- An increase of \$0.4 million in interest income due to higher cash balances following the share placement in October 2013;
- Foreign exchange gains of \$0.9 million (2013: loss of \$1.4 million), mainly due to an increase in value of the Group's US dollar denominated cash balances, following the strengthening of the US dollar against the Australian dollar; and
- A non-cash Impairment loss in 2013 of \$2.7 million following a review of the carrying value of the acquired intellectual property related to Motiva™.

The net loss per share for 2014 was \$0.005 (2013: \$0.008) based on a weighted average number of shares outstanding of 1,552,481,203 (2013: 1,261,220,342).

Cash reserves at 31 December 2014 were \$20.8 million (2013: \$24.4 million). Net cash used in operating activities decreased from \$7.1 million to \$6.4 million, due to a reduction in payments for staff and directors. The exercise of share options provided net cash from financing activities of \$2.2 million. In 2013, net cash provided from financing activities was \$26.2 million, comprising \$3.6 million from the exercise of share options and \$23.5 million from a share placement and share purchase plan, less issue expenses of \$0.9 million.

No dividends were paid in the year, or in the prior year and the Directors recommend none for the year.

## Directors

### *Dr Richard Treagus, BScMed, MBChB, MPharmMed, MBA (Executive Chairman)*

Dr Treagus joined the Neuren Board as Executive Chairman on 31 January 2013. He is a physician and entrepreneur, with more than 20 years' experience in all aspects of the international biopharmaceutical industry. He is a business builder with a track record of delivering strong commercial outcomes and shareholder returns. He has held senior executive roles with pharmaceutical organisations in South Africa and Australia and has successfully established numerous pharmaceutical business partnerships in the US, Europe and Asia. Dr Treagus served as Chief Executive of the ASX-listed company Acrux Limited until 2012.



Under his leadership Acrux gained FDA approval for three drug products and concluded the largest product licensing deal in the history of the Australian biotech industry; a transaction with Eli Lilly worth US\$335m plus royalties. Acrux is now a leading Australian biotechnology company and has been profitable since 2010. In 2010 Dr Treagus was awarded the Ernst and Young Entrepreneur-of-the-Year (Southern Region) in the Listed Company Category and in subsequent years has served on the judging panel.

**Mr Larry Glass (Executive Director and Chief Science Officer)**

Mr Glass joined Neuren in 2004 and has been an Executive Director since May 2012. He has more than 30 years' experience in the life sciences industry, including clinical trials, basic and applied research, epidemiologic studies, diagnostics and pharmaceutical product development. Before he joined Neuren, he worked as an independent consultant for a number of biotech companies in the US and internationally providing management, strategic and business development services. Prior to that, he was CEO of a contract research organisation ("CRO") that provided preclinical research and clinical trials support for major pharmaceutical and biotechnology companies and the US government. For a number of years, the CRO operated as a subsidiary of a NYSE-listed company and was subsequently sold to a European biopharmaceutical enterprise which was then acquired by Johnson & Johnson. Mr Glass is a biologist with additional graduate training in epidemiology and biostatistics.

**Mr Bruce Hancox, BCom (Non-Executive Director)**

Mr Hancox joined the Neuren Board in March 2012. Mr Hancox has had a long and distinguished career in business in New Zealand and Australia. He was for many years involved with Brierley Investments Limited as General Manager, Group Chief Executive and Chairman. He also served as a director of many Brierley subsidiaries in New Zealand, Australia and the United States. Since 2006 he has pursued various private investment interests and has been a director of, and consultant to, a number of companies. He has acted as an advisor on a number of takeover situations. From 2007 to 30 April 2013 he was a director of Australian listed company Retail Food Group Limited and in February 2014 he became a director of Australian listed company Medical Australia Limited.

**Dr Trevor Scott, MNZM, LLD (Hon), BCom, FCA, FNZIM, DF Inst D (Non-Executive Director)**

Dr Scott joined the Neuren Board in March 2002. He is the founder of T.D. Scott and Co., an accountancy and consulting firm, which he formed in 1988. He is an experienced advisor to companies across a variety of industries. Dr Scott serves on numerous corporate boards and is chairman of several.

**Interests Register**

The Company is required to maintain an interests register in which particulars of certain transactions and matters involving Directors must be recorded. Details of the entries in this register for each of the Directors during and since the end of 2014 are as follows:

**Dr R Treagus**

Dr Treagus disclosed directorships of QRx Pharma Limited and Biotech Capital Limited, each listed on the Australian Securities Exchange.

**Mr Larry Glass**

On 5 February 2015, Mr Glass acquired 20,000,000 shares, issued on the exercise of options to acquire ordinary shares in the Company, and sold 35,000,000 options to acquire ordinary shares in the Company. Mr Glass disclosed directorship of Microbial Defence Systems LLC, an unlisted company.

**Mr B Hancox**

Mr Hancox disclosed directorships of QRx Pharma Limited, listed on the Australian Securities Exchange and of Microbial Defence Systems LLC, an unlisted company.

**Dr T D Scott**

On 9 October 2014, Dr Scott acquired 20,000,000 shares, issued on the exercise of options to acquire ordinary shares in the Company at \$0.0377 per share.

**Information used by Directors**

During the year the Board received no notices from Directors of the Company requesting to use Company information received in their capacity as Directors, which would not otherwise have been available to them.

**Indemnification and Insurance of Directors and Officers**

Neuren has arranged Directors and Officers Liability Insurance which provides that Directors and Officers generally will incur no monetary loss as a result of actions undertaken by them as Directors and Officers. The insurance does not cover liabilities arising from criminal activities or deliberate or reckless acts or omissions.

# DIRECTORS' REPORT

continued

## Remuneration of Directors

Remuneration of the Directors is shown in the table below, including fees and the value of benefits, as well as the estimated fair value of share based payments amortised during the year or written back on the lapse of unvested share options.

Remuneration of Directors	Remuneration 2014 \$'000	Share based payments 2014 \$'000	Remuneration 2013 \$'000	Share based payments 2013 \$'000
Dr Richard Treagus	370	475	435	341
Mr Larry Glass	405	–	419	93
Mr Bruce Hancox	50	–	31	–
Dr Trevor Scott	60	–	37	48
Dr Robin Congreve	–	–	16	(114)
Dr John Holaday	–	–	20	12
Dr Doug Wilson	–	–	8	(29)
Dr Graeme Howie	–	–	–	12

## Executive Remuneration

The number of employees, not being directors of the Company, who received remuneration and benefits above NZ \$100,000, shown in bands denominated in Australian dollars, was as follows:

Excluding shared based payments	2014 \$'000	2013 \$'000
\$90,000 – \$99,999	1	1
\$110,000 – \$119,999	–	1
\$120,000 – \$129,999	–	1
\$140,000 – \$149,999	1	–
\$180,000 – \$189,999	–	1
\$240,000 – \$249,999	1	–
\$250,000 – \$259,999	–	1
\$260,000 – \$269,999	1	–

Including shared based payments	2014 \$'000	2013 \$'000
\$90,000 – \$99,999	–	1
\$110,000 – \$119,999	–	1
\$120,000 – \$129,999	–	1
\$140,000 – \$149,999	1	–
\$180,000 – \$189,999	1	1
\$250,000 – \$259,999	–	1
\$350,000 – \$359,999	1	–
\$460,000 – \$469,999	1	–

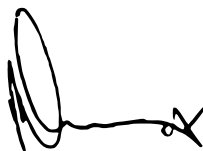
## Donations

The Company made donations of \$2,255 during the year (2013: nil).

## Auditors

PricewaterhouseCoopers are the auditors of the Company. Audit fees in relation to the annual and interim financial statements were \$66,241 (2013: \$48,102). PricewaterhouseCoopers did not receive any fees in relation to other financial advice and services (2013: \$12,487).

For and on behalf of the Board of Directors who authorised the issue of these financial statements on 24 February 2015.



Dr Richard Treagus  
Chairman



Dr Trevor Scott  
Director

# FINANCIAL STATEMENTS

for the year ended 30 December 2014

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# STATEMENTS OF COMPREHENSIVE INCOME

for the year ended 31 December 2014

	Notes	Consolidated		Parent	
		2014 \$'000	2013 Restated \$'000	2014 \$'000	2013 Restated \$'000
Interest income		561	184	560	184
		561	184	560	184
Other income					
Grants		2,931	4,794	–	–
Foreign exchange gain		876	–	876	–
		3,807	4,794	876	–
<b>Total income</b>		<b>4,368</b>	<b>4,978</b>	<b>1,436</b>	<b>184</b>
Research and development costs <sup>1</sup>		(10,016)	(8,653)	(6,913)	(4,461)
Corporate and administrative costs <sup>1</sup>		(1,590)	(1,705)	(1,550)	(1,633)
Foreign exchange loss		–	(1,353)	–	(1,011)
Depreciation and amortisation expense	4	(100)	(395)	(98)	(88)
Share based payment expense		(947)	(657)	(947)	(657)
Impairment loss – Intangible assets	9	(31)	(2,685)	–	–
Impairment loss – Investments	13	–	–	(52)	(3,868)
Provision for doubtful debt	8	–	–	(901)	(761)
<b>Loss before income tax</b>		<b>(8,316)</b>	<b>(10,470)</b>	<b>(9,025)</b>	<b>(12,295)</b>
Income tax expense	5	–	–	–	–
<b>Loss after income tax</b>		<b>(8,316)</b>	<b>(10,470)</b>	<b>(9,025)</b>	<b>(12,295)</b>
<b>Other comprehensive expense, net of tax</b>					
Exchange differences on translation of foreign operations		(138)	(245)	–	–
<b>Total comprehensive loss</b>		<b>(8,454)</b>	<b>(10,715)</b>	<b>(9,025)</b>	<b>(12,295)</b>
<b>Loss after income tax attributable to:</b>					
Equity holders of the company		(8,297)	(10,436)	(9,025)	(12,295)
Non-controlling interest		(19)	(34)	–	–
		(8,316)	(10,470)	(9,025)	(12,295)
<b>Total comprehensive loss attributable to:</b>					
Equity holders of the company		(8,435)	(10,681)	(9,025)	(12,295)
Non-controlling interest		(19)	(34)	–	–
		(8,454)	(10,715)	(9,025)	(12,295)
<b>Basic and diluted loss per share</b>	6	<b>\$0.005</b>	<b>\$0.008</b>		

<sup>1</sup> In the consolidated and parent restated comparative numbers for 2013, expenditure of \$418,378 has been reclassified from corporate and administrative costs to research and development costs in order to present information on a basis consistent with 2014.

The notes on pages 27 to 45 form part of these financial statements



# STATEMENTS OF FINANCIAL POSITION

as at 31 December 2014

	Notes	Consolidated			Parent		
		2014 \$'000	2013 Restated \$'000	2012 Restated \$'000	2014 \$'000	2013 Restated \$'000	2012 Restated \$'000
<b>Assets</b>							
<b>Current assets:</b>							
Cash and cash equivalents	7	20,824	24,379	5,130	20,236	24,286	5,109
Trade and other receivables	8	963	1,664	130	1,231	2,153	1,205
<b>Total current assets</b>		<b>21,787</b>	<b>26,043</b>	<b>5,260</b>	<b>21,467</b>	<b>26,439</b>	<b>6,314</b>
<b>Non-current assets:</b>							
Property, plant and equipment		29	23	25	29	23	25
Intangible assets	9	290	394	3,185	290	361	375
Investments in subsidiaries	13	–	–	–	–	52	3,372
<b>Total non-current assets</b>		<b>319</b>	<b>417</b>	<b>3,210</b>	<b>319</b>	<b>436</b>	<b>3,772</b>
<b>Total assets</b>		<b>22,106</b>	<b>26,460</b>	<b>8,470</b>	<b>21,786</b>	<b>26,875</b>	<b>10,086</b>
<b>Liabilities and equity</b>							
<b>Current liabilities:</b>							
Trade and other payables	10	3,028	2,061	2,119	2,199	1,396	1,099
Lease incentive – short term		–	–	6	–	–	6
<b>Total current liabilities</b>		<b>3,028</b>	<b>2,061</b>	<b>2,125</b>	<b>2,199</b>	<b>1,396</b>	<b>1,105</b>
<b>Non-current liabilities:</b>							
Lease incentive – long term		–	–	13	–	–	13
<b>Total liabilities</b>		<b>3,028</b>	<b>2,061</b>	<b>2,138</b>	<b>2,199</b>	<b>1,396</b>	<b>1,118</b>
<b>Equity</b>							
Share capital	11	104,363	102,177	64,091	104,363	102,177	64,091
Other reserves		(916)	(1,725)	7,800	(260)	(1,207)	8,073
Accumulated deficit		(84,148)	(75,851)	(65,415)	(84,516)	(75,491)	(63,196)
<b>Total Equity attributable to equity holders</b>		<b>19,299</b>	<b>24,601</b>	<b>6,476</b>	<b>19,587</b>	<b>25,479</b>	<b>8,968</b>
Non-controlling interest in equity		(221)	(202)	(144)	–	–	–
<b>Total Equity</b>		<b>19,078</b>	<b>24,399</b>	<b>6,332</b>	<b>19,587</b>	<b>25,479</b>	<b>8,968</b>
<b>Total liabilities and equity</b>		<b>22,106</b>	<b>26,460</b>	<b>8,470</b>	<b>21,786</b>	<b>26,875</b>	<b>10,086</b>

The notes on pages 27 to 45 form part of these financial statements

# STATEMENTS OF CHANGES IN EQUITY

for the year ended 31 December 2014

Consolidated	Share Capital \$'000	Share Option Reserve \$'000	Currency Translation Reserve \$'000	Accumulated Deficit \$'000	Total Attributable to Equity Holders \$'000	Minority Interest \$'000	Total Equity \$'000
<b>Equity as at 1 January 2013 (restated)</b>	64,091	8,073	(273)	(65,415)	6,476	(144)	6,332
Restatement due to change in presentation currency	11,916		(9,937)		1,979	(24)	1,955
Shares issued on option exercise	3,558				3,558		3,558
Shares issued in Share Purchase Plan	2,034				2,034		2,034
Shares issued in private placement	21,505				21,505		21,505
Share issue costs expensed	(927)				(927)		(927)
Share based payments		657			657		657
Comprehensive loss for the period			(245)	(10,436)	(10,681)	(34)	(10,715)
<b>Equity as at 31 December 2013</b>	102,177	8,730	(10,455)	(75,851)	24,601	(202)	24,399
Shares issued on option exercise	2,270				2,270		2,270
Share issue costs expensed	(84)				(84)		(84)
Share based payments		947			947		947
Comprehensive loss for the period			(138)	(8,297)	(8,435)	(19)	(8,454)
<b>Equity as at 31 December 2014</b>	104,363	9,677	(10,593)	(84,148)	19,299	(221)	19,078

The notes on pages 27 to 45 form part of these financial statements

# STATEMENTS OF CHANGES IN EQUITY

for the year ended 31 December 2014  
continued

Parent	Share Capital \$'000	Share Option Reserve \$'000	Currency Translation Reserve \$'000	Accumulated Deficit \$'000	Total Attributable to Equity Holders \$'000
<b>Equity as at 1 January 2013 (restated)</b>	64,091	8,073		(63,196)	8,968
Restatement due to change in presentation currency	11,916		(9,937)		1,979
Shares issued on option exercise	3,558				3,558
Shares issued in Share Purchase Plan	2,034				2,034
Shares issued in private placement	21,505				21,505
Share issue costs expensed	(927)				(927)
Share based payments		657			657
Comprehensive loss for the period				(12,295)	(12,295)
<b>Equity as at 31 December 2013</b>	102,177	8,730	(9,937)	(75,491)	25,479
Shares issued on option exercise	2,270				2,270
Share issue costs expensed	(84)				(84)
Share based payments		947			947
Comprehensive loss for the period				(9,025)	(9,025)
<b>Equity as at 31 December 2014</b>	<b>104,363</b>	<b>9,677</b>	<b>(9,937)</b>	<b>(84,516)</b>	<b>19,587</b>

The notes on pages 27 to 45 form part of these financial statements

# STATEMENTS OF CASH FLOWS

for the year ended 31 December 2014

	Consolidated		Parent	
	2014 \$'000	2013 \$'000	2014 \$'000	2013 \$'000
<b>Cash flows from operating activities:</b>				
Receipts from grants	3,549	3,463	–	–
Interest received	569	130	568	130
GST refunded	194	51	194	51
Payments for employees and directors	(1,488)	(2,348)	(1,488)	(2,348)
Payments to other suppliers	(9,234)	(8,401)	(6,182)	(3,793)
<b>Net cash used in operating activities</b>	<b>(6,410)</b>	<b>(7,105)</b>	<b>(6,908)</b>	<b>(5,960)</b>
<b>Cash flows from investing activities:</b>				
Purchase of property, plant and equipment	(34)	(16)	(34)	(16)
Purchase of intangible assets	(3)	–	(3)	–
Proceeds from sale of property, plant and equipment	3	2	3	2
Advance (to)/from subsidiaries	–	–	53	(1,226)
<b>Net cash used in investing activities</b>	<b>(34)</b>	<b>(14)</b>	<b>19</b>	<b>(1,240)</b>
<b>Cash flows from financing activities:</b>				
Proceeds from the issue of shares	–	23,539	–	23,539
Proceeds from the exercise of options	2,270	3,558	2,293	3,558
Payment of share issue expenses	(61)	(927)	(84)	(927)
<b>Net cash provided from financing activities</b>	<b>2,209</b>	<b>26,170</b>	<b>2,209</b>	<b>26,170</b>
Net (decrease) increase in cash	(4,235)	19,051	(4,680)	18,970
Effect of exchange rate changes on cash balances	680	198	630	207
Cash at the beginning of the year	24,379	5,130	24,286	5,109
<b>Cash at the end of the year</b>	<b>20,824</b>	<b>24,379</b>	<b>20,236</b>	<b>24,286</b>
<b>Reconciliation with loss after income tax:</b>				
Loss after income tax	(8,316)	(10,470)	(9,025)	(12,295)
<i>Non-cash items requiring adjustment:</i>				
Depreciation of property, plant and equipment	24	19	24	20
Amortisation of intangible assets	76	376	74	68
Impairment loss	31	2,685	52	3,868
Provision for doubtful debt	–	–	901	761
Share option compensation expense	947	657	947	657
Foreign exchange (gain) loss	(817)	1,240	(818)	1,042
Lease incentive recognition and amortisation	–	(20)	–	(20)
<i>Changes in working capital:</i>				
Trade and other receivables	746	(1,535)	134	(170)
Trade and other payables	899	(57)	803	109
<b>Net cash used in operating activities</b>	<b>(6,410)</b>	<b>(7,105)</b>	<b>(6,908)</b>	<b>(5,960)</b>

The notes on pages 27 to 45 form part of these financial statements

# NOTES TO THE FINANCIAL STATEMENTS

for the year ended 31 December 2014

## 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 symptoms resulting from acute traumatic brain injury, as well as symptoms of chronic conditions such as Rett syndrome and Fragile X syndrome.

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 ordinary shares are listed on the Australian Securities Exchange (ASX code: NEU).

These consolidated financial statements have been approved for issue by the Board of Directors on 24 February 2015.

### Inherent Uncertainties

- There are inherent uncertainties associated with assessing the carrying value of the acquired intellectual property. The ultimate realisation of the carrying values of intellectual property is dependent on the Company and Group successfully developing its products, on licensing the products, or divesting the intellectual property so that it generates future economic benefits to the Company and Group.
- The Group's research and development activities involve inherent risks. These risks include, among others: dependence on, and the Group's ability to retain key personnel; the Group's ability to protect its intellectual property and prevent other companies from using the technology; the Group's business is based on novel and unproven technology; the Group's ability to sufficiently complete the clinical trials process; and technological developments by the Group's competitors may render its products obsolete.
- The Company has a business plan which will require expenditure in excess of revenue until sales revenue streams are established and therefore expects to continue to incur additional net losses until then. In the future, the Company may need to raise further financing through other public or private equity financings, collaborations or other arrangements with corporate sources, or other sources of financing to fund operations. There can be no assurance that such additional financing, if available, can be obtained on terms reasonable to the Company.

## 2. Summary of significant accounting policies

These general-purpose financial statements are for the year ended 31 December 2014 and have been prepared in accordance with and comply with generally accepted accounting practice in New Zealand, International Financial Reporting Standards, New Zealand equivalents to International Financial Reporting Standards (NZ IFRS) and other applicable Financial Reporting Standards as appropriate for profit-oriented entities.

### (a) Basis of preparation

#### *Entities Reporting*

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of the Group as at 31 December 2014 and the results of all subsidiaries for the year then ended. Neuren Pharmaceuticals Limited and its subsidiaries, which are designated as profit-oriented entities for financial reporting purposes, together are referred to in these financial statements as the Group.

The financial statements of the 'Parent' are for the Company as a separate legal entity.

#### *Statutory Base*

Neuren is registered under the New Zealand Companies Act 1993 and is an issuer in terms of the New Zealand Securities Act 1978. Neuren is also registered as a foreign company under the Australian Corporations Act 2001.

These financial statements have been prepared in accordance with the requirements of the Financial Reporting Act 1993 and the Companies Act 1993.

#### *Historical cost convention*

These financial statements have been prepared under the historical cost convention as modified by certain policies below.

#### *Critical accounting estimates*

The preparation of financial statements requires the use of certain critical accounting estimates. It also requires the Company and Group to exercise its judgement in the process of applying the Company and Group's accounting policies such as in relation to impairment, if any, of intangible assets set out in Note 9. Actual results may differ from those estimates.



# NOTES TO THE FINANCIAL STATEMENTS

continued

## 2. Summary of significant accounting policies (continued)

### *Changes in accounting policies*

#### *Change in functional and presentation currency*

An entity's functional currency is the currency of the primary economic environment in which the entity operates.

Effective 1 January 2014, the functional currency of the Company changed from New Zealand dollars to Australian dollars. The change in functional currency resulted from the transfer of the Company's place of business from New Zealand to Australia and it reflects the underlying transactions, events and conditions that are relevant to the Company. The new functional currency has been applied prospectively from 1 January 2014, in accordance with IAS 21. Also effective 1 January 2014, the Group's presentation currency was changed from New Zealand dollars to Australian dollars. Prior period comparative numbers for the Company and Group in these financial statements have been restated in Australian dollars in order to provide meaningful comparable information.

To give effect to the change in functional currency, the assets, liabilities and equity of the Company in New Zealand dollars at 31 December 2013 were converted into Australian dollars on 1 January 2014 at a fixed exchange rate of A\$1: NZ\$1.086.

In order to derive comparatives, for the Company and Group, in the presentation currency of Australian dollars:

- the New Zealand dollar and US dollar functional currency assets and liabilities were converted into Australian dollars at the period end exchange rates. For 2013 these were A\$1: NZ\$1.086 and A\$1: US\$0.892 and for 2012 these were A\$1: NZ\$1.262 and A\$1: US\$1.038.
- revenue and expenses were converted at the average exchange rates for the reporting period. For 2013 these were A\$1: NZ\$1.177 and A\$1: US\$0.964.
- Items directly recognised in equity were translated using the period end exchange rates.

The loss per share for 2013 has also been restated in Australian dollars to reflect the change in the presentation currency (refer to Note 6).

Comparative information has been restated to apply the change in presentation currency from the earliest date practicable.

There have been no other significant changes in accounting policies in the year ended 31 December 2014.

#### *New standards first applied in the period*

The following standards have been adopted by the group for the first time for the financial year beginning on or after 1 January 2014 and have a material impact on the group:

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 2014 do not have a material impact on the group.

#### *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.

There are no other standards, amendments or interpretations to existing standards which have been issued, but are not yet effective, which are expected to impact the Company or Group.

### **(b) Principles of Consolidation**

#### *Subsidiaries*

Subsidiaries are all entities (including structured entities) over which the group has control. The group controls an entity when the group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the group. They are deconsolidated from the date that control ceases.

Inter-company transactions, balances and unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated. When necessary, amounts reported by subsidiaries have been adjusted to conform with the group's accounting policies.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 2. Summary of significant accounting policies (continued)

### (c) Segment Reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments.

### (d) Foreign Currency Translation

#### (i) Functional and Presentation Currency

Effective 1 January 2014, the functional currency of the Company and the presentation currency of the Group each changed from New Zealand dollars to Australian dollars. The new functional currency was applied prospectively from 1 January 2014, in accordance with IAS 21. Prior period comparative numbers for the Company and Group in these financial statements have been restated in Australian dollars in order to provide meaningful comparable information.

#### (ii) Transactions and Balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the Statement of Comprehensive Income, except when deferred in equity as qualifying cash flow hedges and qualifying net investment hedges.

#### (iii) Foreign Operations

The results and financial position of foreign entities (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each statement of financial position presented are translated at the closing rate at the date of that statement of financial position;
- income and expenses for each Statement of Comprehensive Income are translated at average exchange rates; and
- all resulting exchange differences are recognised as a separate component of equity.

Exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other currency instruments designated as hedges of such investments, are taken to shareholders' equity.

Goodwill and fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the closing rate.

### (e) Revenue recognition

#### Grants

Grants received are recognised in the Statement of Comprehensive Income over the periods in which the related costs for which the grants are intended to compensate are recognised expenses and when the requirements under the grant agreement have been met. Any grants received for which the requirements under the grant agreement have not been completed are carried as liabilities until all the conditions have been fulfilled.

#### Interest income

Interest income is recognised on a time-proportion basis using the effective interest method.

### (f) Research and development

Research costs include direct and directly attributable overhead expenses for drug discovery, research and pre-clinical and clinical trials. Research costs are expensed as incurred.

When a project reaches the stage where it is reasonably certain that future expenditure can be recovered through the process or products produced, development expenditure is recognised as a development asset using the following criteria:

- a product or process is clearly defined and the costs attributable to the product or process can be identified separately and measured reliably;
- the technical feasibility of the product or process can be demonstrated;
- the existence of a market for the product or process can be demonstrated and the Group intends to produce and market the product or process;
- adequate resources exist, or their availability can be reasonably demonstrated to complete the project and market the product or process.

In such cases the asset is amortised from the commencement of commercial production of the product to which it relates on a straight-line basis over the years of expected benefit. Research and development costs are otherwise expensed as incurred.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 2. Summary of significant accounting policies (continued)

### (g) Income tax

The income tax expense for the period is the tax payable on the period's taxable income or loss using tax rates enacted at the balance sheet date and adjusted by changes in deferred tax assets and liabilities attributable to temporary differences between the tax bases of assets and liabilities and their carrying amounts in the financial statements, and to unused tax losses.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to apply when the assets are recovered or liabilities are settled, based on those tax rates which are enacted or substantively enacted at the balance sheet date. The relevant tax rates are applied to the cumulative amounts of deductible and taxable temporary differences to measure the deferred tax asset or liability. An exception is made for certain temporary differences arising from the initial recognition of an asset or a liability. No deferred tax asset or liability is recognised in relation to these temporary differences if they arose in a transaction, other than a business combination, that at the time of the transaction did not affect either accounting profit or taxable profit or loss.

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

Current and deferred tax balances attributable to amounts recognised directly in equity are also recognised directly in equity.

### (h) Leases

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) are charged to the comprehensive income statement on a straight-line basis over the period of the lease.

### (i) Impairment of non-financial assets

Assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment. Assets that are subject to amortisation are reviewed whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. The carrying amount of a long-lived asset is considered impaired when the recoverable amount from such asset is less than its carrying value.

In that event, a loss is recognised in the Statement of Comprehensive Income based on the amount by which the carrying amount exceeds the fair market value less costs to sell of the long-lived asset. Fair market value is determined using the anticipated cash flows discounted at a rate commensurate with the risk involved.

### (j) Goods and services tax (GST)

The financial statements have been prepared so that all components are presented exclusive of GST. All items in the statement of financial position are presented net of GST, with the exception of receivables and payables, which include GST invoiced.

### (k) Intellectual property

Costs in relation to protection and maintenance of intellectual property are expensed as incurred unless the project has yet to be recognised as commenced, in which case the expense is deferred and recognised as contract work in progress until the revenues and costs associated with the project are recognised.

### (l) Cash and cash equivalents

Cash and cash equivalents comprises cash and demand deposits held with established financial institutions and highly liquid investments, which have maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

### (m) Accounts receivable

Trade receivables are recognised initially at fair value and subsequently measured at amortised cost, less provision for doubtful debts.

Collectability of trade receivables is reviewed on an ongoing basis. Debts which are known to be uncollectible are written off. A provision for doubtful receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of receivables.

### (n) Property, plant and equipment

Property, plant and equipment are stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Company and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the Statement of Comprehensive Income during the financial period in which they are incurred.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 2. Summary of significant accounting policies (continued)

Depreciation is determined principally using the straight-line method to allocate their cost, net of their residual values, over their estimated useful lives, as follows:

Scientific equipment	4 years
Computer equipment	2-10 years
Office furniture, fixtures & fittings	3-4 years
Leasehold Improvements	Term of lease

### (o) Intangible assets

#### *Intellectual property*

Acquired patents, trademarks and licences have finite useful lives and are carried at cost less accumulated amortisation and impairment losses. Amortisation is calculated using the straight line method to allocate the cost over the anticipated useful lives, which are aligned with the unexpired patent term or agreement over trademarks and licences.

#### *Acquired software*

Acquired software licences are capitalised on the basis of the costs incurred to acquire and bring to use the specific software. These costs are amortised over their estimated useful lives (two years).

### (p) Employee benefits

#### *Wages and salaries and annual leave*

Liabilities for wages and salaries, bonuses and annual leave expected to be settled within 12 months of the reporting date are recognised in accrued liabilities in respect of employees' services up to the reporting date and are measured at the amounts expected to be paid when the liabilities are settled. Liabilities for non-accumulating personal leave are recognised when the leave is taken and measured at the rates paid or payable.

#### *Share-based payments*

Neuren operates equity-settled share option and share plans. The fair value of the services received in exchange for the grant of the options or shares is recognised as an expense with a corresponding increase in other reserve equity over the vesting period. The total amount to be expensed over the vesting period is determined by reference to the fair value of the options or shares at grant date. At each balance sheet date, the Company revises its estimates of the number of options that are expected to vest and become exercisable. It recognises the impact of the revision of original estimates, if any, in the Statement of Comprehensive Income, and a corresponding adjustment to equity over the remaining vesting period.

When options are exercised, the proceeds received net of any directly attributable transaction costs are credited to share capital.

### (q) Share issue costs

Costs associated with the issue of shares which are recognised in shareholders' equity are treated as a reduction of the amount collected per share.

### (r) Financial instruments

Financial instruments recognised in the statement of financial position include cash and cash equivalents, trade and other receivables and payables and equipment finance. The Company believes that the amounts reported for financial instruments approximate fair value due to their short term nature.

Although it is exposed to interest rate and foreign currency risks, the Company does not utilise derivative financial instruments.

#### *Financial assets: Loans and receivables*

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for maturities greater than 12 months after the balance sheet date. These are classified as non-current assets. The Group's loans and receivables comprise 'trade and other receivables' and "cash and cash equivalents" in the statement of financial position. Loans and receivables are measured at amortised cost using the effective interest method less impairment.

### (s) Earnings per share

Basic and diluted earnings per share are calculated by dividing the profit attributable to equity holders of the Company by the weighted average number of ordinary shares outstanding during the period.

## 3. 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.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 4. Expenses

	Consolidated		Parent	
	2014 \$'000	2013 \$'000	2014 \$'000	2013 \$'000
<b>Loss before income tax includes the following specific expenses:</b>				
<b>Depreciation – property, plant and equipment</b>				
Computer equipment	(17)	(15)	(17)	(15)
Fixtures and fittings	(17)	–	(17)	–
<b>Total depreciation</b>	<b>(34)</b>	<b>(15)</b>	<b>(34)</b>	<b>(15)</b>
<b>Amortisation – intangible assets</b>				
Intellectual property	31	2,685	787	716
Software	–	–	7	4
<b>Total amortisation</b>	<b>31</b>	<b>2,685</b>	<b>794</b>	<b>720</b>
<b>Remuneration of auditors (PwC)</b>				
Audit and review of financial statements	66	48	66	48
Tax advisory services	–	12	–	12
<b>Total remuneration of auditors</b>	<b>66</b>	<b>60</b>	<b>66</b>	<b>60</b>
<b>Employee benefits expense</b>				
Salaries and wages – research & development	558	541	558	541
Salaries and wages - corporate & administrative	391	368	391	368
Share based payment	412	20	412	20
<b>Total employee benefits expense</b>	<b>1,361</b>	<b>929</b>	<b>1,361</b>	<b>929</b>
<b>Directors' fees – research &amp; development</b>	<b>405</b>	<b>419</b>	<b>405</b>	<b>419</b>
<b>Directors' fees – corporate &amp; administrative</b>	<b>480</b>	<b>547</b>	<b>480</b>	<b>547</b>
<b>Directors' share based payment compensation</b>	<b>475</b>	<b>363</b>	<b>475</b>	<b>363</b>
<b>Other shared based payments</b>	<b>60</b>	<b>274</b>	<b>60</b>	<b>274</b>
<b>Lease expense</b>	<b>115</b>	<b>116</b>	<b>115</b>	<b>116</b>



# NOTES TO THE FINANCIAL STATEMENTS

continued

## 5. Income tax

	Consolidated		Parent	
	2014 \$'000	2013 \$'000	2014 \$'000	2013 \$'000
<b>Income tax expense</b>				
Current tax	–	–	–	–
Deferred tax	–	–	–	–
Income tax expense	–	–	–	–
<b>Numerical reconciliation of income tax expense to prima facie tax receivable:</b>				
Loss before income tax	(8,316)	(10,470)	(9,025)	(12,295)
Tax at applicable rates	(2,495)	(3,223)	(2,708)	(3,443)
Tax effect of amounts not deductible in calculating taxable income:				
Share option compensation	284	202	284	184
Impairment loss	9	826	16	1,083
Provision for doubtful debt	–	–	270	213
	(2,202)	(2,195)	(2,138)	(1,963)
Subsidiary tax losses in prior years not recoverable	4,319	–	–	–
(Over) under provision in prior years	(497)	61	205	61
Deferred tax assets not recognised	(1,620)	2,134	1,933	1,902
Income tax expense	–	–	–	–

## 6. Loss per share

Basic loss per share is based upon the weighted average number of outstanding ordinary shares. For the years ended 31 December 2014 and 2013, the Company's potentially dilutive ordinary share equivalents (being the options over ordinary shares set out in Note 11) have an anti-dilutive effect on loss per share and, therefore, have not been included in determining the total weighted average number of ordinary shares outstanding for the purpose of calculating diluted loss per share.

The Group has made a change in accounting policy that, as outlined in Note 2(a), resulted in a restatement of profit attributable to equity holders of the parent and earnings per share.

	Consolidated	
	2014 \$'000	2013 \$'000
Loss after income tax attributable to equity holders	(8,297)	(10,436)
Weighted average shares outstanding (basic)	1,552,481,203	1,261,220,342
Weighted average shares outstanding (diluted)	1,552,481,203	1,261,220,342
Basic and diluted loss per share	(\$0.005)	(\$0.008)

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 7. Cash and cash equivalents

	Consolidated			Parent		
	2014 \$'000	2013 \$'000	2012 \$'000	2014 \$'000	2013 \$'000	2012 \$'000
Cash	8,014	1,475	41	7,915	1,438	30
Demand and short-term deposits	12,810	22,904	5,089	12,321	22,848	5,079
	<b>20,824</b>	<b>24,379</b>	<b>5,130</b>	<b>20,236</b>	<b>24,286</b>	<b>5,109</b>

## 8. Trade and other receivables

	Consolidated			Parent		
	2014 \$'000	2013 \$'000	2012 \$'000	2014 \$'000	2013 \$'000	2012 \$'000
Trade receivables	912	1,563	11	18	124	9
Interest receivable	51	58	–	51	58	–
Prepayments	–	43	119	–	43	26
Due from subsidiaries	–	–	–	2,063	2,689	1,170
Provision for doubtful debt	–	–	–	(901)	(761)	–
	<b>963</b>	<b>1,664</b>	<b>130</b>	<b>1,231</b>	<b>2,153</b>	<b>1,205</b>

In 2013 a provision was made against the full amount receivable from the subsidiary Hamilton Pharmaceuticals Inc. following a review of the carrying value of the subsidiary's intellectual property relating to Motiva.

In 2014 a provision was made against the full amount receivable from the subsidiary Perseis Therapeutics Limited of \$833,000 following a review of the carrying value of the subsidiary's intellectual property. In addition a provision of \$68,000 was made against the increase in the value of the amount receivable from Hamilton Pharmaceuticals Inc. receivable.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 9. Intangible assets

Consolidated	Intellectual Property \$'000	Acquired Software \$'000	Total \$'000
<b>As at 1 January 2013</b>			
Cost	5,214	6	5,220
Accumulated amortisation	(2,034)	(1)	(2,035)
Net book value	3,180	5	3,185
<b>Movements in the year ended 31 December 2013</b>			
Opening net book value	3,180	5	3,185
Restatement due to change in presentation currency	517	–	517
Amortisation	(374)	(2)	(376)
Impairment loss	(2,685)	–	(2,685)
Exchange differences	(247)	–	(247)
Closing net book value	391	3	394
<b>As at 31 December 2013</b>			
Cost	1,134	7	1,141
Accumulated amortisation	(743)	(4)	(747)
Net book value	391	3	394
<b>Movements in the year ended 31 December 2014</b>			
Opening net book value	391	3	394
Additions	–	3	3
Amortisation	(73)	(3)	(76)
Impairment loss	(31)	–	(31)
Closing net book value	287	3	290
<b>As at 31 December 2014</b>			
Cost	1,074	10	1,084
Accumulated amortisation	(787)	(7)	(794)
Net book value	287	3	290
<b>Intellectual Property</b>	<b>NNZ-2566</b>	<b>Motiva</b>	<b>TFF/hGH</b>
Opening net book value	358	–	33
Amortisation	(71)	–	(2)
Impairment loss	–	–	(31)
Closing net book value	287	–	–
Remaining amortisation period	4 years		

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

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 9. Intangible assets (continued)

Parent	Intellectual Property \$'000	Acquired Software \$'000	Total \$'000
<b>As at 1 January 2013</b>			
Cost	924	6	930
Accumulated amortisation	(554)	(1)	(555)
Net book value	370	5	375
<b>Movements in the year ended 31 December 2013</b>			
Opening net book value	370	5	375
Restatement due to change in presentation currency	55	–	55
Amortisation	(67)	(2)	(69)
Closing net book value	358	3	361
<b>As at 31 December 2013</b>			
Cost	1,074	7	1,081
Accumulated amortisation	(716)	(4)	(720)
Net book value	358	3	361
<b>Movements in the year ended 31 December 2014</b>			
Opening net book value	358	3	361
Additions	–	3	3
Amortisation	(71)	(3)	(74)
Closing net book value	287	3	290
<b>As at 31 December 2014</b>			
Cost	1,074	10	1,084
Accumulated amortisation	(787)	(7)	(794)
Net book value	287	3	290

## 10. Trade and other payables

	Consolidated			Parent		
	2014 \$'000	2013 \$'000	2012 \$'000	2014 \$'000	2013 \$'000	2012 \$'000
Trade payables	2,755	1,853	1,717	1,927	1,188	736
Accruals	135	109	285	134	109	246
Employee benefits	138	99	117	138	99	117
	<b>3,028</b>	<b>2,061</b>	<b>2,119</b>	<b>2,199</b>	<b>1,396</b>	<b>1,099</b>

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 11. Share Capital

Consolidated and Parent	2014 Shares	2013 Shares	2014 \$'000	2013 \$'000
<b>Issued share capital</b>				
Ordinary shares on issue at beginning of year	1,512,528,963	1,182,786,570	102,177	64,091
Restatement on change in presentation currency				11,916
Shares issued in private placement	–	187,000,000	–	21,505
Shares issued in Share Purchase Plan	–	17,606,589	–	2,034
Shares issued in Loan Funded Share Plan	30,000,000	40,000,000	–	–
Shares issued on option exercise	82,712,463	85,135,804	2,270	3,558
Share issue expenses – cash issue costs	–	–	(84)	(927)
	<b>1,625,241,426</b>	<b>1,512,528,963</b>	<b>104,363</b>	<b>102,177</b>

### (a) Ordinary Shares

The ordinary shares have no par value and all ordinary shares are fully paid-up and rank equally as to dividends and liquidation, with one vote attached to each fully paid ordinary share.

### (b) Share Options

Movements in the number of share options were as follows:

Consolidated and Parent	Options	Weighted Average Exercise Price (AUD\$)	Exercisable	Weighted Average Exercise Price (AUD\$)
<b>Outstanding at 1 January 2013</b>	298,555,024	\$0.031	251,221,695	\$0.032
Lapsed	(15,000,000)	\$0.038		
Exercised	(85,135,804)	\$0.042		
<b>Outstanding at 31 December 2013</b>	198,419,220	\$0.023	193,419,220	\$0.023
Exercised	(82,712,463)	\$0.027		
<b>Outstanding at 31 December 2014</b>	115,706,757	\$0.019	115,706,757	\$0.019

In 2011 the Company granted 39,273,507 options in conjunction with monthly conversions and final conversion on termination of convertible notes under a convertible loan facility. The options have a term of 4 years from their grant date and are exercisable into ordinary shares on a one-for-one basis with exercise prices ranging from A\$0.0146 to A\$0.0163 per share. 16,706,757 of these options remained outstanding at 31 December 2014. These options were otherwise issued on terms and conditions not materially different to those of the Share Option Plan described below.

### Share Option Plan

The Company has a Share Option Plan to assist in the retention and motivation of senior employees and certain consultants ("Participants"). Under the Share Option Plan, options may be offered to Participants by the Remuneration and Audit Committee. The maximum number of options to be issued and outstanding under the Share Option Plan is 15% of the issued ordinary shares of the Company at any time, with one third of these available to the directors with the approval of shareholders. No payment is required for the grant of options under the Share Option Plan. Each option is an option to subscribe in cash for one ordinary share, but does not carry any right to vote. Upon the exercise of an option by a Participant, each ordinary share issued will rank equally with other ordinary shares of the Company. Options granted under the Share Option Plan generally vest over three years' service by the Participant and lapse five years after grant date. At 31 December 2014 there were 99,000,000 options outstanding under the Share Option Plan (2013: 122,800,000).

No options were granted during 2014 or 2013.



# NOTES TO THE FINANCIAL STATEMENTS

continued

## 11. Share Capital (continued)

The weighted average remaining contractual life of outstanding share options at 31 December 2014 is 1.3 years (2013: 1.9 years). The outstanding share options are detailed in the following table. The exercise price per share and the total exercise price are stated in Australian dollars.

Number of options	Expiry date	Exercise price per share (A\$)	Total exercise price (A\$)
20,000,000	3/25/2015	0.0300	\$600,000
3,000,000	3/25/2015	0.0300	\$90,000
3,000,000	3/25/2015	0.0300	\$90,000
397,059	1/19/2015	0.0163	\$6,472
397,059	2/18/2015	0.0163	\$6,472
442,623	3/21/2015	0.0146	\$6,462
457,031	4/20/2015	0.0154	\$7,038
421,874	4/20/2015	0.0154	\$6,497
6,774,444	6/6/2015	0.0162	\$109,746
7,816,667	6/6/2015	0.0162	\$126,630
35,000,000	10/26/2016	0.0130	\$455,000
15,000,000	10/26/2016	0.0130	\$195,000
7,000,000	10/26/2016	0.0130	\$91,000
5,000,000	10/26/2016	0.0377	\$188,500
11,000,000	8/7/2017	0.0190	\$209,000
115,706,757			\$2,187,818

### (c) Loan funded shares

In 2013 the Company established a Loan Funded Share Plan to support the achievement of the Company's business strategy by linking executive reward to improvements in the financial performance of the Company and aligning the interests of executives with shareholders. Under the Loan Funded Share Plan, loan funded shares may be offered to employees or consultants ("Participants") by the Remuneration and Audit Committee. The Company issues new ordinary shares, which are placed in a trust to hold the shares on behalf of the Participant. The trustee issues a limited-recourse, interest-free loan to the participant, which is equal to the number of shares multiplied by the issue price. A limited-recourse loan means that the repayment amount will be the lesser of the outstanding loan and the market value of the shares that are subject to the loan. The trustee continues to hold the shares on behalf of the Participant until all vesting conditions have been satisfied and the Participant chooses to settle the loan, at which point ownership of the shares is transferred from the trust to the Participant.

Any dividends paid by the Company while the shares are held by the trust are applied as repayment of the loan at the after-tax value of the dividend. The directors may apply vesting conditions to be satisfied before the shares can be transferred to the Participant.

All shares issued prior to 31 December 2014 have been issued subject to the following vesting conditions:

- The Participant is continuously a director or employee of the Company for a period of three years commencing on the day on which the directors resolved to issue the Loan Funded Shares ("Issue Date") and finishing on the third anniversary of the issue date (or such other date on which the directors make a determination as to whether the vesting conditions have been met) (the "Vesting Period"); and
- 50% of the Loan Funded Shares shall each vest where the following performance conditions are met:
  - The Total Shareholder Return (TSR) on the Company's ASX-listed ordinary shares equals or exceeds 75% over the Vesting Period. The TSR is calculated using the average closing share price over the period of 30 consecutive trading days concluding on the Issue Date and the average closing share price over the period of 30 consecutive trading days concluding on the date on which the Vesting Period ends; and
  - Within the Vesting Period, either:
    - The Company determines to progress a product candidate to a Phase 2b or Phase 3 clinical trial following a positive Phase 2 clinical trial outcome and a national regulatory authority approves the initiation of such trial, or
    - A material partnering or licensing transaction is concluded.

Before the shares can be issued, The New Zealand Companies Act requires the Company to obtain shareholder approval to provide financial assistance to the Participant in the form of the loan to purchase the shares.

The estimated fair value of the shares has been determined using the Black-Scholes valuation model. The significant inputs into the model were the share price on the date of valuation, the estimated future volatility of the share price, a dividend yield of 0%, an expected life of 3 years, and an annual risk-free interest rate of 2.50%. The estimated future volatility of the share price was derived by analysing the historic volatility of the share price during a relevant period.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 11. Share Capital (continued)

Details of the shares issued prior to 31 December 2014, the estimated fair value and variable inputs into the valuation model are shown in the following table:

Number of shares	40 million	30 million
Issue date	29 May 2013	28 May 2014
Issue price per share	\$0.039	\$0.092
Share price on date of valuation	\$0.039	\$0.069
Fair value per share	\$0.03	\$0.04
Estimated future volatility	119%	101%

On 24 September 2014, the directors resolved to issue under the Loan Funded Share Plan 20 million shares at \$0.082 per share to the Director of Product Development and Technical Affairs, Clive Blower, however the shares cannot be issued before obtaining approval from shareholders at the 2015 Annual General Meeting to provide financial assistance in the form of the loan to purchase the shares. After issue, these shares will be subject to the same vesting conditions as the shares previously issued. The shares have been valued at the date on which the directors resolved to issue the shares. The estimated fair value, determined using the Black-Scholes valuation model, was \$0.05 per share. The significant inputs into the model were a share price of 0.082, estimated future volatility of 95%, dividend yield of 0%, an expected life of 3 years from the date of issue, and an annual risk-free interest rate of 2.50%.

### (d) Equity Performance Rights

The Company has issued equity performance rights ("EPR") to certain executives, calculated as a fixed amount divided by the average closing price of the listed ordinary shares of the Company over the five trading days immediately preceding the date of acceptance of an offer of employment ("measurement date"). Subject to continuous service by the recipient, each EPR vests three years from the date on which service commences ("vesting date"). When vested, the Company will issue at no cost one new ordinary share for each EPR exercised. The issued shares shall rank equally with the Company's other issued ordinary shares and the recipient shall be free to deal with the issued shares in accordance with the Company's Securities Trading Policy. The EPR will vest automatically upon any effective change in control of the Company, control being when a person and their associates become the holder of greater than 50% of the ordinary share voting rights. Any unvested EPR will expire if the recipient ceases to be an employee or director of the Company.

The estimated fair value of each EPR has been determined using the Black-Scholes valuation model. The significant inputs into the model were the grant date share price, estimated future volatility of the share price, dividend yield of 0%, an expected life of 3 years, and an annual risk-free interest rate of 2.5%. The estimated future share price volatility was derived by analysing the historic volatility of the Company's shares over a relevant period.

Details of the EPR issued prior to 31 December 2014, the estimated fair value and variable inputs into the valuation model are shown in the following table:

Number of EPR	9,615,385	2,666,667	643,225	1,308,901
Issue date	29 May 2013	31 May 2014	31 May 2014	24 September 2014
Fair value per share	\$0.033	\$0.038	\$0.117	\$0.076
Measurement date	31 January 2013	14 May 2013	16 August 2013	15 May 2014
Vesting date	31 January 2016	18 August 2016	25 August 2016	25 August 2017
Estimated future volatility	121%	101%	101%	95%

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 12. Deferred tax

	Consolidated		Parent	
	2014 \$'000	2013 \$'000	2014 \$'000	2013 \$'000
<b>Deferred tax asset (liability)</b>				
<b>Amounts recognised in profit or loss</b>				
Provisions and accruals	19	8	19	8
Intangible assets	27	(725)	27	43
Exchange Differences	(190)	–	(190)	–
Tax losses	20,688	22,880	20,688	18,561
	20,544	22,163	20,544	18,612
Unrecognised deferred tax assets	(20,544)	(22,163)	(20,544)	(18,612)
Deferred tax asset (liability)	–	–	0	–
<b>Movements</b>				
Deferred tax asset (liability) at the beginning of the year	–	–	–	–
Credited (charged) to the income statement (Note 5)	(1,620)	2,134	1,933	1,902
Effect of change in tax rates	–	–	–	–
Exchange differences	–	–	–	–
Change in unrecognised deferred tax assets	1,620	(2,134)	(1,933)	(1,902)
Deferred tax asset (liability) at the end of the year	–	–	–	–

The unrecognised deferred tax assets at 31 December 2014 include \$18.1 million for New Zealand tax losses. The Company may not be able to generate future taxable profits in New Zealand to utilise those losses.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 13. Subsidiaries

### (a) Investment in subsidiaries

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiaries in accordance with the accounting policy described in Note 2(b).

Name of entity	Date of incorporation	Principle activities	Interest held	Domicile	Investment			Amount due to Parent		
					2014 \$'000	2013 \$'000	2012 \$'000	2014 \$'000	2013 \$'000	2012 \$'000
AgVentures Limited	7-Oct-03	Dormant	100%	NZ	–	–	–	–	–	–
NeuroendocrinZ Limited	10-Jul-02	Dormant	100%	NZ	–	–	–	–	–	–
Neuren Pharmaceuticals Inc.	20-Aug-02	Development services	100%	USA	–	–	–	1,162	1,158	21
Hamilton Pharmaceuticals Inc.	2-Apr-04	Clinical research	100%	USA	3,868	3,868	3,327	68	761	616
Less: Impairment loss and provision for doubtful debt:					(3,868)	(3,868)	–	(68)	(761)	–
Neuren Pharmaceuticals (Australia) Pty Ltd	9-Nov-06	Dormant	100%	Australia	–	–	–	–	–	–
Perseis Therapeutics Limited	25-Mar-09	Preclinical research	72.20%	NZ	52	52	45	833	770	533
Less: Impairment loss and provision for doubtful debt:					(52)	–	–	(833)	–	–

In 2013 an Impairment loss and a provision for doubtful debt were made against the full investment and amount receivable from Hamilton Pharmaceuticals Inc. following a review of the carrying value of the subsidiary's intellectual property relating to Motiva.

In 2014 an Impairment loss and a provision for doubtful debt were made against the full investment and amount receivable from Perseis Therapeutics Limited following a review of the carrying value of the subsidiary's intellectual property.

All subsidiaries have a balance date of 31 December, except Perseis Therapeutics which has a 31 March year end.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 14. Commitments and contingencies

### (a) Operating leases

The following aggregate future non-cancellable minimum lease payments for premises have been committed to by the Company, but not recognised in the financial statements. The Company's first premises commitment is for a two years and six months lease commencing June 2013, with an option to renew for a further term of three years, and annual rental reviews throughout. The Company's second premises commitment is for a two years and six months lease commencing September 2014, with an option to renew for a further term of three years, and annual rental reviews throughout.

Consolidated and Parent	2014 AUD\$'000	2013 AUD\$'000	2012 AUD\$'000
Not later than one year	128	58	65
Later than one year and not later than five years	85	53	171
	213	111	236

### (b) Legal claims

The Company had no significant legal matter contingencies as at 31 December 2014 or at 31 December 2013.

### (c) Capital commitments

The Company is not committed to the purchase of any property, plant or equipment as at 31 December 2014 (2013: nil).

## 15. Related party transactions

### (a) Key Management Personnel

The Key Management Personnel of the Group (KMP) include the directors of the Company and direct reports to the Executive Chairman. Compensation for KMP was as follows:

	2014 \$'000	2013 \$'000
<b>Directors:</b>		
Fees and other short term benefits	885	966
Share based payment compensation	475	363
<b>Management:</b>		
Short-term benefits	948	752
Share based payment compensation	473	234
	2,781	2,315

As detailed in Note 11 (c), during the year ended 31 December 2014, 30 million (2013: 40 million) ordinary shares were issued to a trust to hold on behalf of KMP under the Company's Loan Funded Share Plan. In accordance with the terms of the Plan, limited-recourse interest-free loans of \$2,760,000 (2013: \$1,560,000) were provided to those KMP. Further details of the terms and conditions of the loans are disclosed in Note 11 (c).

As detailed in Note 11 (d), during the year ended 31 December 2014, 4,618,793 (2013: 9,615,385) equity performance rights (EPR) were issued to KMP. Further details of the terms and conditions of the EPR are disclosed in Note 11 (d).



# NOTES TO THE FINANCIAL STATEMENTS

continued

## 15. Related party transactions (continued)

### (b) Subsidiaries

The ultimate parent company in the Group is Neuren Pharmaceuticals Limited ("Parent"). The Parent funds the activities of the subsidiaries throughout the year as needed. Interests in and amounts due from subsidiaries are set out in Note 13. All amounts due between entities in the Group are payable on demand and bear no interest.

During the year ended 31 December 2013 the Parent charged Perseis Therapeutics fees of \$28,000 for management, intellectual property and administrative services. There were no charges for the year ended 31 December 2014. During the year ended 31 December 2014 Neuren Pharmaceuticals Inc charged the Parent fees of US\$1,088,276 for pharmaceutical research services and the Parent charged Neuren Pharmaceuticals Inc fees of US\$56,000 for administrative services. There were no charges for the year ended 31 December 2013.

## 16. Events after balance date

As at the date of these financial statements there were no events arising since 31 December 2014 which require disclosure.

## 17. Financial instruments and risk management

### (a) Categories of financial instruments

	Consolidated		Parent	
	2014 \$'000	2013 \$'000	2014 \$'000	2013 \$'000
<b>Financial assets</b>				
Cash and cash equivalents	20,824	24,379	20,236	24,286
Trade and other receivables	963	1,621	1,231	2,110
Total financial assets (loans and receivables classification)	21,787	26,000	21,467	26,396
<b>Financial liabilities</b>				
Amortised cost:				
Trade and other payables	3,028	2,061	2,199	1,396
Total financial liabilities	3,028	2,061	2,199	1,396

### (b) Risk management

The Company and its subsidiaries are subject to a number of financial risks which arise as a result of its activities.

#### Currency risk

During the normal course of business the Company and its subsidiaries enter into contracts with overseas customers or suppliers or consultants that are denominated in foreign currency. As a result of these transactions there is exposure to fluctuations in foreign exchange rates. The Company also has a net investment in a foreign operation, whose net assets are exposed to foreign currency translation risk.

The principle currency risk faced by the business is the exchange rate between the Australian dollar and the US dollar. The majority of the Company's cash reserves are denominated in Australian dollars and the majority of its future expenditure is expected to be denominated in US dollars.

A foreign exchange gain of \$876,000 is included in results for the year ended 31 December 2014 (2013: loss of \$1,353,000). The majority of the gain relates to the revaluation for reporting purposes of the Company's US dollar denominated cash reserves into Australian dollars and the significant strengthening of the US dollar against the Australian dollar in the latter part of 2014.

Where possible, the Group matches foreign currency income and expenditure as a natural hedge. When foreign currency expenditure exceeds revenue (such as US dollar expenditure), the group purchases foreign currency to meet future anticipated requirements under spot and forward contracts. This may result in the Group holding significant amounts of cash denominated in US dollars. The Group does not designate formal hedges. At 31 December 2014, there were no forward contracts outstanding.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 17. Financial instruments and risk management (continued)

The carrying amounts of US dollar denominated financial assets and liabilities are as follows:

	Consolidated		Parent	
	2014 \$'000	2013 \$'000	2014 \$'000	2013 \$'000
<b>Assets</b>				
US dollars	9,387	3,079	9,073	2,707
<b>Liabilities</b>				
US dollars	2,121	1,210	1,294	545

An increase of 10% in the value of the US dollar against the Australian dollar as at the reporting date would have increased the consolidated loss after income tax by \$661,000 (2013: \$170,000). A decrease of 10% in the value of the US dollar against the Australian dollar as at the reporting date would have decreased the consolidated loss after income tax by \$807,000 (2013: \$208,000).

An increase of 10% in the value of the US dollar against the Australian dollar as at the reporting date would have increased the parent's loss after income tax by \$707,000 (2013: \$197,000). A decrease of 10% in the value of the US dollar against the Australian dollar as at the reporting date would have decreased the parent's loss after income tax by \$864,000 (2013: \$240,000).

### Interest rate risk

The Company and the Group are exposed to interest rate risk as entities in the Group hold cash and cash equivalents.

The effective interest rates on financial assets are as follows:

	Consolidated		Parent	
	2014 \$'000	2013 \$'000	2014 \$'000	2013 \$'000
<b>Financial assets</b>				
Cash and cash equivalents				
Australian dollar cash deposits	12,311	23,083	12,311	23,084
Australian dollar interest rate	3.47%	3.50%	3.47%	3.50%
US dollar cash deposits	8,499	968	7,911	877
US dollar interest rate	0.03%	0.01%	0.03%	0.01%
New Zealand dollar cash deposits	14	192	14	190
New Zealand dollar interest rate	3.22%	3.00%	3.22%	3.00%
Sterling cash deposits	–	136	–	135
Sterling interest rate		0.00%		0.00%

The Company and Group do not have any interest bearing financial liabilities. Trade and other receivables and payables do not bear interest and are not interest rate sensitive.

A 10% change in average market interest rates would have changed reported profit after tax by approximately \$56,000.

# NOTES TO THE FINANCIAL STATEMENTS

continued

## 17. Financial instruments and risk management (continued)

### *Credit risk*

The Company and its subsidiaries incur credit risk from transactions with trade receivables and financial institutions in the normal course of its business. The credit risk on loans and receivables of the Group, which have been recognised in the statement of financial position, is the carrying amount, net of any allowance for doubtful debts. At 31 December 2014, \$888,000 was receivable from the US government (2013: \$1,439,000). Cash and cash equivalents held with financial institutions are exposed to credit risk. These have been assessed by S&P as having a financial credit rating of AA.

The Company and its subsidiaries do not require any collateral or security to support transactions with financial institutions. The counterparties used for banking and finance activities are financial institutions with high credit ratings.

### *Liquidity risk*

The Company and Group's financial liabilities, comprising trade and other payables, are generally repayable within 1 – 2 months, and are managed together with capital risk as noted below.

### *Capital risk*

The Company manages its capital to ensure that constituent entities are able to meet their estimated commitments as they fall due. The capital structure of the group consists of cash and cash equivalents, and equity of the parent, comprising issued capital, reserves and accumulated deficit.

# INDEPENDENT AUDITORS' REPORT



## ***Independent Auditors' Report***

to the shareholders of Neuren Pharmaceuticals Limited

### ***Report on the Financial Statements***

We have audited the Group financial statements of Neuren Pharmaceuticals Limited ("the Company") on pages 22 to 45, which comprise the statement of financial position as at 31 December 2014, the statement of comprehensive income, the statement of changes in equity and the statement of cash flows for the year then ended, and the notes to the financial statements that include a summary of significant accounting policies and other explanatory information for the Group. The Group comprises the Company and the entities it controlled at 31 December 2014 or from time to time during the financial year.

### ***Directors' Responsibility for the Financial Statements***

The Directors are responsible for the preparation and fair presentation of these financial statements in accordance with New Zealand Equivalents to International Financial Reporting Standards 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.

### ***Auditors' Responsibility***

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing (New Zealand) and International Standards on Auditing. These standards require that we comply with relevant ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditors consider the internal controls relevant to the Company's preparation of financial statements that give a true and fair view of the matters to which they relate in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Other than in our capacity as auditors we have no relationship with, or interests in, Neuren Pharmaceuticals or any of its subsidiaries.

# INDEPENDENT AUDITORS' REPORT

continued



## ***Independent Auditors' Report***

Neuren Pharmaceuticals Limited

### ***Opinion***

In our opinion, the financial statements on pages 22 to 45:

- (i) comply with generally accepted accounting practice in New Zealand; and
- (ii) comply with International Financial Reporting Standards; and
- (iii) give a true and fair view of the financial position of the Company and the Group as at 31 December 2014, and their financial performance and cash flows for the year then ended.

### ***Report on Other Legal and Regulatory Requirements***

We also report in accordance with Sections 16(1)(d) and 16(1)(e) of the Financial Reporting Act 1993. In relation to our audit of the financial statements for the year ended 31 December 2014:

- (i) we have obtained all the information and explanations that we have required; and
- (ii) in our opinion, proper accounting records have been kept by the Company as far as appears from an examination of those records.

### ***Restriction on Use of our Report***

This report is made solely to the Company's shareholders, as a body, in accordance with the Companies Act 1993. Our audit 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 auditors' 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 audit work, for this report or for the opinions we have formed.

A handwritten signature in blue ink that reads 'Price Waterhouse Coopers' with a long horizontal flourish underneath.

Chartered Accountants  
24 February 2015

Auckland

# ADDITIONAL INFORMATION

## Equity Securities Held by Directors as at 24 February 2015

Director	Interests in Ordinary Shares		Interests in Options		Interests in Equity Performance Rights	
	Direct	Indirect	Direct	Indirect	Direct	Indirect
Richard Treagus	–	40,000,000	–	–	9,615,385	–
Larry Glass	20,000,000	–	–	–	–	–
Bruce Hancox	–	–	–	–	–	–
Trevor Scott	20,000,000	50,118,249	–	–	–	–

## Directors of subsidiary companies at 31 December 2014

	Richard Treagus	Larry Glass	Bruce Hancox	Trevor Scott	Jon Pilcher
AgVentures Limited				√	
NeuroendocrinZ Limited					√
Neuren Pharmaceuticals Inc.	√	√			
Hamilton Pharmaceuticals Inc.	√	√			
Neuren Pharmaceuticals (Australia) Pty Ltd		√	√		
Perseis Therapeutics Limited	√	√			

## Australian Stock Exchange Disclosures

Neuren Pharmaceuticals Limited is incorporated in New Zealand under the Companies Act 1993.

The Company is not subject to Chapters 6, 6A, 6B and 6C of the Corporations Act, Australia, dealing with the acquisition of shares (such as substantial holdings and takeovers).

Limitations on the acquisition of shares are imposed by the following New Zealand legislation: Companies Act 1993, Securities Act 1978, Securities Markets Act 1988, Takeovers Act 1993, Overseas Investment Act 2005, Commerce Act 1986, Financial Markets Conduct Act 2013 and various regulations and codes promulgated under such Acts.

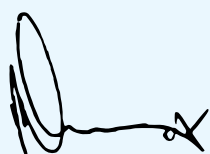
## Corporations Act, Australia – Directors' declaration

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

- The financial statements on pages 22 to 45 of Neuren and its subsidiaries for the year ended 31 December 2014 and the notes to those financial statements:
  - comply with the accounting standards issued by the Institute of Chartered Accountants of New Zealand; and
  - give a true and fair view of the financial position as at 31 December 2014 and of the performance for the 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 declaration is made in accordance with a resolution of the Board of Directors dated 24 February 2015.

On behalf of the Board



Dr Richard Treagus  
Chairman



Dr Trevor Scott  
Director



# ADDITIONAL INFORMATION

continued

## Equity Securities information

The Company has only one class of shares, being ordinary shares. Each ordinary share is entitled to one vote when a poll is called; otherwise on a show of hands at a shareholder meeting every member present in person or by proxy has one vote. There are no securities subject to escrow and there is no current on-market buy-back of securities.

The following information is based on share registry information processed up to and including 25 February 2015.

The number of ordinary shareholdings held in less than marketable parcels at 25 February 2015 was 315, holding 205,958 ordinary shares.

## Distribution of security holders

Ordinary shares	Number of ordinary shares	%	Number of holders	%
100,001 and Over	1,542,414,635	93.70	1,176	25.77
10,001 to 100,000	97,078,149	5.90	2,157	47.27
5,001 to 10,000	4,884,874	0.30	584	12.80
1,001 to 5,000	1,614,662	0.10	408	8.94
1 to 1,000	43,224	0.00	238	5.22
<b>Total</b>	<b>1,646,035,544</b>	<b>100.00</b>	<b>4,563</b>	<b>100.00</b>

Unquoted options to acquire ordinary shares	Number of options	%	Number of holders	%
100,001 and Over	115,706,757	100.00	7	100.00
<b>Total</b>	<b>115,706,757</b>	<b>100.00</b>	<b>7</b>	<b>100.00</b>

Unquoted equity performance rights to acquire ordinary shares (EPR)	Number of EPR	%	Number of holders	%
100,001 and Over	14,234,178	100.00	4	100.00
<b>Total</b>	<b>14,234,178</b>	<b>100.00</b>	<b>4</b>	<b>100.00</b>

Substantial Security Holders	Number of ordinary shares
Langley Alexander Walker (through Auckland Trust Company Limited in its capacity as trustee)	266,525,690

# ADDITIONAL INFORMATION

continued

Twenty Largest Holders of ordinary shares:	Number of ordinary shares	% of issued share capital	
AUCKLAND TRUST COMPANY LIMITED	266,525,690	16.19%	
UBS NOMINEES PTY LTD	70,848,669	4.30%	
NEUREN TRUSTEE LIMITED	70,000,000	4.25%	
CAMERON RICHARD PTY LTD	65,000,000	3.95%	
ESSEX CASTLE LIMITED	45,400,303	2.76%	
ABN AMRO CLEARING SYDNEY NOMINEES PTY LTD	45,156,252	2.74%	
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	36,396,329	2.21%	
CITICORP NOMINEES PTY LIMITED	33,804,005	2.05%	
INVESTMENT CUSTODIAL SERVICES LIMITED	29,611,730	1.80%	
SMITHLEY SUPER PTY LTD	26,000,000	1.58%	
UBS NOMINEES PTY LTD	24,628,249	1.50%	
LINWIERIK SUPER PTY LTD	21,000,000	1.28%	
LARRY GLASS	20,000,000	1.22%	
DR TREVOR SCOTT	20,000,000	1.22%	
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	19,713,684	1.20%	
ROXTRUS PTY LIMITED	19,000,000	1.15%	
NATIONAL NOMINEES LIMITED	17,787,500	1.08%	
J P MORGAN NOMINEES AUSTRALIA LIMITED	15,876,910	0.96%	
FORSYTH BARR CUSTODIANS LTD	14,956,276	0.91%	
CENTRALO LIMITED	11,925,508	0.72%	
BNP PARIBAS NOMS PTY LTD	11,919,759	0.72%	
	<b>Total</b>	<b>885,550,864</b>	<b>53.80%</b>
	<b>Balance of share register</b>	<b>760,484,680</b>	<b>46.20%</b>
	<b>Total issued share capital</b>	<b>1,646,035,544</b>	<b>100.00%</b>





neuren

pharmaceuticals

**Neuren Pharmaceuticals Limited**

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**ABN:** 72 111 496 130  
**ASX code:** NEU

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